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Health-related quality of life and wellbeing in people over 75 years of age with end-stage kidney disease managed with dialysis or comprehensive conservative care: a cross-sectional study in the UK and Australia

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ABSTRACT

Objective

Decisions regarding treatment of older people with end-stage kidney disease need to be supported by information about the impact of dialysis on health-related quality of life (HRQoL) and wellbeing. Few data exist from patients aged 75 years of age or older.

Design

Prospective cross-sectional study.

Setting

3 renal units in the UK and Australia.

Participants

129 ESKD patients managed with dialysis or with an estimated glomerular filtration (eGFR)≤10ml/min/1.73m^2 and managed with comprehensive conservative, non-dialytic care.

Outcome measures

HRQoL and wellbeing were assessed using Short-Form six dimensions (SF-6D, 0-1 scale); KDQOL-36 (0-100 scale) and Investigating Choice Experiments Capability Measure–Older people (ICECAP-O, 0-1 scale). Linear regression assessed associations between treatment, HRQoL and wellbeing. Pearson's correlation coefficient assessed convergent validity between instruments.

Results

Median age of 81 years [IQR 78–85], 65% males; 83(64%) were managed with dialysis and 46(36%) with conservative care. When adjusted for treatment type and sociodemographic variables, those managed on dialysis reported lower mean SF-6D utility (-0.05, 95%CI -0.12 to 0.01); lower KDQOL Physical component summary score (-3.17, 95%CI -7.61 to 1.27); lower Mental component summary score (-2.41, 95%CI -7.66 to 2.84); lower quality of life due to burden (-28.59, 95%CI -41.77 to -15.42); symptoms (-5.93, 95%CI -14.61 to 2.73), and

effects of kidney disease (-16.49, 95%CI -25.98 to -6.99); and lower overall ICECAP-O wellbeing (-0.07, 95%CI -0.16 to 0.02) than those managed conservatively. Correlation between ICECAP-O wellbeing and SF-6D utility scores was strong overall, 0.65 (p<0.001), but weak to moderate at domain level.

Conclusions

Older people on dialysis report significantly higher burden and effects of kidney disease than those on conservative care. Lower HRQoL and wellbeing may be associated with dialysis treatment, and should inform shared decision making about treatment options.

Trial registration

UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36).

KEYWORDS

Chronic Kidney Failure, Chronic Renal Insufficiency, Renal Dialysis, Quality Of Life, Palliative Care

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The strengths of our study include a prospective assessment of HRQoL in people over 75 years of age, and the use of a novel measure to value wellbeing.
- This information is essential for doctors to discuss the relative benefits of dialysis compared with conservative care.
- The limitation of this study is that, the sample size may not have been sufficient to detect a statistically significant difference in mean scores if one existed.
- We did not have complete data on patient's comorbid conditions that may have impacted our ability to explore the associations between comorbid conditions and HRQoL or wellbeing.
- Considering the cross-sectional nature of the data, we were unable to analyse any changes relating to individuals' HRQoL or wellbeing over time, which might be captured in a longitudinal study.

INTRODUCTION

Comprehensive conservative care services were developed for people with end-stage kidney disease (ESKD) in the UK and Australia following the substantial increase in the number of older people aged ≥75 years being referred to nephrologists for dialysis,[1]. Comprehensive conservative care includes interventions to delay the progression of kidney disease and minimise complications, as well as detailed communication, shared decision-making, advance care planning, and psychologic and family support, but does not include dialysis,[2]. For older patients who often have high levels of comorbidity (such as diabetes and heart disease) and poor functional status, the survival advantage of dialysis may be limited, and comprehensive conservative management may be considered; however, robust comparative evidence remains minimal,[2]. Considerations such as symptoms, quality of life, and hospital-free days are sometimes more important for patients and families, than expected length of survival,[2].

Traditionally, economists attempt to assist resource allocation decisions by focusing on measuring and valuing health (in its broadest sense), using health-related quality of life (HRQoL) measures and survival, in particular combined in the quality-adjusted life year (QALY),[3]. In QALY calculations, values (often referred to as utility scores) are assigned to different health states, which allows the quantification of health gains comprising both length and quality of life gains from medical interventions,[3, 4]. Utilities are preference weights, where preference can be equated with value or desirability,[5, 6]. The quality adjusted life years (QALYs) value is then calculated by combining the length of survival and the utility weights.

However, many healthcare interventions may impact more broadly on quality of life (assumed to encompass the broad range of factors that are important to people in living their lives) rather than just health (which centers on physical and mental health),[3]. These broad factors could

be related to health and non-health factors that may impact the overall quality of life of a patient,[4]. Measures that look only at health in assessing the impact of these interventions would be very likely to underestimate this impact,[3, 7].

Dialysis has a large impact on the quality of life of both patients and their families; however, traditional HRQoL measures, such as the Short Form 36 (SF-36) and Kidney Disease Quality of Life (KDQOL-36) surveys may be too narrowly focused to detect all of the critical aspects of dialysis that increase or decrease an individual's quality of life,[8]. KDQOL-36™ is a short form questionnaire that includes the SF-12, a generic quality of life questionnaire,[9, 10] plus disease-specific domains including the burden of kidney disease, symptoms/problems of kidney disease, and effects of kidney disease. For this purpose, broader HRQoL measures, often named wellbeing measures, could be used to capture more facets of peoples' lives than health status alone,[4].

New instruments have been developed that provide information across health and social care, rather than just across health,[3]. The recently developed "Investigating Choice Experiments Capability Measure (ICECAP)" family of instruments have been designed to incorporate such dimensions,[11]. These instruments have their theoretical grounding in Amartya Sen's work on the relationships between functioning and capability,[11, 12]. They seek to measure a conceptually different evaluative space through a focus on capabilities: that is, what a person is able to do and who they are able to be, rather than on functioning: what a person actually does and who they become,[13]. Capabilities refer to the potential to achieve certain states and perform certain actions,[4]. Having the capability to live life the way one desires is obviously important, also to older people, and reduction of this capability limits their wellbeing,[4, 14, 15]. There is little research on how the ICECAP-O is related to other conceptualisations of

wellbeing, and the relationships between the ICECAP-O and measures of health (physical, psychological, and social) remain underexplored,[16].

The aims of the study were to measure HRQoL using SF-12 questionnaire, kidney disease quality of life using KDQOL-36™ questionnaire, and wellbeing using ICECAP-O questionnaire; to determine the association between treatment type and socio-demographic characteristics on these outcome measures; to assess the convergent validity between the ICECAP-O wellbeing and the SF-6D utility (derived from SF-12 questionnaire); and to assess the feasibility and acceptability of questionnaires in older ESKD patients.

MATERIALS AND METHODS

Study design

We conducted a cross-sectional study of patients with ESKD treated with dialysis or comprehensive conservative care in the UK and Australia between 2014 and 2017. The study was performed in accordance with the Australian National Statement on Ethical Conduct in Human Research (2007), and relevant guidance in the UK. Each renal unit participating in the study obtained the approval of their Institutional Research Boards UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36). The study design conformed to the STROBE guidelines for observational studies (Item S1). Eligible subjects were fully informed about the purpose, benefits and risks of the study, and signed an approved participant consent form.

Setting and participants

The study was undertaken at three renal units in the UK and Australia. Included were males and females aged ≥75 years with ESKD, managed with dialysis (facility hemodialysis, home hemodialysis, and peritoneal dialysis) or with an estimated glomerular filtration (eGFR)

≤10ml/min/1.73m^2 and managed with comprehensive conservative, non-dialytic care. The exclusion criteria comprised cognitive impairment; patients unable to read English; and patients who were legally blind. To reduce selection bias, nephrologists and clinical nurses in each participating renal unit reviewed their clinic lists for all patients that met the eligibility criteria.

Patient and public involvement

The research question was developed from prior qualitative work with people with end-stage kidney disease and their carers,[17-19]. Patients were not directly involved in the design of this research study. Patients and their caregivers were informed of the study and invited to participate by the renal unit's research nurses. Participants were provided with an information sheet and consent from for them to read. If they were interested in participating they were asked to sign the consent form and then were provided with the surveys. Patients and their caregivers were assured that participation was entirely voluntary, that they did not have to participate and that their decision either way would not affect their clinical care.

Outcomes and variables

The key outcomes were SF-6D utilities derived from the SF-12 questions, KDQOL scores from the KDQOL-36 questions, ICECAP-O capability index derived from the ICECAP-O questions. Other outcomes were convergent validity between ICECAP-O wellbeing and the SF-6D utility instrument measured using the Pearson's correlation coefficient; and the feasibility and acceptability of the ICECAP-O and SF-12 questionnaires, assessed by response rate and specific items asking the patient whether the questionnaire was easy to complete, and whether it covered questions important to their quality of life and wellbeing.

Data sources/measurement

All eligible patients were invited to complete the KDQOL-36™ (Item S2) and the five-question ICECAP-O questionnaire (Item S3) while at their renal clinic. Relevant sociodemographic details such as age, sex, country, educational attainment, private health insurance and questions assessing feasibility and acceptability of the ICECAP-O and SF-12 questionnaire were collected (Item S4). Kidney treatment type (facility hemodialysis, home hemodialysis, peritoneal dialysis, and comprehensive conservative care), dialysis status (if currently on dialysis, and time of initiation) and renal transplant status were documented.

Health related quality of life questionnaire

The KDQOL-36 has 36 items: the SF-12 version 1 and another 24 kidney specific items,[20]. The SF-12 responses on the KDQOL-36 were transformed into HRQoL weights, known as utilities, using a published SF-6D algorithm,[21]. The SF-6D is a generic preference-based single measure of health used to generate utilities from six domains: physical, role, social, pain, mental, and vital (Item S5). The SF-6D utilities generated are measured on a 0 (death) to 1 (full health) scale, and were reported with mean and standard deviations (SDs) using UK population values,[21-23].

The SF-12 section of KDQOL-36 also yields PCS (Physical Component Summary) and MCS (Mental Component Summary) scores, both of which are scored on a T-score metric (mean = 50, SD = 10, for the US general population),[20, 24]. The three kidney specific scales assess Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease. Each of these scales is scored by transforming all items to a 0 to 100 possible range and averaging across the items on each scale to create scale scores,[20]. KDQOL-36 items are all scaled so that higher scores indicate better HRQoL,[20, 25].

Wellbeing questionnaire

The ICECAP-O questionnaire measures capabilities and covers five domains of wellbeing, including attachment (love and friendship); security (thinking about the future without concern); role (doing things that make you feel valued); enjoyment (enjoyment and pleasure); and control (independence),[26]. It has four-level response options, representing four levels of capability: none, a little, a lot, and all. The responses on the ICECAP-O questions were transformed to a ICECAP-O capability index ranging from 0 (no capability) to 1 (full capability), and presented with mean and SDs using UK population weights,[3].

Quantitative variables

The SF-6D utilities, KDQOL scores, ICECAP-O capability index, and patients' age were treated as continuous, while patients' sex, treatment type (dialysis, conservative care), education (some high school or lower levels, completed high school or higher levels), private health insurance (yes, no), and health system (UK, Australia) were analysed as categorical variables. Age was also additionally dichotomised (less than or equal to, versus greater than the median age [81 years]).

Statistical methods

The analysis of data involved descriptive statistics assessing proportions and mean values of the SF-6D utilities, PCS, MCS, Burden of Kidney Disease, Symptoms of Kidney Disease, Effects of Kidney Disease scores, and the ICECAP-O capability index for the entire cohort. Hypothesis testing with a two-tailed Student's t-test was used to detect differences in the mean values of SF-6D utilities, KDQOL-36 scores, and ICECAP-O capability index for patients' treatment type and socio-demographic characteristics. We hypothesised that HRQoL and wellbeing measures in each treatment group would be equivalent.

Linear regression with multivariable models was undertaken to determine the association between treatment type and patient characteristics on SF-6D utilities, KDQOL scores and ICECAP-O capability index. In the multivariable linear regression, age, sex, treatment type, education, private health insurance, and health system were included as covariates on the basis of *a priori* knowledge of their associations with the HRQoL and wellbeing measures.

Pearson's correlation coefficient was used to determine the convergent validity of the ICECAP-O wellbeing with the SF-6D utility instrument. The correlations were assessed for the overall ICECAP-O and SF-6D utility scores and their domains. We hypothesised, moderate to strong positive correlations because both these instruments measures some similar facets of quality of life. Correlations above 0.5 were considered strong, between 0.3 and 0.5 as moderate, and below 0.3 as weak,[16].

Complete case analysis was performed for all outcomes. All statistical analyses were performed with SAS Version 9.4 (SAS Institute, Cary, NC). A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 129 patients were recruited, including 83 (64%) managed with dialysis and 46 (36%) patients managed with comprehensive conservative care. Overall, 65% were male, and the median age of the entire cohort was 81 years [IQR 75–78]. Patient characteristics are shown in Table 1.

Health-related quality of life SF-6D utilities

Of 129 patients, the mean utility for 116 patients with complete data was 0.62 (SD 0.14) (n =13 missing values). The mean SF-6D utilities for the dialysis group were 0.61 (SD 0.13), and 0.65 (SD 0.15) for the conservative care group (Table S1). The "vitality" domain reported the highest average score, and was responsible for the highest decrement in utilities in both treatment groups (Table S2).

The mean SF-6D utilities were 0.07 (SD 0.14) lower for females than for males (p = 0.006); 0.06 (SD 0.14) lower for patients residing in the UK compared with those residing in Australia (p = 0.03); and 0.07 (SD 0.14) lower for patients without a private health insurance compared to patients with a private health insurance (p = 0.03) (Table S1). When adjusted for all variables, the mean SF-6D utilities were 0.09 lower for females compared to males (95 % lower CI = -0.14 and upper CI = -0.03, p = 0.002). There was no significant difference in the mean utilities observed between two treatments when adjusted for other variables (Table 2).

KDQOL scores

The mean KDQOL scores on the five domains for patients with complete data were as follows: PCS score of 32.41 (n = 115, SD 9.68); MCS score of 47.25 (n = 115, SD 11.34); Burden of Kidney Disease score of 44.46 (n = 127, SD 31.28); Symptom/Problems of Kidney Disease score of 72.78 (n = 125, SD 19.03); and Effects of Kidney Disease score of 70.24 (n = 127, SD 22.35).

In univariate analysis the PCS score was 5.46 points lower in females than males (p = 0.004) (i.e. lower physical health); the MCS score was 4.63 points lower in Australian versus UK patients (p = 0.03) (i.e. lower mental health) table S1 and table S3. The Burden of Kidney Disease score was 28.12 points lower in the dialysis group than the conservative care group (p

< 0.001) (indicating a higher burden of disease and lower quality of life); 14.06 points lower in UK versus Australian patients (p = 0.01) (indicating higher burden of disease); 13.70 points lower in patients without private health insurance compared to those with private health insurance (p = 0.04) (indicating a higher burden of disease). The Effects of Kidney Disease score was 17.11 points lower in the dialysis group compared to the conservative care group (p < 0.001) (indicating higher effects of the disease and lower quality of life); 8.35 points lower in UK versus Australian patients (p = 0.03) (indicating higher effects of the disease).

The dialysis group reported a higher MCS score (47.67 vs 46.56), indicating marginally better mental health than the conservative care group. (Table S2).

When adjusted for other variables, the mean score for the Burden of Kidney Disease sub-scale was 28.59 lower (i.e. more burdensome) for patients on dialysis compared with patients on conservative care (p<0.001) (Table 2, Figure 1). The mean score for Effects of Kidney Disease when adjusted for all the other variables, was 16.49 lower (i.e. higher disease related effects) for patients on dialysis compared with patients on comprehensive conservative care (p<0.001) (Table 2, Figure 2). Adjusted scores were lower but not statistically, significantly different for PCS, MCS and Symptoms of Kidney Disease between the two treatment groups.

ICECAP-O capability index

The mean ICECAP-O capability index for 126 patients with complete data was 0.72 (SD 0.19) (n=3 missing values). In the dialysis group, the mean capability index was 0.71 (SD 0.19), and 0.76 (SD 0.20) for the conservative care group (Table S1), but not significantly different. Overall, the dialysis treatment group reported a lower wellbeing score on all five domains compared to the conservative care group. The "attachment" domain showed the highest average

score, and was responsible for the highest contribution to capabilities in both treatment groups (Table S2). When adjusted for other variables, there were no significant differences in the mean capability index observed between the two treatments (Table 2).

Convergent validity

For 114 observations the SF-6D utilities score and the pain domain of the SF-6D were strongly correlated with the overall ICECAP-O capability index with a Pearson's coefficient of 0.65 ($p<0.001$) and 0.56 ($p<0.001$) respectively. At the domain level, the role and control domains of the ICECAP-O questionnaire were strongly correlated with the pain domain of the SF-6D, with a Pearson's coefficient of 0.51 ($p<0.001$) and 0.53 ($p<0.001$) respectively. All other domains of the ICECAP-O were weakly or moderately correlated with SF-6D domains, values ranging from 0.02 to 0.49 (Table 3).

Feasibility and acceptability

115 of 129 patients completed the questionnaire, with 14 patients missing items for the ICECAP-O and 10 patients missing items for the SF-12. Overall, patients found both questionnaires easy to use and relevant to assessing their wellbeing. They responded with an average score of 1.78 out of 5 (1 = strongly agree, 5 = completely disagree) on questions assessing ease of use; and with an average score 1.77 and 1.79 out of 5 on the questions assessing the relevance of ICECAP-O and the SF-12 questions respectively.

DISCUSSION

This prospective cross-sectional study determined the mean SF-6D utilities, KDQOL scores and ICECAP-O capability index for patients with ESKD according to treatment, and socio-demographic variables. Our findings suggest females compared with males, patients residing

in the UK compared with those residing in Australia, and patients without private health insurance compared with those with private health insurance have significantly lower SF-6D utilities. However, when adjusted for the other variables, only females reported significantly lower utilities compared with males. Furthermore, the study determined the convergent validity between the ICECAP-O wellbeing and SF-6D utility instrument and assessed the feasibility and acceptability of the ICECAP-O wellbeing and SF-12 questionnaire in older people with ESKD.

The dialysis group reported 0.05 lower SF-6D utilities compared with the conservative care group reflecting a potentially clinically meaningful difference related to treatment, however, this difference was not statistically significant. Meaningful differences or the minimal important difference (MID) in utility-based HRQoL reported in 11 studies using the SF-6D utilities ranged from 0.011 to 0.097, with a mean MID of 0.041,[27]. It is therefore likely our study has detected a meaningful difference. In addition, a 0.05 difference in ICECAP-O wellbeing for dialysis patients may also represent a clinically meaningful difference, however, MIDs for ICECAP-O have not yet been published.

In our study, with the exception of a strong correlation between the "control" and "role" domain of the ICECAP-O with the "pain" domain on the SF-6D, most of the ICECAP-O domains were found to have weak to moderate correlations with the SF-6D corresponding domains. This indicates the newly developed capability instrument does measure different aspects of quality of life or wellbeing, and offers additional information when compared to measures of health, such as the SF-6D used in the conventional QALY approach. In addition, we observed a higher score for the feasibility and acceptability of the ICECAP-O questions indicating it to be acceptable and as relevant as SF-12 (an established HRQoL measure).

There is debate in the health economics literature concerning the ways to apply the capability approach in economic evaluations with some suggesting that QALYs alone are adequate, while others argue this approach is too narrow, and that direct measures of capability or wellbeing provide a more extensive application of Sen's paradigm,[28]. Capability is empirically distinct from functioning and the content of capability instruments is not subsumed by the content of instruments used to capture changes in HRQoL for QALYs,[28].

Health economic analyses would benefit from the inclusion of individual capability measures; whether the focus should be only upon people's *achievements*—their "functioning"—or people's *capability to achieve* is contested,[28]. Sen's example of the fasting man versus the starving man serves as a key example for focusing on capability: two people, one of whom is starving and the other, who is fasting, have comparable functioning in terms of nourishment, but their capabilities to be nourished are notably different,[28]. The argument is that focusing on functioning alone would miss important distinctions, such as differences in freedom and choice between individuals,[28].

There are some limitations to this study. First, the sample size may not have been sufficient to detect a statistically significant difference in mean scores if one existed. Second, we did not have complete data on patient's comorbid conditions that may have impacted our ability to explore the associations between comorbid conditions and HRQoL or wellbeing. Third, considering the cross-sectional nature of the data, we were unable to analyse any changes relating to individuals' HRQoL or wellbeing over time, which might be captured in a longitudinal study. The strengths of our study include a prospective assessment of HRQoL in people over 75 years of age, and the use of a novel measure to value wellbeing. This

information is essential for doctors to discuss the relative benefits of dialysis compared with conservative care.

In conclusion, we observed lower quality of life and wellbeing for older patients with ESKD managed on dialysis compared to comprehensive conservative care. Furthermore, measuring wellbeing using a capability index provides additional insights into the impact of dialysis on older people than HRQoL measurement alone and has potential to improve the economic evaluation of treatment for ESKD.

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Authors' Contributions

Authors FM, KM, SC, AB, and RM designed the study. RM, SC and AB led the data collection. KS conducted the analysis and drafted the first version of the manuscript. RM, AT and KM supported the data analysis and interpretation of the results, and all authors revised the final version of the manuscript.

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Competing interests

None of the authors declare a conflict of interest. The results presented in this paper have not been published previously elsewhere, either in whole or part, except in abstract format.

Ethics approval

The study was performed in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (Commonwealth of Australia, 2007), and relevant guidance in the

UK. Each renal unit participating in the study obtained the approval of the Institutional Health Research Ethics Committee to conduct the study. The study approval numbers are as follow: UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36).

Data sharing statement

Data for the study can be provided for specific research questions that are available from the corresponding author on request

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Table 1: Patients characteristics according to treatment group

Patient Characteristics	Dialysis	Conservative Care	Total
	n = 83	n = 46	n = 129
	n (%)	n (%)	n (%)
Dialysis			
Facility Haemodialysis	68 (82%)	-	68 (53%)
Home Haemodialysis	2 (2%)	-	2 (2%)
Peritoneal Dialysis	13 (16%)	-	13 (10%)
Median age (y)	81 [78-84]	83 [81-87]	81 [78-85]
Age group			
≤81 years	50 (60%)	19 (41%)	69 (53%)
>81 years	33 (40%)	27 (59%)	60 (47%)
Sex			
Males	57 (69%)	27 (59%)	84 (65%)
Females	26 (31%)	19 (41%)	45 (35%)
Country			
United Kingdom	58 (70%)	9 (20%)	67 (52%)
Australia	25 (30%)	37 (80%)	62 (48%)
Education			
Primary school	26 (31%)	19 (41%)	45 (35%)
Some high school	35 (42%)	17 (37%)	52 (40%)
Completed high school	8 (10%)	3 (7%)	11 (9%)
Completed diploma	6 (7%)	3 (7%)	9 (7%)
Completed university degree	7 (8%)	3 (7%)	10 (8%)
Private Health Insurance			
Yes	15 (18%)	14 (30%)	29 (22%)
No	65 (78%)	29 (63%)	94 (73%)
Unknown	1 (1%)	1 (2%)	2 (2%)

Table 2: Adjusted Difference in SF-6D utilities, KDQOL-36 scores, and ICECAP-O capability index for dialysis compared with conservative care (fully adjusted)

	Differences†	95 % Lower CI	95 % Upper CI	p value
SF-6D utilities	-0.05	-0.12	0.01	0.12
KDQOL-PCS	-3.17	-7.61	1.27	0.16
KDQOL-MCS	-2.41	-7.66	2.84	0.37
KDQOL-Burden of Disease	-28.59	-41.77	-15.42	<0.001*
KDQOL-Symptoms of Disease	-5.93	-14.61	2.73	0.18
KDQOL-Effects of Disease	-16.49	-25.98	-6.99	<0.001*
ICECAP-O capability index	-0.07	-0.16	0.02	0.12

† Difference in scores adjusted for age, gender, country, education, and health insurance status. * $p < 0.001$, statistical significance. CI - Confidence interval. KDQOL-36 - Kidney disease quality of life with 36 items. PCS - Physical Component Summary. MCS -Mental Component Summary.

Table 3: Convergent validity between ICECAP-O and SF-6D measures (n = 114)† using Pearson's correlation coefficient

	ICECAP-O overall	ICECAP-O domain				
		Attachment	Security	Role	Enjoyment	Control
SF-6D overall	0.65**	-	-	-	-	-
SF-6D domain						
Physical health	0.43**	0.08	0.31*	0.40**	0.32*	0.40**
Role limitations	0.30*	0.05	0.21*	0.28*	0.14	0.31*
Social functioning	0.41**	0.18	0.25*	0.34*	0.30*	0.35*
Pain	**0.56****	0.17	0.29*	**0.51****	0.43**	**0.53****
Mental health	0.39**	0.19*	0.35*	0.30*	0.27*	0.27*
Vitality	0.44**	0.17	0.21*	0.41**	0.28*	0.42**

† Observations with missing values on either SF-12 or ICECAP-O questions were removed from the analysis (n = 15). * $p < 0.05$, statistical significance. ** $p < 0.001$, statistical significance.

Figure Legends

Figure 1- *Title:* KDQOL-36 Burden of Kidney Disease score according to treatment group.

Label: (a) Dialysis group (n=83), (b) Conservative Care group (n=44).

Explanatory text: A higher score indicates lower burden of disease and better quality of life.

Figure 2- *Title:* KDQOL-36 Effects of Kidney Disease score according to treatment group.

Label: (a) Dialysis group (n=82), (b) Conservative Care group (n=45).

Explanatory text: A higher score indicates lower effects of disease and better quality of life.

Supplementary Material

Supplementary Table 1 (Table S1): SF-6D utilities, SF-12 PCS and MCS scores, and ICECAP-O capability index according to patient characteristics

Supplementary Table 2 (Table S2): Mean scores and weights of SF-6D, KDQOL-36 and ICECAP-O according to treatment group

Supplementary Table 3 (Table S3): KDQOL-36 Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease scores according to patient characteristics

Supplementary Item 1 (Item S1): STROBE Statement: checklist of items that should be included in reports of observational studies

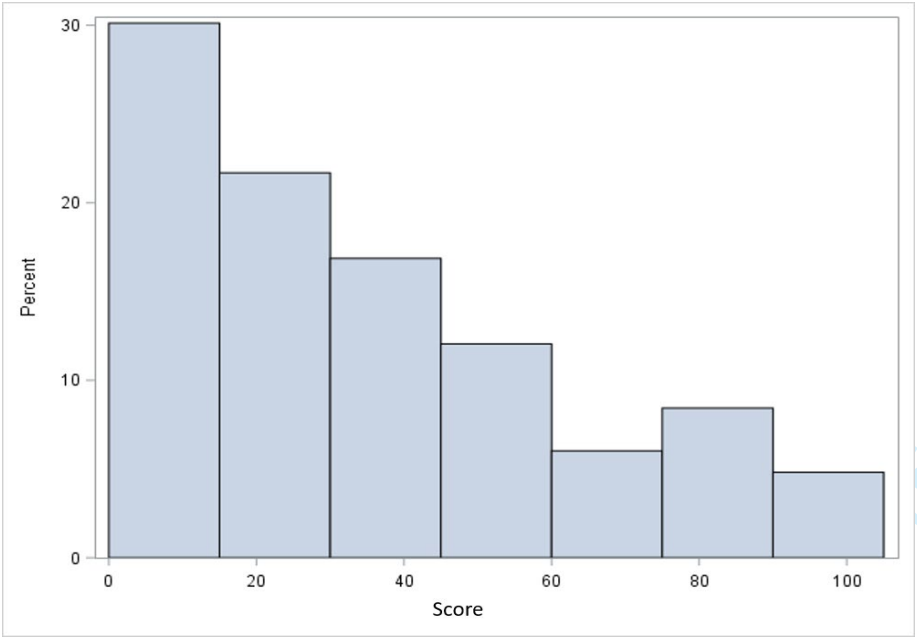
Supplementary Item 2 (Item S2): KDQOL-36 Questionnaire (SF-12: Questions 1 – 12 (converted to SF-utilities), KDQOL scores (PCS and MCS scores: Questions 1 – 12, burden of kidney disease: Questions 13 – 16, effects of kidney disease: Questions 17 – 28, symptoms of kidney disease: Questions 29 – 36)

Supplementary Item 3 (Item S3): ICECAP-O Questionnaire

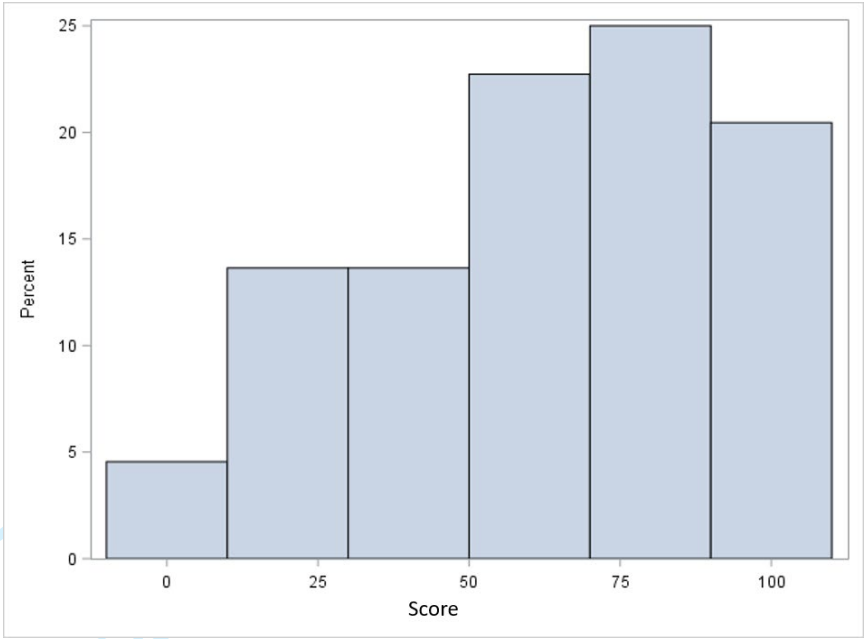
Supplementary Item 4 (Item S4): Background Questions

Supplementary Item 5 (Item S5): SF-6D domains

Figure 1: KDQOL-36 Burden of Kidney Disease score according to treatment group.



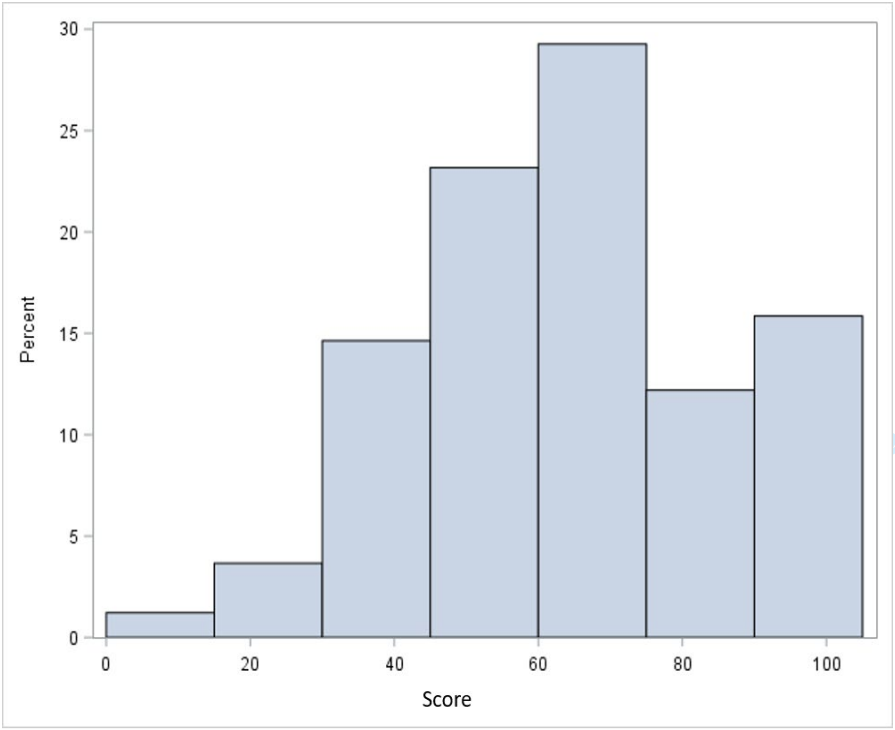
(a) Dialysis group (n=83)



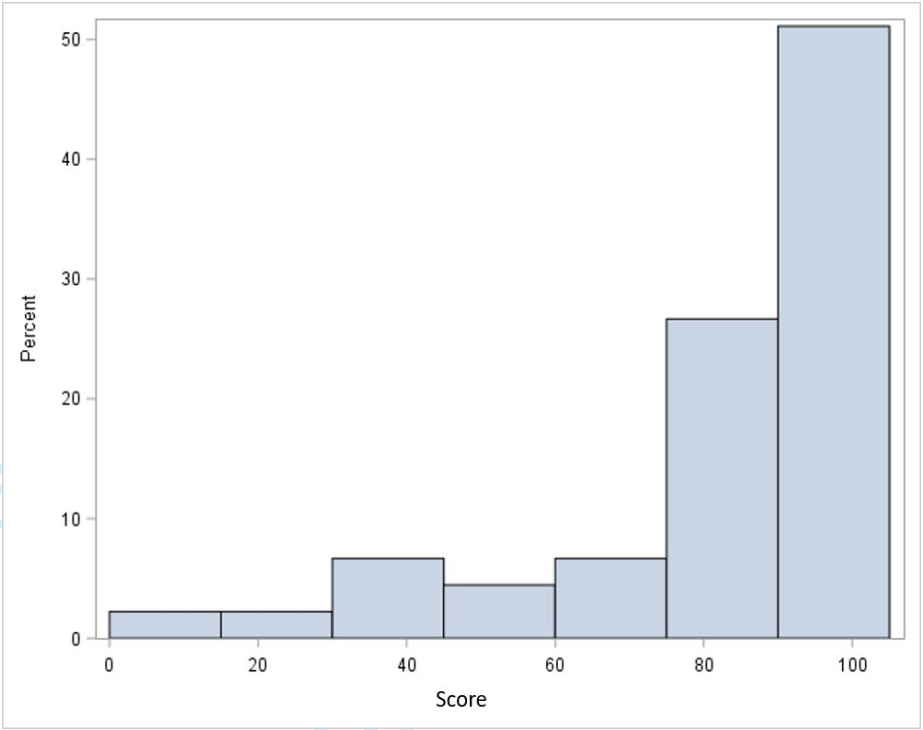
(b) Conservative Care group (n=44)

A higher score indicates lower burden of disease and better quality of life.

Figure 2*:* KDQOL-36 Effects of Kidney Disease score according to treatment group.



(a) Dialysis group (n=82)



(b) Conservative Care group (n=45)

A higher score indicates lower effects of disease and better quality of life.

Supplementary Table 1 (Table S3): SF-6D utilities, SF-12 PCS and MCS scores, and ICECAP-O capability index according to patient characteristics

Characteristics	SF-6D (n = 116)†	PCS (n = 115)††	MCS (n = 115)‡	ICECAP-O (n = 126)‡‡
	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)
Age				
≤81 years	0.63 (0.60-0.67)	32.71 (30.31-35.10)	48.35 (45.51-51.19)	0.73 (0.69-0.78)
>81 years	0.62 (0.58-0.65)	32.08 (29.33-34.84)	46.04 (42.89-49.20)	0.72 (0.67-0.77)
Gender				
Males	0.65 (0.62-0.68)*	34.31 (32.00-36.62)*	47.92 (45.44-50.40)	0.73 (0.68-0.77)
Females	0.58 (0.53-0.62)*	28.85 (26.31-31.39)*	45.98 (42.03-49.93)	0.72 (0.67-0.78)
Treatment**				
Dialysis	0.61 (0.57-0.64)	31.22 (29.02-33.43)	47.67 (45.03-50.30)	0.71 (0.66-0.75)
Conservative Care	0.65 (0.61-0.70)	34.32 (31.27-37.38)	46.56 (42.98-50.15)	0.76 (0.70-0.82)
Country				
United Kingdom	0.60 (0.56-0.63)*	30.76 (28.30-33.22)	49.62 (46.66-52.58)*	0.72 (0.67-0.76)
Australia	0.65 (0.61-0.69)*	33.98 (31.38-36.57)	44.99 (42.06-47.92)*	0.73 (0.68-0.79)
Education §				
Attended some high school	0.62 (0.59-0.65)	31.87 (29.84-33.91)	46.98 (44.43-49.53)	0.72 (0.68-0.76)
Completed high school or tertiary education	0.63 (0.58-0.69)	34.19 (30.22-38.17)	48.09 (44.21-51.97)	0.73 (0.66-0.80)
Private Health Insurance ¶				
Yes	0.68 (0.62-0.73)*	33.03 (29.55-36.50)	49.50 (44.82-54.18)	0.79 (0.73-0.85)
No/Unknown	0.61 (0.58-0.64)*	32.25 (30.09-34.40)	46.77 (44.40-49.13)	0.71 (0.67-0.75)

† Specific SF-6D algorithms were used to convert the SF-12 scores to preference based SF-6D utilities for the UK and the Australian population. 13 out of 129 observations had missing values on SF-12 questionnaire and their SF-6D utilities were not calculated; the remaining had 2 observations missing value for education variable; 3 observations missing value for health insurance variable. †† 14 out of 129 observations had missing values on SF-12 questionnaire and their PCS score were not calculated; the remaining had 1 observation missing value for education variable; 2 observations missing value for health insurance variable. ‡ 14 out of 129 observations had missing values on SF-12 and their MCS score were not calculated; the remaining had 1 observation missing value for education variable; 2 observations missing value for health insurance variable. ‡‡ 3 out of 129 observations had missing values on ICECAP-O questionnaire and their capability index were not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. * $p < 0.05$, statistical significance. ** The dialysis group consist of Facility Haemodialysis, Home Haemodialysis and Peritoneal dialysis. § Individual responses to Primary school/Some high school were merged into one category as "Attended some high school" and the responses to GCSEs/Completed high school/Diploma/TAGE/ Completed A- levels/ University degree were merged into one category as "Completed high school or tertiary education". ¶ Individual responses to "No" and "Unknown" were merged into one category as "No/Unknown". CI - Confidence interval. SF-12 - Short form survey with 12 items. PCS - Physical Component Summary. MCS - Mental Component Summary.

Supplementary Table 2 (Table S2): Mean scores and weights of SF-6D, KDQOL-36 and ICECAP-O according to treatment group

Instrument	Score Mean (SD)	Weights Mean (SD)	Score Mean (SD)	Weights Mean (SD)
SF-6D‡				
Physical functioning	2.47 (1.04)	-0.02 (0.02)	2.26 (0.68)	-0.018 (0.02)
Role limitations	3.22 (1.44)	-0.06 (0.02)	2.84 (1.28)	-0.05 (0.03)
Social functioning	3.33 (1.62)	-0.06 (0.03)	2.65 (1.25)	-0.06 (0.03)
Pain	3.29 (2.13)	-0.05 (0.05)	2.60 (1.37)	-0.04 (0.05)
Mental health	2.90 (1.92)	-0.05 (0.04)	2.33 (1.10)	-0.05 (0.04)
Vitality	3.86 (1.72)	-0.09 (0.02)	3.57 (1.13)	-0.09 (0.01)
KDQOL-36				
Physical Component Summary (PCS)	31.22 (9.32)	-	34.32 (10.05)	-
Mental Component Summary (MCS)	47.67 (11.12)	-	46.56 (11.78)	-
Burden of Kidney Disease	34.71 (27.77)	-	62.83 (29.45)	-
Symptom of Kidney Disease	70.71 (18.74)	-	76.61 (19.18)	-
Effects of Kidney Disease	64.18 (20.27)	-	81.29 (21.92)	-
ICECAP-O‡‡				
Attachment (love and friendship)	3.25 (0.87)	0.22 (0.06)	3.27 (0.81)	0.22 (0.05)
Security (thinking about future without concern)	2.42 (0.99)	0.09 (0.05)	2.71 (0.92)	0.10 (0.05)
Role (doing things that make you feel valued)	2.51 (0.82)	0.15 (0.04)	2.69 (0.85)	0.15 (0.05)
Enjoyment (enjoyment and pleasure)	2.52 (0.94)	0.13 (0.04)	2.80 (0.97)	0.14 (0.04)
Control (independence)	2.51 (0.94)	0.13 (0.08)	2.82 (1.01)	0.15 (0.09)

† 6 observations missing values on SF-6D Role limitation domain; 12 observations missing PCS and MCS score; 2 observations missing Symptoms of Kidney Disease score; 1 observations missing Effects of Kidney Disease score; 2 observations missing values on ICECAP-O Attachment domain. †† 1 observation missing value on SF-6D Role limitation domain; 2 observations missing KDQOL-36 PCS, MCS, Burden of Kidney Disease, and Symptoms of Kidney Disease score; 1 observation missing KDQOL-36 Effects of Kidney Disease score; 1 observation missing value on all ICECAP-O domains. ‡ SF-6D domain scores are weighted decrements. ‡‡ ICECAP-O domain scores are weighted increments. SD - Standard deviation. KDQOL-36 - Kidney disease quality of life with 36 items.

Supplementary Table 3 (Table S3): KDQOL-36 Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease scores according to patient characteristics

Characteristics	Burden of Kidney Disease (n = 127)†	Symptoms of Kidney Disease (n = 125)††	Effects of Kidney Disease (n = 127)‡
	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)
Age			
≤81 years	41.80 (34.47-49.12)	72.21 (67.15-77.27)	69.15 (63.05-75.25)
>81 years	47.16 (38.81-55.50)	73.35 (68.76-77.95)	71.35 (66.26-76.43)
Gender			
Males	44.43 (37.70-51.15)	74.00 (70.01-78.00)	71.48 (66.72-76.23)
Females	44.51 (34.62-54.39)	70.46 (64.13-76.79)	67.91 (60.77-75.05)
Treatment**			
Dialysis	34.71 (28.65-40.78)*	70.71 (66.56-74.85)	64.18 (59.72-68.63)*
Conservative Care	62.83 (53.88-71.78)*	76.61 (70.78-82.44)	81.29 (74.70-87.88)*
Country			
United Kingdom	37.81 (30.68-44.94)*	71.97 (67.37-76.58)	66.29 (61.31-71.28)*
Australia	51.88 (43.59-60.16)*	73.72 (68.64-78.81)	74.65 (68.52-80.77)*
Education§			
Attended some high school	45.32 (38.85-51.79)	71.42 (67.21-75.63)	70.93 (66.29-75.57)
Completed high school or tertiary education	43.53 (32.44-54.61)	76.87 (72.15-81.59)	68.92 (61.06-76.79)
Private Health Insurance¶			
Yes	55.32 (41.82-68.83)*	73.33 (65.11-81.54)	75.85 (67.67-84.02)
No/Unknown	41.62 (35.62-47.63)*	72.88 (69.03-76.73)	69.32 (64.80-73.84)

† 2 out of 129 observations had missing values on burden of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. †† 4 out of 129 observations had missing values on symptoms of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. ‡ 2 out of 129 observations had missing values on effects of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. * $p < 0.05$, statistical significance. ** The dialysis group consist of Facility Haemodialysis, Home Haemodialysis and Peritoneal dialysis. § Individual responses to Primary school/Some high school were merged into one category as "Attended some high school" and the responses to GCSEs/Completed high school/Diploma/TAFE/ Completed A- levels/ University degree were merged into one category as "Completed high school or tertiary education". ¶ Individual responses to "No" and "Unknown" were merged into one category as "No/Unknown". CI - Confidence interval. KDQOL-36 - Kidney disease quality of life with 36 items.

Supplementary Item 1 (Item S1): STROBE Statement: checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Yes/No/NA
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes
Objectives	3	State specific objectives, including any pre-specified hypotheses	Yes
Methods			
Study design	4	Present key elements of study design early in the paper	Yes
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Yes
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Yes

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes
Bias	9	Describe any efforts to address potential sources of bias	Yes
Study size	10	Explain how the study size was arrived at	Yes
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes
		(*b*) Describe any methods used to examine subgroups and interactions	Yes
		(*c*) Explain how missing data were addressed	Yes
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	No – screening logs at each site were not available
		(b) Give reasons for non-participation at each stage	No
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders	Yes
		(b) Indicate number of participants with missing data for each variable of interest	Yes
		(c) *Cohort study*—Summarise follow-up time (e.g., average and total amount)	NA
Outcome data	15*	*Cross-sectional study*—Report numbers of outcome events or summary measures	Yes
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes
		(*b*) Report category boundaries when continuous variables were categorised	Yes
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA

Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Yes
Discussion			
Key results	18	Summarise key results with reference to study objectives	Yes
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes
Generalisability	21	Discuss the generalisability (external validity) of the study results	Yes
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes

Supplementary Item 2 (Item S2): KDQOL-36 Questionnaire (SF-12: Questions 1 – 12 (converted to SF-utilities), KDQOL scores (PCS and MCS scores: Questions 1 – 12, burden of kidney disease: Questions 13 – 16, effects of kidney disease: Questions 17 – 28, symptoms of kidney disease: Questions 29 – 36)

Your Health

– and –

Well-Being

Kidney Disease and Quality of Life (KDQOL™-36)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Thank you for completing these questions!

Your Health

This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.

1. In general, would you say your health is: [Mark an ☒ in the one box that best describes your answer.]

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [Mark an ☒ in a box on each line.]

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
3. Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐ 1	☐ 2
5. Were limited in the kind of work or other activities	☐ 1	☐ 2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐ 1	☐ 2
7. Didn't do work or other activities as carefully as usual	☐ 1	☐ 2

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Your Kidney Disease

How true or false is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
13. My kidney disease interferes too much with my life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. Too much of my time is spent dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. I feel frustrated dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. I feel like a burden on my family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the <u>past 4 weeks</u>, to what extent were you bothered by each of the following?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
17. Soreness in your muscles?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18. Chest pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19. Cramps?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. Itchy skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. Dry skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22. Shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
23. Faintness or dizziness?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24. Lack of appetite?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25. Washed out or drained?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26. Numbness in hands or feet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27. Nausea or upset stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[a]. (Hemodialysis patient only) Problems with your access site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[b]. (Peritoneal dialysis patient only) Problems with your catheter site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Effects of Kidney Disease on Your Daily Life

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease bother you in each of the following areas?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
29. Fluid restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30. Dietary restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31. Your ability to work around the house?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32. Your ability to travel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33. Being dependent on doctors and other medical staff?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34. Stress or worries caused by kidney disease?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35. Your sex life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36. Your personal appearance?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Supplementary Item 3 (Item S3): ICECAP-O Questionnaire

ABOUT YOUR QUALITY OF LIFE

By placing a tick (✓) in ONE box in EACH group below, please indicate which statement best describes your quality of life at the moment.

1. Love and Friendship		
I can have all of the love and friendship that I want	☐	4
I can have a lot of the love and friendship that I want	☐	3
I can have a little of the love and friendship that I want	☐	2
I cannot have any of the love and friendship that I want	☐	1
2. Thinking about the future		
I can think about the future without any concern	☐	4
I can think about the future with only a little concern	☐	3
I can only think about the future with some concern	☐	2
I can only think about the future with a lot of concern	☐	1
3. Doing things that make you feel valued		
I am able to do all of the things that make me feel valued	☐	4
I am able to do many of the things that make me feel valued	☐	3
I am able to do a few of the things that make me feel valued	☐	2
I am unable to do any of the things that make me feel valued	☐	1
4. Enjoyment and pleasure		
I can have all of the enjoyment and pleasure that I want	☐	4
I can have a lot of the enjoyment and pleasure that I want	☐	3
I can have a little of the enjoyment and pleasure that I want	☐	2
I cannot have any of the enjoyment and pleasure that I want	☐	1
5. Independence		
I am able to be completely independent	☐	4
I am able to be independent in many things	☐	3
I am able to be independent in a few things	☐	2
I am unable to be at all independent	☐	1

Tick one box only in each section

Supplementary Item 4 (Item S4): Background Questions

Q1. What is your full name? _____

Q2. What is your date of birth? _____ (*dd/mm/yyyy*)

Q3. Gender (*please tick one*)

Male □

Female □

Q4. What is your main residential postcode? _____

Q5. What was your country of birth? _____

Q6. What is the highest level of education you have completed? (*please tick the box that best describes you*)

Primary school □

Some high school □

Completed high school □

Completed Diploma/ TAFE course □

Completed University Degree □

Q7. Do you have private health insurance? (*please tick one*)

Yes □

No □

Don't know □

Q8. What type of kidney treatment are you ***currently*** having? (*please tick one*)

Hemodialysis (satellite or hospital) □

Hemodialysis at home □

Peritoneal dialysis □

Non-dialysis renal supportive care □

Q9. If you are currently on dialysis when did you first start dialysis?

_____ *(*mm/yyyy)

Q10. Have you ever had a kidney transplant before? (*please tick one*)

Yes □ No □

Q11. The next two questions are about the **ICECAP-O survey.** On the scale below please rate how <u>easy</u> this survey was to complete *(circle a number between 1 and 5)*

Very easy	Somewhat easy	Neutral	Somewhat difficult	Very difficult
1	2	3	4	5

Q12. Did this survey measure the things that you consider <u>important</u> to your quality of life? *(circle a number between 1 and 5)*

Completely agree	Somewhat agree	Neutral	Somewhat disagree	Completely disagree
1	2	3	4	5

Q13. If you responded with 'somewhat disagree' or 'completely disagree,' would you like to tell us what you think the **ICECAP-O survey** was missing?

_____

_____

_____

_____

_____

Q14. The next two questions are about the **SF-12 survey.** On the scale below please rate how easy this survey was to complete *(circle a number between 1 and 5)*

Very easy	Somewhat easy	Neutral	Somewhat difficult	Very difficult
1	2	3	4	5

Q15. Did this survey measure the things that you consider important to your quality of life? *(circle a number between 1 and 5)*

Completely agree	Somewhat agree	Neutral	Somewhat disagree	Completely disagree
1	2	3	4	5

Q16. If you responded with 'somewhat disagree' or 'completely disagree,' would you like to tell us what you think the **SF-12 survey** was missing?

_____

_____

_____

_____

Supplementary Item 5 (Item S5): SF-6D domains

Level	SF-6D
	Physical Functioning
1	Your health does not limit you in *vigorous activities*
2	Your health limits you a little in *vigorous activities*
3	Your health limits you a little in *moderate activities*
4	Your health limits you a lot in *moderate activities*
5	Your health limits you *a little in bathing and dressing*
6	Your health limits you *a lot in bathing and dressing*
	Role limitations
1	You have *no* problems with your work or other regular daily activities as a result of your physical health or any emotional problems
2	You are limited in the kind of work or other activities as a result of your physical health
3	You accomplish less than you would like as a result of emotional problems
4	You are limited in the kind of work or other activities as a result of your physical health and accomplish less than you would like as a result of emotional problems
	Social functioning
1	Your health limits your social activities *none of the time*
2	Your health limits your social activities *a little of the time*
3	Your health limits your social activities *some of the time*
4	Your health limits your social activities *most of the time*
5	Your health limits your social activities *all of the time*
	Pain
1	You have *no* pain
2	You have pain but it does not interfere with your normal work (both outside the home and housework)
3	You have pain that interferes with your normal work (both outside the home and housework) *a little bit*
4	You have pain that interferes with your normal work (both outside the home and housework) *moderately*
5	You have pain that interferes with your normal work (both outside the home and housework) *quite a bit*
6	You have pain that interferes with your normal work (both outside the home and housework) *extremely*
	Mental health
1	You feel tense or downhearted and low *none of the time*
2	You feel tense or downhearted and low *a little of the time*
3	You feel tense or downhearted and low *some of the time*
4	You feel tense or downhearted and low *most of the time*
5	You feel tense or downhearted and low *all of the time*
	Vitality
1	You have a lot of energy *all of the time*
2	You have a lot of energy *most of the time*
3	You have a lot of energy *some of the time*
4	You have a lot of energy *a little of the time*
5	You have a lot of energy *none of the time*

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Health-related quality of life and wellbeing in people over 75 years of age with end-stage kidney disease managed with dialysis or comprehensive conservative care: a cross-sectional study in the UK and Australia

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Title: Health-related quality of life and wellbeing in people over 75 years of age with end-stage kidney disease managed with dialysis or comprehensive conservative care: a cross-sectional study in the UK and Australia

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ABSTRACT

Objective

Decisions regarding treatment of older people with end-stage kidney disease need to be supported by information about the impact of dialysis on health-related quality of life (HRQoL) and wellbeing. Few data exist from patients aged 75 years of age or older.

Design

Prospective cross-sectional study.

Setting

3 renal units in the UK and Australia.

Participants

129 ESKD patients managed with dialysis or with an estimated glomerular filtration (eGFR)≤10ml/min/1.73m^2 and managed with comprehensive conservative, non-dialytic care.

Outcome measures

HRQoL and wellbeing were assessed using Short-Form six dimensions (SF-6D, 0-1 scale); KDQOL-36 (0-100 scale) and Investigating Choice Experiments Capability Measure–Older people (ICECAP-O, 0-1 scale). Linear regression assessed associations between treatment, HRQoL and wellbeing. Pearson's correlation coefficient assessed convergent validity between instruments.

Results

Median age of 81 years [IQR 78–85], 65% males; 83(64%) were managed with dialysis and 46(36%) with conservative care. When adjusted for treatment type and sociodemographic variables, those managed on dialysis reported lower mean SF-6D utility (-0.05, 95%CI -0.12 to 0.01); lower KDQOL Physical component summary score (-3.17, 95%CI -7.61 to 1.27); lower Mental component summary score (-2.41, 95%CI -7.66 to 2.84); lower quality of life due to burden (-28.59, 95%CI -41.77 to -15.42); symptoms (-5.93, 95%CI -14.61 to 2.73), and

effects of kidney disease (-16.49, 95%CI -25.98 to -6.99); and lower overall ICECAP-O wellbeing (-0.07, 95%CI -0.16 to 0.02) than those managed conservatively. Correlation between ICECAP-O wellbeing and SF-6D utility scores was strong overall, 0.65 (p<0.001), but weak to moderate at domain level.

Conclusions

Older people on dialysis report significantly higher burden and effects of kidney disease than those on conservative care. Lower HRQoL and wellbeing may be associated with dialysis treatment, and should inform shared decision making about treatment options.

Trial registration

UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36).

KEYWORDS

Chronic Kidney Failure, Chronic Renal Insufficiency, Renal Dialysis, Quality Of Life, Palliative Care

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The strengths of our study include a prospective assessment of HRQoL in people over 75 years of age, and the use of a novel measure to value wellbeing.
- This information is essential for doctors to discuss the relative benefits of dialysis compared with conservative care.
- The limitation of this study is that, the sample size may not have been sufficient to detect a statistically significant difference in mean scores if one existed.
- We did not have complete data on patient's comorbid conditions that may have impacted our ability to explore the associations between comorbid conditions and HRQoL or wellbeing.
- Considering the cross-sectional nature of the data, we were unable to analyse any changes relating to individuals' HRQoL or wellbeing over time, which might be captured in a longitudinal study.

INTRODUCTION

Comprehensive conservative care services were developed for people with end-stage kidney disease (ESKD) in the UK and Australia following the substantial increase in the number of older people aged ≥75 years being referred to nephrologists for dialysis,[1]. Comprehensive conservative care includes interventions to delay the progression of kidney disease and minimise complications, as well as detailed communication, shared decision-making, advance care planning, and psychologic and family support, but does not include dialysis,[2]. For older patients who often have high levels of comorbidity (such as diabetes and heart disease) and poor functional status, the survival advantage of dialysis may be limited, and comprehensive conservative management may be considered; however, robust comparative evidence remains minimal,[2]. Considerations such as symptoms, quality of life, and hospital-free days are sometimes more important for patients and families, than expected length of survival,[2].

Traditionally, economists attempt to assist resource allocation decisions by focusing on measuring and valuing health (in its broadest sense), using health-related quality of life (HRQoL) measures and survival, in particular combined in the quality-adjusted life year (QALY),[3]. In QALY calculations, values (often referred to as utility scores) are assigned to different health states, which allows the quantification of health gains comprising both length and quality of life gains from medical interventions,[3, 4]. Utilities are preference weights, where preference can be equated with value or desirability,[5, 6]. The quality adjusted life years (QALYs) value is then calculated by combining the length of survival and the utility weights.

However, many healthcare interventions may impact more broadly on quality of life (assumed to encompass the broad range of factors that are important to people in living their lives) rather than just health (which centers on physical and mental health),[3]. These broad factors could

be related to health and non-health factors that may impact the overall quality of life of a patient,[4]. Measures that look only at health in assessing the impact of these interventions would be very likely to underestimate this impact,[3, 7].

Dialysis has a large impact on the quality of life of both patients and their families; however, traditional HRQoL measures, such as the Short Form 36 (SF-36) and Kidney Disease Quality of Life (KDQOL-36) surveys may be too narrowly focused to detect all of the critical aspects of dialysis that increase or decrease an individual's quality of life,[8]. KDQOL-36™ is a short form questionnaire that includes the SF-12, a generic quality of life questionnaire,[9, 10] plus disease-specific domains including the burden of kidney disease, symptoms/problems of kidney disease, and effects of kidney disease. For this purpose, broader HRQoL measures, often named wellbeing measures, could be used to capture more facets of peoples' lives than health status alone,[4].

New instruments have been developed that provide information across health and social care, rather than just across health,[3]. The recently developed "Investigating Choice Experiments Capability Measure (ICECAP)" family of instruments have been designed to incorporate such dimensions,[11]. These instruments have their theoretical grounding in Amartya Sen's work on the relationships between functioning and capability,[11, 12]. They seek to measure a conceptually different evaluative space through a focus on capabilities: that is, what a person is able to do and who they are able to be, rather than on functioning: what a person actually does and who they become,[13]. Capabilities refer to the potential to achieve certain states and perform certain actions,[4]. Having the capability to live life the way one desires is obviously important, also to older people, and reduction of this capability limits their wellbeing,[4, 14, 15]. The ICECAP-O instrument was specifically developed to measure capability in older

people. There is little research on how the ICECAP-O is related to other conceptualisations of wellbeing, and the relationships between the ICECAP-O and measures of health (physical, psychological, and social) remain underexplored,[16].

The aims of the study were to measure HRQoL using SF-12 questionnaire, kidney disease quality of life using KDQOL-36™ questionnaire, and wellbeing using ICECAP-O questionnaire; to determine the association between treatment type and socio-demographic characteristics on these outcome measures; to assess the convergent validity between the ICECAP-O wellbeing and the SF-6D utility (derived from SF-12 questionnaire); and to assess the feasibility and acceptability of questionnaires in older ESKD patients.

MATERIALS AND METHODS

Study design

We conducted a cross-sectional study of patients with ESKD treated with dialysis or comprehensive conservative care in the UK and Australia between 2014 and 2017. The study was performed in accordance with the Australian National Statement on Ethical Conduct in Human Research (2007), and relevant guidance in the UK. Each renal unit participating in the study obtained the approval of their Institutional Research Boards UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36). The study design conformed to the STROBE guidelines for observational studies (Item S1),[17]. Eligible subjects were fully informed about the purpose, benefits and risks of the study, and signed an approved participant consent form.

Setting and participants

The study was undertaken at three renal units in the UK and Australia. Included were males and females aged ≥75 years with ESKD, managed with dialysis (facility hemodialysis, home

hemodialysis, and peritoneal dialysis) or with an estimated glomerular filtration (eGFR) ≤10ml/min/1.73m^2 and managed with comprehensive conservative, non-dialytic care. The exclusion criteria comprised cognitive impairment; patients unable to read English; and patients who were legally blind. To reduce selection bias, nephrologists and clinical nurses in each participating renal unit reviewed their clinic lists for all patients that met the eligibility criteria.

Patient and public involvement

The research question was developed from prior qualitative work with people with end-stage kidney disease and their carers,[18-20]. Patients were not directly involved in the design of this research study. Patients and their caregivers were informed of the study and invited to participate by the renal unit's research nurses. Participants were provided with an information sheet and consent from for them to read. If they were interested in participating they were asked to sign the consent form and then were provided with two surveys contained in the one booklet, (the ICECAP-O survey and the standard KDQOL-36^{TM}) while at their renal clinic. Patients and their caregivers were assured that participation was voluntary, that they did not have to participate and that their decision either way would not affect their clinical care.

Outcomes and variables

The key outcomes were SF-6D utilities derived from the SF-12 questions, KDQOL scores from the KDQOL-36 questions, ICECAP-O capability index derived from the ICECAP-O questions. Other outcomes were convergent validity between ICECAP-O wellbeing and the SF-6D utility instrument measured using the Pearson's correlation coefficient; and the feasibility and acceptability of the ICECAP-O and SF-12 questionnaires, assessed by response rate and

specific items asking the patient whether the questionnaire was easy to complete, and whether it covered questions important to their quality of life and wellbeing.

Data sources/measurement

All eligible patients were invited to complete the KDQOL-36™ (Item S2) and the five-question ICECAP-O questionnaire (Item S3) while at their renal clinic. Relevant sociodemographic details such as age, sex, country, educational attainment, private health insurance and questions assessing feasibility and acceptability of the ICECAP-O and SF-12 questionnaire were collected (Item S4). Kidney treatment type (facility hemodialysis, home hemodialysis, peritoneal dialysis, and comprehensive conservative care), dialysis status (if currently on dialysis, and time of initiation) and renal transplant status were documented.

Health related quality of life questionnaire

The KDQOL-36 has 36 items: the SF-12 version 1 and another 24 kidney specific items,[21]. The SF-12 responses on the KDQOL-36 were transformed into HRQoL weights, known as utilities, using a published SF-6D algorithm,[22]. The SF-6D is a generic preference-based single measure of health used to generate utilities from six domains: physical, role, social, pain, mental, and vital (Item S5). The SF-6D utilities generated are measured on a 0 (death) to 1 (full health) scale, and were reported with mean and standard deviations (SDs) using UK population values,[22-24].

The SF-12 section of KDQOL-36 also yields PCS (Physical Component Summary) and MCS (Mental Component Summary) scores, both of which are scored on a T-score metric (mean = 50, SD = 10, for the US general population),[21, 25]. The three kidney specific scales assess Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease. Each

of these scales is scored by transforming all items to a 0 to 100 possible range and averaging across the items on each scale to create scale scores,[21]. KDQOL-36 items are all scaled so that higher scores indicate better HRQoL,[21, 26].

Wellbeing questionnaire

The ICECAP-O questionnaire measures capabilities and covers five domains of wellbeing, including attachment (love and friendship); security (thinking about the future without concern); role (doing things that make you feel valued); enjoyment (enjoyment and pleasure); and control (independence),[27]. It has four-level response options, representing four levels of capability: none, a little, a lot, and all. The responses on the ICECAP-O questions were transformed to a ICECAP-O capability index ranging from 0 (no capability) to 1 (full capability), and presented with mean and SDs using UK population weights,[3].

Quantitative variables

The SF-6D utilities, KDQOL scores, ICECAP-O capability index, and patients' age were treated as continuous, while patients' sex, treatment type (dialysis, conservative care), education (some high school or lower levels, completed high school or higher levels), private health insurance (yes, no), and health system (UK, Australia) were analysed as categorical variables. Age was also additionally dichotomised (less than or equal to, versus greater than the median age [81 years]).

Statistical methods

The analysis of data involved descriptive statistics assessing proportions and mean values of the SF-6D utilities, PCS, MCS, Burden of Kidney Disease, Symptoms of Kidney Disease, Effects of Kidney Disease scores, and the ICECAP-O capability index for the entire cohort.

Hypothesis testing with a two-tailed Student's t-test was used to detect differences in the mean values of SF-6D utilities, KDQOL-36 scores, and ICECAP-O capability index for patients' treatment type and socio-demographic characteristics. We hypothesised that HRQoL and wellbeing measures in each treatment group would be equivalent. Linear regression with multivariable models was undertaken to determine the association between treatment type and patient characteristics on SF-6D utilities, KDQOL scores and ICECAP-O capability index. In the multivariable linear regression, age, sex, treatment type, education, private health insurance, and health system were included as covariates on the basis of *a priori* knowledge of their associations with the HRQoL and wellbeing measures.

Pearson's correlation coefficient was used to determine the convergent validity of the ICECAP-O wellbeing with the SF-6D utility instrument. The correlations were assessed for the overall ICECAP-O and SF-6D utility scores and their domains. We hypothesised, moderate to strong positive correlations because both these instruments measures some similar facets of quality of life. Correlations above 0.5 were considered strong, between 0.3 and 0.5 as moderate, and below 0.3 as weak,[16].

Complete case analysis was performed for all outcomes. All statistical analyses were performed with SAS Version 9.4 (SAS Institute, Cary, NC). A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 129 patients were recruited, including 83 (64%) managed with dialysis and 46 (36%) patients managed with comprehensive conservative care. Overall, 65% were male, and the

median age of the entire cohort was 81 years [IQR 75–78]. Patient characteristics are shown in Table 1.

Health-related quality of life SF-6D utilities

Of 129 patients, the mean utility for 116 patients with complete data was 0.62 (SD 0.14) (n =13 missing values). The mean SF-6D utilities for the dialysis group were 0.61 (SD 0.13), and 0.65 (SD 0.15) for the conservative care group (Table S1). The "vitality" domain reported the highest average score, and was responsible for the highest decrement in utilities in both treatment groups (Table S2).

The mean SF-6D utilities were 0.07 (SD 0.14) lower for females than for males (p = 0.006); 0.06 (SD 0.14) lower for patients residing in the UK compared with those residing in Australia (p = 0.03); and 0.07 (SD 0.14) lower for patients without a private health insurance compared to patients with a private health insurance (p = 0.03) (Table S1). When adjusted for all variables, the mean SF-6D utilities were 0.09 lower for females compared to males (95 % lower CI = -0.14 and upper CI = -0.03, p = 0.002). There was no significant difference in the mean utilities observed between two treatments when adjusted for other variables (Table 2).

KDQOL scores

The mean KDQOL scores on the five domains for patients with complete data were as follows: PCS score of 32.41 (n = 115, SD 9.68); MCS score of 47.25 (n = 115, SD 11.34); Burden of Kidney Disease score of 44.46 (n = 127, SD 31.28); Symptom/Problems of Kidney Disease score of 72.78 (n = 125, SD 19.03); and Effects of Kidney Disease score of 70.24 (n = 127, SD 22.35).

In univariate analysis the PCS score was 5.46 points lower in females than males (p = 0.004) (i.e. lower physical health); the MCS score was 4.63 points lower in Australian versus UK patients (p = 0.03) (i.e. lower mental health) table S1 and table S3. The Burden of Kidney Disease score was 28.12 points lower in the dialysis group than the conservative care group (p < 0.001) (indicating a higher burden of disease and lower quality of life); 14.06 points lower in UK versus Australian patients (p = 0.01) (indicating higher burden of disease); 13.70 points lower in patients without private health insurance compared to those with private health insurance (p = 0.04) (indicating a higher burden of disease). The Effects of Kidney Disease score was 17.11 points lower in the dialysis group compared to the conservative care group (p < 0.001) (indicating higher effects of the disease and lower quality of life); 8.35 points lower in UK versus Australian patients (p = 0.03) (indicating higher effects of the disease).

The dialysis group reported a higher MCS score (47.67 vs 46.56), indicating marginally better mental health than the conservative care group. (Table S2).

When adjusted for other variables, the mean score for the Burden of Kidney Disease sub-scale was 28.59 lower (i.e. more burdensome) for patients on dialysis compared with patients on conservative care (p<0.001) (Table 2, Figure 1 and Figure 2). The mean score for Effects of Kidney Disease when adjusted for all the other variables, was 16.49 lower (i.e. higher disease related effects) for patients on dialysis compared with patients on comprehensive conservative care (p<0.001) (Table 2, Figure 3 and 4). Adjusted scores were lower but not statistically, significantly different for PCS, MCS and Symptoms of Kidney Disease between the two treatment groups.

ICECAP-O capability index

The mean ICECAP-O capability index for 126 patients with complete data was 0.72 (SD 0.19) (n=3 missing values). In the dialysis group, the mean capability index was 0.71 (SD 0.19), and 0.76 (SD 0.20) for the conservative care group (Table S1), but not significantly different. Overall, the dialysis treatment group reported a lower wellbeing score on all five domains compared to the conservative care group. The "attachment" domain showed the highest average score, and was responsible for the highest contribution to capabilities in both treatment groups (Table S2). When adjusted for other variables, there were no significant differences in the mean capability index observed between the two treatments (Table 2).

Convergent validity

For 114 observations the SF-6D utilities score and the pain domain of the SF-6D were strongly correlated with the overall ICECAP-O capability index with a Pearson's coefficient of 0.65 ($p<0.001$) and 0.56 ($p<0.001$) respectively. At the domain level, the role and control domains of the ICECAP-O questionnaire were strongly correlated with the pain domain of the SF-6D, with a Pearson's coefficient of 0.51 ($p<0.001$) and 0.53 ($p<0.001$) respectively. All other domains of the ICECAP-O were weakly or moderately correlated with SF-6D domains, values ranging from 0.02 to 0.49 (Table 3).

Feasibility and acceptability

115 of 129 patients completed the questionnaire, with 14 patients missing items for the ICECAP-O and 10 patients missing items for the SF-12. Overall, patients found both questionnaires easy to use and relevant to assessing their wellbeing. They responded with an average score of 1.78 out of 5 (1 = strongly agree, 5 = completely disagree) on questions assessing ease of use; and with an average score 1.77 and 1.79 out of 5 on the questions assessing the relevance of ICECAP-O and the SF-12 questions respectively.

DISCUSSION

This prospective cross-sectional study determined the mean SF-6D utilities, KDQOL scores and ICECAP-O capability index for patients with ESKD according to treatment, and socio-demographic variables. Our findings suggest females compared with males, patients residing in the UK compared with those residing in Australia, and patients without private health insurance compared with those with private health insurance have significantly lower SF-6D utilities. However, when adjusted for the other variables, only females reported significantly lower utilities compared with males. Furthermore, the study determined the convergent validity between the ICECAP-O wellbeing and SF-6D utility instrument and assessed the feasibility and acceptability of the ICECAP-O wellbeing and SF-12 questionnaire in older people with ESKD.

The dialysis group reported 0.05 lower SF-6D utilities compared with the conservative care group reflecting a potentially clinically meaningful difference related to treatment, however, this difference was not statistically significant. Meaningful differences or the minimal important difference (MID) in utility-based HRQoL reported in 11 studies using the SF-6D utilities ranged from 0.011 to 0.097, with a mean MID of 0.041,[28]. It is therefore likely our study has detected a meaningful difference. In addition, a 0.05 difference in ICECAP-O wellbeing for dialysis patients may also represent a clinically meaningful difference, however, MIDs for ICECAP-O have not yet been published. Similarly, the KDQOL-36^{TM} instrument identified a higher burden of disease, and greater effects of the disease for those on dialysis. This finding needs to be explored further in a larger sample size to investigate the potential detrimental effects of dialysis on HRQoL.

In our study, with the exception of a strong correlation between the "control" and "role" domain of the ICECAP-O with the "pain" domain on the SF-6D, most of the ICECAP-O domains were found to have weak to moderate correlations with the SF-6D corresponding domains. This indicates the newly developed capability instrument does measure different aspects of quality of life or wellbeing, and offers additional information when compared to measures of health, such as the SF-6D used in the conventional QALY approach. In addition, we observed a higher score for the feasibility and acceptability of the ICECAP-O questions indicating it to be acceptable and as relevant as SF-12 (an established HRQoL measure).

There is debate in the health economics literature concerning the ways to apply the capability approach in economic evaluations with some suggesting that QALYs alone are adequate, while others argue this approach is too narrow, and that direct measures of capability or wellbeing provide a more extensive application of Sen's paradigm,[29]. Capability is empirically distinct from functioning and the content of capability instruments is not subsumed by the content of instruments used to capture changes in HRQoL for QALYs,[29].

Health economic analyses would benefit from the inclusion of individual capability measures; whether the focus should be only upon people's *achievements*—their "functioning"—or people's *capability to achieve* is contested,[29]. Sen's example of the fasting man versus the starving man serves as a key example for focusing on capability: two people, one of whom is starving and the other, who is fasting, have comparable functioning in terms of nourishment, but their capabilities to be nourished are notably different,[29]. The argument is that focusing on functioning alone would miss important distinctions, such as differences in freedom and choice between individuals,[29].

There are some limitations to this study. First, the sample size may not have been sufficient to detect a statistically significant difference in mean scores if one existed. Second, our observational study of older patients with end-stage kidney disease may not have perfectly matched the two groups with respect to co-morbid conditions. We did not have complete data on comorbidities and this may have impacted our ability to explore the associations between treatment type, HRQoL or wellbeing. Third, considering the cross-sectional nature of the data, we were unable to analyse any changes relating to individuals' HRQoL or wellbeing over time, which might be captured in a longitudinal study. The strengths of our study include a prospective assessment of HRQoL in people over 75 years of age, and the use of a novel measure to value wellbeing. This information is essential for doctors to discuss the relative benefits of dialysis compared with conservative care.

In conclusion, we observed lower quality of life and wellbeing for older patients with ESKD managed on dialysis compared to comprehensive conservative care. Furthermore, measuring wellbeing using a capability index provides additional insights into the impact of dialysis on older people than HRQoL measurement alone and has potential to improve the economic evaluation of treatment for ESKD.

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Authors' Contributions

Authors FM, KM, SC, AB, and RM designed the study. RM, SC and AB led the data collection. KS conducted the analysis and drafted the first version of the manuscript. RM, AT and KM supported the data analysis and interpretation of the results, and all authors revised the final version of the manuscript.

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Competing interests

None of the authors declare a conflict of interest. The results presented in this paper have not been published previously elsewhere, either in whole or part, except in abstract format.

Ethics approval

The study was performed in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (Commonwealth of Australia, 2007), and relevant guidance in the

UK. Each renal unit participating in the study obtained the approval of the Institutional Health Research Ethics Committee to conduct the study. The study approval numbers are as follow: UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36).

Data sharing statement

Data for the study can be provided for specific research questions that are available from the corresponding author on request

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Table 1: Patients characteristics according to treatment group

Patient Characteristics	Dialysis	Conservative Care	Total
	n = 83	n = 46	n = 129
	n (%)	n (%)	n (%)
Dialysis			
Facility Haemodialysis	68 (82%)	-	68 (53%)
Home Haemodialysis	2 (2%)	-	2 (2%)
Peritoneal Dialysis	13 (16%)	-	13 (10%)
Median age (y)	81 [78-84]	83 [81-87]	81 [78-85]
Age group			
≤81 years	50 (60%)	19 (41%)	69 (53%)
>81 years	33 (40%)	27 (59%)	60 (47%)
Sex			
Males	57 (69%)	27 (59%)	84 (65%)
Females	26 (31%)	19 (41%)	45 (35%)
Country			
United Kingdom	58 (70%)	9 (20%)	67 (52%)
Australia	25 (30%)	37 (80%)	62 (48%)
Education			
Primary school	26 (31%)	19 (41%)	45 (35%)
Some high school	35 (42%)	17 (37%)	52 (40%)
Completed high school	8 (10%)	3 (7%)	11 (9%)
Completed diploma	6 (7%)	3 (7%)	9 (7%)
Completed university degree	7 (8%)	3 (7%)	10 (8%)
Private Health Insurance			
Yes	15 (18%)	14 (30%)	29 (22%)
No	65 (78%)	29 (63%)	94 (73%)
Unknown	1 (1%)	1 (2%)	2 (2%)

Table 2: Adjusted Difference in SF-6D utilities, KDQOL-36 scores, and ICECAP-O capability index for dialysis compared with conservative care (fully adjusted)

	Differences†	95 % Lower CI	95 % Upper CI	p value
SF-6D utilities	-0.05	-0.12	0.01	0.12
KDQOL-PCS	-3.17	-7.61	1.27	0.16
KDQOL-MCS	-2.41	-7.66	2.84	0.37
KDQOL-Burden of Disease	-28.59	-41.77	-15.42	<0.001*
KDQOL-Symptoms of Disease	-5.93	-14.61	2.73	0.18
KDQOL-Effects of Disease	-16.49	-25.98	-6.99	<0.001*
ICECAP-O capability index	-0.07	-0.16	0.02	0.12

† Difference in scores adjusted for age, gender, country, education, and health insurance status. * $p < 0.001$, statistical significance. CI - Confidence interval. KDQOL-36 - Kidney disease quality of life with 36 items. PCS - Physical Component Summary. MCS -Mental Component Summary.

Table 3: Convergent validity between ICECAP-O and SF-6D measures (n = 114)† using Pearson's correlation coefficient

	ICECAP-O overall	ICECAP-O domain				
		Attachment	Security	Role	Enjoyment	Control
SF-6D overall	0.65**	-	-	-	-	-
SF-6D domain						
Physical health	0.43**	0.08	0.31*	0.40**	0.32*	0.40**
Role limitations	0.30*	0.05	0.21*	0.28*	0.14	0.31*
Social functioning	0.41**	0.18	0.25*	0.34*	0.30*	0.35*
Pain	**0.56****	0.17	0.29*	**0.51****	0.43**	**0.53****
Mental health	0.39**	0.19*	0.35*	0.30*	0.27*	0.27*
Vitality	0.44**	0.17	0.21*	0.41**	0.28*	0.42**

† Observations with missing values on either SF-12 or ICECAP-O questions were removed from the analysis (n = 15). * $p < 0.05$, statistical significance. ** $p < 0.001$, statistical significance.

Figure Legends

Figure 1- *Title:* KDQOL-36 Burden of Kidney Disease score for Dialysis group (n = 83).

Explanatory text: A higher score indicates lower burden of disease and better quality of life.

Figure 2- *Title:* KDQOL-36 Burden of Kidney Disease score Conservative Care group (n = 44).

Explanatory text: A higher score indicates lower burden of disease and better quality of life.

Figure 3- *Title:* KDQOL-36 Effects of Kidney Disease score for Dialysis group (n = 82).

Explanatory text: A higher score indicates lower effects of disease and better quality of life.

Figure 4- *Title:* KDQOL-36 Effects of Kidney Disease score for Conservative Care group (n = 45).

Explanatory text: A higher score indicates lower effects of disease and better quality of life.

Supplementary Material

Supplementary Table 1 (Table S1): SF-6D utilities, SF-12 PCS and MCS scores, and ICECAP-O capability index according to patient characteristics

Supplementary Table 2 (Table S2): Mean scores and weights of SF-6D, KDQOL-36 and ICECAP-O according to treatment group

Supplementary Table 3 (Table S3): KDQOL-36 Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease scores according to patient characteristics

Supplementary Item 1 (Item S1): STROBE Statement: checklist of items that should be included in reports of observational studies

Supplementary Item 2 (Item S2): KDQOL-36 Questionnaire (SF-12: Questions 1 – 12 (converted to SF-utilities), KDQOL scores (PCS and MCS scores: Questions 1 – 12, burden of kidney disease: Questions 13 – 16, effects of kidney disease: Questions 17 – 28, symptoms of kidney disease: Questions 29 – 36)

Supplementary Item 3 (Item S3): ICECAP-O Questionnaire

Supplementary Item 4 (Item S4): Background Questions

Supplementary Item 5 (Item S5): SF-6D domains

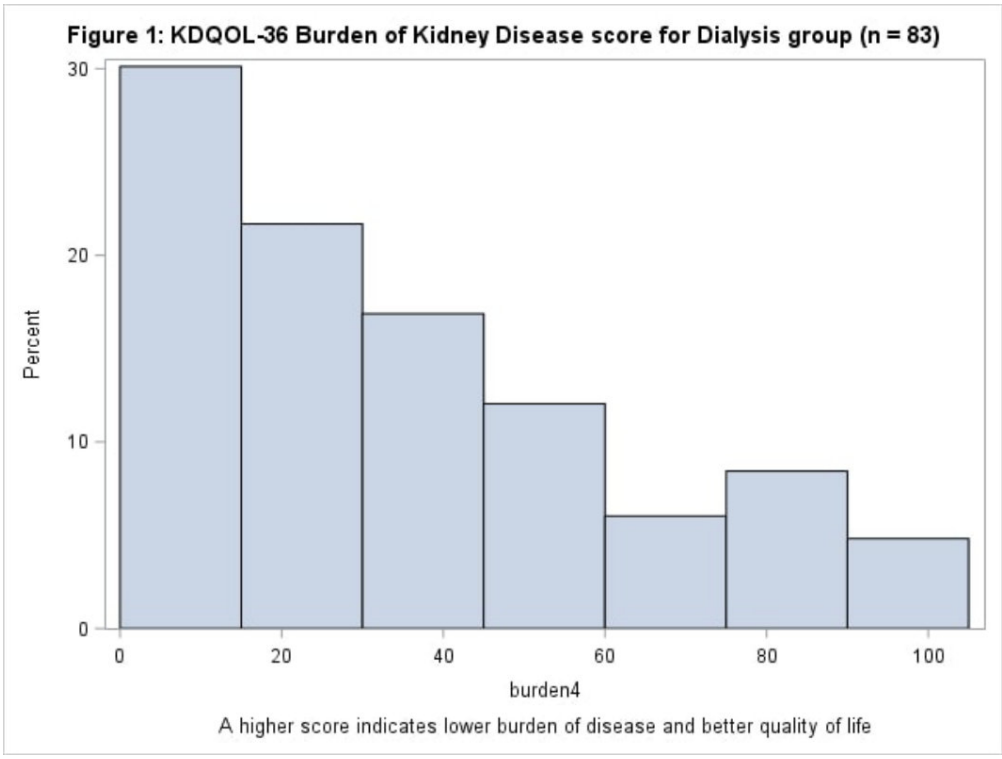

Figure 1: KDQOL-36 Burden of Kidney Disease score for Dialysis group (n = 83). A higher score indicates lower burden of disease and better quality of life.

90x67mm (300 x 300 DPI)

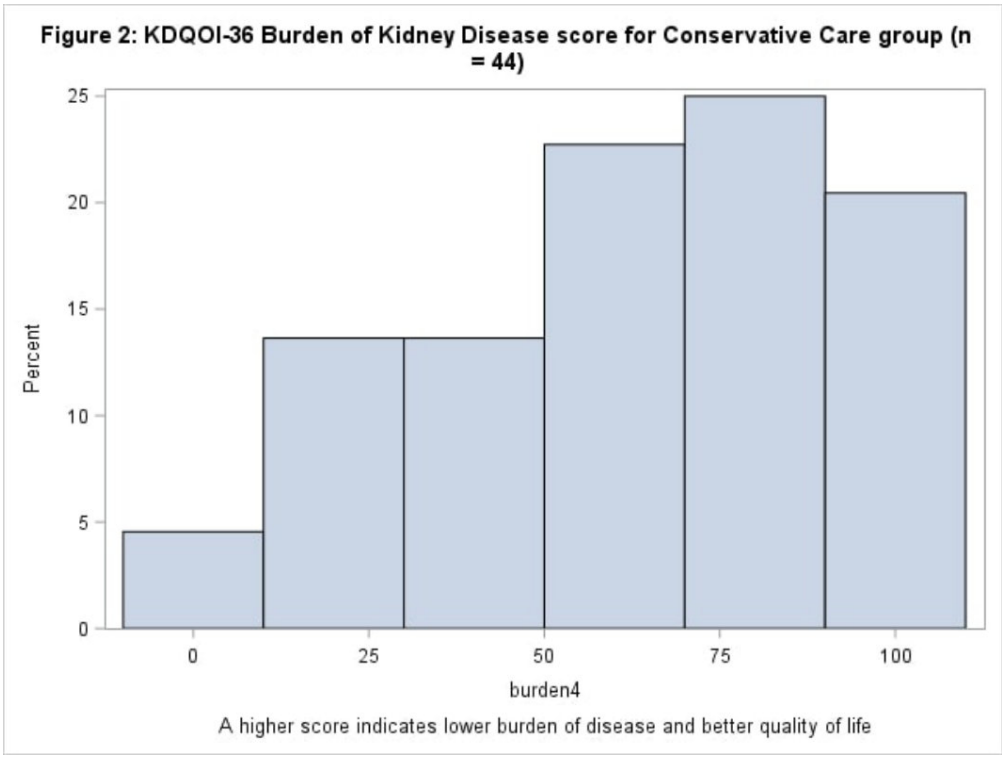

Figure 2: KDQOL-36 Burden of Kidney Disease score for Conservative Care group (n = 44). A higher score indicates lower burden of disease and better quality of life.

90x67mm (300 x 300 DPI)

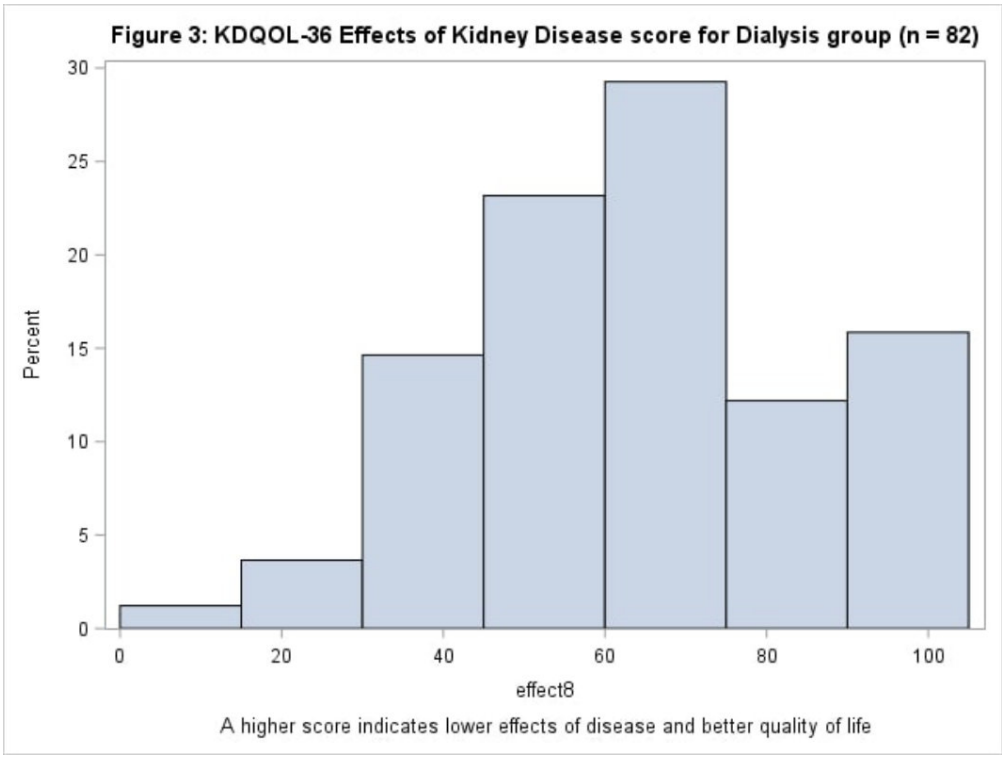

Figure 3: KDQOL-36 Effects of Kidney Disease score for Dialysis group (n = 82). A higher score indicates lower effects of disease and better quality of life.

90x67mm (300 x 300 DPI)

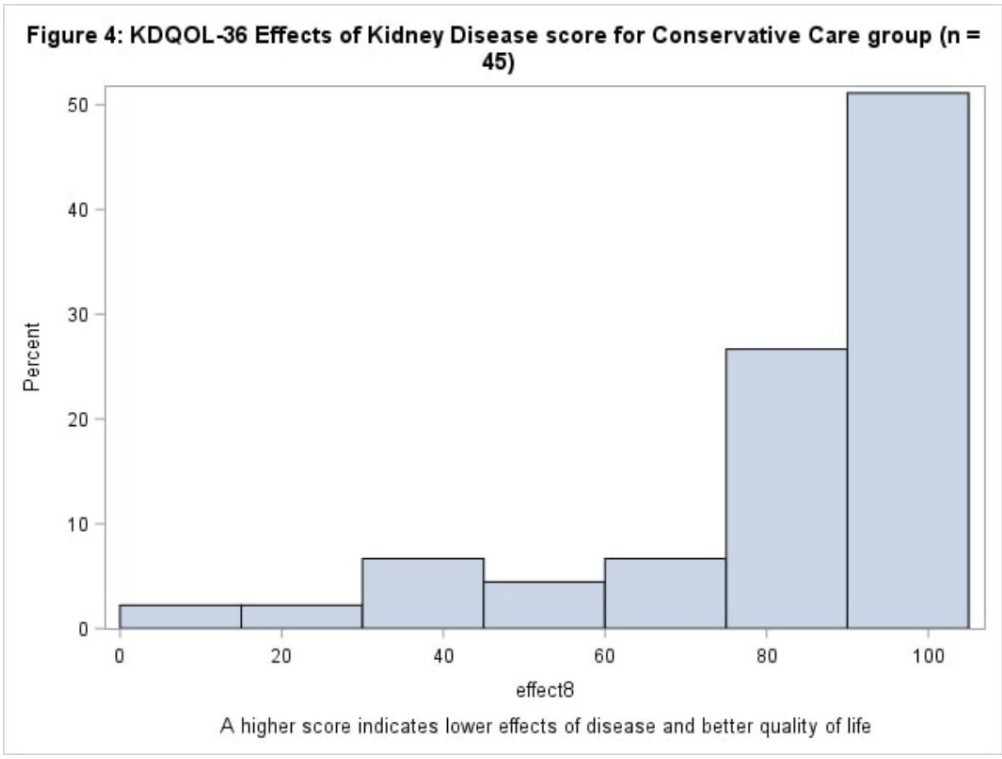

Figure 4: KDQOL-36 Effects of Kidney Disease score for Conservative Care group (n = 45). A higher score indicates lower effects of disease and better quality of life.

90x67mm (300 x 300 DPI)

Supplementary Table 1 (Table S3): SF-6D utilities, SF-12 PCS and MCS scores, and ICECAP-O capability index according to patient characteristics

Characteristics	SF-6D (n = 116)†	PCS (n = 115)††	MCS (n = 115)‡	ICECAP-O (n = 126)‡‡
	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)
Age				
≤81 years	0.63 (0.60-0.67)	32.71 (30.31-35.10)	48.35 (45.51-51.19)	0.73 (0.69-0.78)
>81 years	0.62 (0.58-0.65)	32.08 (29.33-34.84)	46.04 (42.89-49.20)	0.72 (0.67-0.77)
Gender				
Males	0.65 (0.62-0.68)*	34.31 (32.00-36.62)*	47.92 (45.44-50.40)	0.73 (0.68-0.77)
Females	0.58 (0.53-0.62)*	28.85 (26.31-31.39)*	45.98 (42.03-49.93)	0.72 (0.67-0.78)
Treatment**				
Dialysis	0.61 (0.57-0.64)	31.22 (29.02-33.43)	47.67 (45.03-50.30)	0.71 (0.66-0.75)
Conservative Care	0.65 (0.61-0.70)	34.32 (31.27-37.38)	46.56 (42.98-50.15)	0.76 (0.70-0.82)
Country				
United Kingdom	0.60 (0.56-0.63)*	30.76 (28.30-33.22)	49.62 (46.66-52.58)*	0.72 (0.67-0.76)
Australia	0.65 (0.61-0.69)*	33.98 (31.38-36.57)	44.99 (42.06-47.92)*	0.73 (0.68-0.79)
Education §				
Attended some high school	0.62 (0.59-0.65)	31.87 (29.84-33.91)	46.98 (44.43-49.53)	0.72 (0.68-0.76)
Completed high school or tertiary education	0.63 (0.58-0.69)	34.19 (30.22-38.17)	48.09 (44.21-51.97)	0.73 (0.66-0.80)
Private Health Insurance ¶				
Yes	0.68 (0.62-0.73)*	33.03 (29.55-36.50)	49.50 (44.82-54.18)	0.79 (0.73-0.85)
No/Unknown	0.61 (0.58-0.64)*	32.25 (30.09-34.40)	46.77 (44.40-49.13)	0.71 (0.67-0.75)

† Specific SF-6D algorithms were used to convert the SF-12 scores to preference based SF-6D utilities for the UK and the Australian population. 13 out of 129 observations had missing values on SF-12 questionnaire and their SF-6D utilities were not calculated; the remaining had 2 observations missing value for education variable; 3 observations missing value for health insurance variable. †† 14 out of 129 observations had missing values on SF-12 questionnaire and their PCS score were not calculated; the remaining had 1 observation missing value for education variable; 2 observations missing value for health insurance variable. ‡ 14 out of 129 observations had missing values on SF-12 and their MCS score were not calculated; the remaining had 1 observation missing value for education variable; 2 observations missing value for health insurance variable. ‡‡ 3 out of 129 observations had missing values on ICECAP-O questionnaire and their capability index were not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. * $p < 0.05$, statistical significance. ** The dialysis group consist of Facility Haemodialysis, Home Haemodialysis and Peritoneal dialysis. § Individual responses to Primary school/Some high school were merged into one category as "Attended some high school" and the responses to GCSEs/Completed high school/Diploma/TAFE/ Completed A- levels/ University degree were merged into one category as "Completed high school or tertiary education". ¶ Individual responses to "No" and "Unknown" were merged into one category as "No/Unknown". CI - Confidence interval. SF-12 - Short form survey with 12 items. PCS - Physical Component Summary. MCS - Mental Component Summary.

Supplementary Table 2 (Table S2): Mean scores and weights of SF-6D, KDQOL-36 and ICECAP-O according to treatment group

Instrument	Score Mean (SD)	Weights Mean (SD)	Score Mean (SD)	Weights Mean (SD)
SF-6D‡				
Physical functioning	2.47 (1.04)	-0.02 (0.02)	2.26 (0.68)	-0.018 (0.02)
Role limitations	3.22 (1.44)	-0.06 (0.02)	2.84 (1.28)	-0.05 (0.03)
Social functioning	3.33 (1.62)	-0.06 (0.03)	2.65 (1.25)	-0.06 (0.03)
Pain	3.29 (2.13)	-0.05 (0.05)	2.60 (1.37)	-0.04 (0.05)
Mental health	2.90 (1.92)	-0.05 (0.04)	2.33 (1.10)	-0.05 (0.04)
Vitality	3.86 (1.72)	-0.09 (0.02)	3.57 (1.13)	-0.09 (0.01)
KDQOL-36				
Physical Component Summary (PCS)	31.22 (9.32)	-	34.32 (10.05)	-
Mental Component Summary (MCS)	47.67 (11.12)	-	46.56 (11.78)	-
Burden of Kidney Disease	34.71 (27.77)	-	62.83 (29.45)	-
Symptom of Kidney Disease	70.71 (18.74)	-	76.61 (19.18)	-
Effects of Kidney Disease	64.18 (20.27)	-	81.29 (21.92)	-
ICECAP-O‡‡				
Attachment (love and friendship)	3.25 (0.87)	0.22 (0.06)	3.27 (0.81)	0.22 (0.05)
Security (thinking about future without concern)	2.42 (0.99)	0.09 (0.05)	2.71 (0.92)	0.10 (0.05)
Role (doing things that make you feel valued)	2.51 (0.82)	0.15 (0.04)	2.69 (0.85)	0.15 (0.05)
Enjoyment (enjoyment and pleasure)	2.52 (0.94)	0.13 (0.04)	2.80 (0.97)	0.14 (0.04)
Control (independence)	2.51 (0.94)	0.13 (0.08)	2.82 (1.01)	0.15 (0.09)

† 6 observations missing values on SF-6D Role limitation domain; 12 observations missing PCS and MCS score; 2 observations missing Symptoms of Kidney Disease score; 1 observations missing Effects of Kidney Disease score; 2 observations missing values on ICECAP-O Attachment domain. †† 1 observation missing value on SF-6D Role limitation domain; 2 observations missing KDQOL-36 PCS, MCS, Burden of Kidney Disease, and Symptoms of Kidney Disease score; 1 observation missing KDQOL-36 Effects of Kidney Disease score; 1 observation missing value on all ICECAP-O domains. ‡ SF-6D domain scores are weighted decrements. ‡‡ ICECAP-O domain scores are weighted increments. SD - Standard deviation. KDQOL-36 - Kidney disease quality of life with 36 items.

Supplementary Table 3 (Table S3): KDQOL-36 Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease scores according to patient characteristics

Characteristics	Burden of Kidney Disease (n = 127)†	Symptoms of Kidney Disease (n = 125)††	Effects of Kidney Disease (n = 127)‡
	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)
Age			
≤81 years	41.80 (34.47-49.12)	72.21 (67.15-77.27)	69.15 (63.05-75.25)
>81 years	47.16 (38.81-55.50)	73.35 (68.76-77.95)	71.35 (66.26-76.43)
Gender			
Males	44.43 (37.70-51.15)	74.00 (70.01-78.00)	71.48 (66.72-76.23)
Females	44.51 (34.62-54.39)	70.46 (64.13-76.79)	67.91 (60.77-75.05)
Treatment**			
Dialysis	34.71 (28.65-40.78)*	70.71 (66.56-74.85)	64.18 (59.72-68.63)*
Conservative Care	62.83 (53.88-71.78)*	76.61 (70.78-82.44)	81.29 (74.70-87.88)*
Country			
United Kingdom	37.81 (30.68-44.94)*	71.97 (67.37-76.58)	66.29 (61.31-71.28)*
Australia	51.88 (43.59-60.16)*	73.72 (68.64-78.81)	74.65 (68.52-80.77)*
Education§			
Attended some high school	45.32 (38.85-51.79)	71.42 (67.21-75.63)	70.93 (66.29-75.57)
Completed high school or tertiary education	43.53 (32.44-54.61)	76.87 (72.15-81.59)	68.92 (61.06-76.79)
Private Health Insurance¶			
Yes	55.32 (41.82-68.83)*	73.33 (65.11-81.54)	75.85 (67.67-84.02)
No/Unknown	41.62 (35.62-47.63)*	72.88 (69.03-76.73)	69.32 (64.80-73.84)

† 2 out of 129 observations had missing values on burden of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. †† 4 out of 129 observations had missing values on symptoms of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. ‡ 2 out of 129 observations had missing values on effects of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. * $p < 0.05$, statistical significance. ** The dialysis group consist of Facility Haemodialysis, Home Haemodialysis and Peritoneal dialysis. § Individual responses to Primary school/Some high school were merged into one category as "Attended some high school" and the responses to GCSEs/Completed high school/Diploma/TAFE/ Completed A- levels/ University degree were merged into one category as "Completed high school or tertiary education". ¶ Individual responses to "No" and "Unknown" were merged into one category as "No/Unknown". CI - Confidence interval. KDQOL-36 - Kidney disease quality of life with 36 items.

Supplementary Item 1 (Item S1): STROBE Statement: checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Yes/No/NA, Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes, page 1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes, Page 2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes, Page 4-7
Objectives	3	State specific objectives, including any pre-specified hypotheses	Yes, Page 7
Methods			
Study design	4	Present key elements of study design early in the paper	Yes, Page 7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Yes, Page 7-8
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Yes, Page 7-8

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes, Page 8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes, Page 9-10
Bias	9	Describe any efforts to address potential sources of bias	Yes, Page 8
Study size	10	Explain how the study size was arrived at	Yes, Protocol Page 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes, Page 10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes, Page 10-11
		(*b*) Describe any methods used to examine subgroups and interactions	Yes, Page 10-11
		(*c*) Explain how missing data were addressed	Yes, Page 10-11
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	NA

		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	No – screening logs at each site were not available
		(b) Give reasons for non-participation at each stage	No
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders	Yes, Page 7-8, 22
		(b) Indicate number of participants with missing data for each variable of interest	Yes, Page 12-14, 24
		(c) *Cohort study*—Summarise follow-up time (e.g., average and total amount)	NA
Outcome data	15*	*Cross-sectional study*—Report numbers of outcome events or summary measures	Yes, Page 11-14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes, Page 11-14, 23-24

		(*b*) Report category boundaries when continuous variables were categorised	Yes, Page 11-14, 23-24
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Yes, Page 11-14
Discussion			
Key results	18	Summarise key results with reference to study objectives	Yes, Page 15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes, Page 17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes, Page 17
Generalisability	21	Discuss the generalisability (external validity) of the study results	Yes, Page 17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes, Page 18

Supplementary Item 2 (Item S2): KDQOL-36 Questionnaire (SF-12: Questions 1 – 12 (converted to SF-utilities), KDQOL scores (PCS and MCS scores: Questions 1 – 12, burden of kidney disease: Questions 13 – 16, effects of kidney disease: Questions 17 – 28, symptoms of kidney disease: Questions 29 – 36)

Your Health

– and –

Well-Being

Kidney Disease and Quality of Life (KDQOL™-36)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Thank you for completing these questions!

Your Health

This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.

1. In general, would you say your health is: [Mark an ☒ in the one box that best describes your answer.]

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [Mark an ☒ in a box on each line.]

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
3. Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐ 1	☐ 2
5. Were limited in the kind of work or other activities	☐ 1	☐ 2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐ 1	☐ 2
7. Didn't do work or other activities as carefully as usual	☐ 1	☐ 2

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Your Kidney Disease

How true or false is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
13. My kidney disease interferes too much with my life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. Too much of my time is spent dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. I feel frustrated dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. I feel like a burden on my family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the <u>past 4 weeks</u>, to what extent were you bothered by each of the following?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
17. Soreness in your muscles?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18. Chest pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19. Cramps?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. Itchy skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. Dry skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22. Shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
23. Faintness or dizziness?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24. Lack of appetite?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25. Washed out or drained?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26. Numbness in hands or feet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27. Nausea or upset stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[a]. (Hemodialysis patient only) Problems with your access site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[b]. (Peritoneal dialysis patient only) Problems with your catheter site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Effects of Kidney Disease on Your Daily Life

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease <u>bother</u> you in each of the following areas?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
29. Fluid restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30. Dietary restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31. Your ability to work around the house?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32. Your ability to travel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33. Being dependent on doctors and other medical staff?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34. Stress or worries caused by kidney disease?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35. Your sex life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36. Your personal appearance?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Supplementary Item 3 (Item S3): ICECAP-O Questionnaire

ABOUT YOUR QUALITY OF LIFE

By placing a tick (✓) in ONE box in EACH group below, please indicate which statement best describes your quality of life at the moment.

1. Love and Friendship		
I can have all of the love and friendship that I want		4
I can have a lot of the love and friendship that I want		3
I can have a little of the love and friendship that I want		2
I cannot have any of the love and friendship that I want		1
2. Thinking about the future		
I can think about the future without any concern		4
I can think about the future with only a little concern		3
I can only think about the future with some concern		2
I can only think about the future with a lot of concern		1
3. Doing things that make you feel valued		
I am able to do all of the things that make me feel valued		4
I am able to do many of the things that make me feel valued		3
I am able to do a few of the things that make me feel valued		2
I am unable to do any of the things that make me feel valued		1
4. Enjoyment and pleasure		
I can have all of the enjoyment and pleasure that I want		4
I can have a lot of the enjoyment and pleasure that I want		3
I can have a little of the enjoyment and pleasure that I want		2
I cannot have any of the enjoyment and pleasure that I want		1
5. Independence		
I am able to be completely independent		4
I am able to be independent in many things		3
I am able to be independent in a few things		2
I am unable to be at all independent		1

Tick one box only in each section

Supplementary Item 4 (Item S4): Background Questions

Q1. What is your full name? _____

Q2. What is your date of birth? _____ (*dd/mm/yyyy*)

Q3. Gender (*please tick one*)

Male □

Female □

Q4. What is your main residential postcode? _____

Q5. What was your country of birth? _____

Q6. What is the highest level of education you have completed? (*please tick the box that best describes you*)

Primary school □

Some high school □

Completed high school □

Completed Diploma/ TAFE course □

Completed University Degree □

Q7. Do you have private health insurance? (*please tick one*)

Yes □

No □

Don't know □

Q8. What type of kidney treatment are you ***currently*** having? (*please tick one*)

Hemodialysis (satellite or hospital) □

Hemodialysis at home □

Peritoneal dialysis □

Non-dialysis renal supportive care □

Q9. If you are currently on dialysis when did you first start dialysis?

_____ *(*mm/yyyy)

Q10. Have you ever had a kidney transplant before? (*please tick one*)

Yes □ No □

Q11. The next two questions are about the **ICECAP-O survey.** On the scale below please rate how <u>easy</u> this survey was to complete *(circle a number between 1 and 5)*

Very easy	Somewhat easy	Neutral	Somewhat difficult	Very difficult
1	2	3	4	5

Q12. Did this survey measure the things that you consider <u>important</u> to your quality of life? *(circle a number between 1 and 5)*

Completely agree	Somewhat agree	Neutral	Somewhat disagree	Completely disagree
1	2	3	4	5

Q13. If you responded with 'somewhat disagree' or 'completely disagree,' would you like to tell us what you think the **ICECAP-O survey** was missing?

_____

_____

_____

_____

_____

Q14. The next two questions are about the **SF-12 survey.** On the scale below please rate how easy this survey was to complete *(circle a number between 1 and 5)*

Very easy	Somewhat easy	Neutral	Somewhat difficult	Very difficult
1	2	3	4	5

Q15. Did this survey measure the things that you consider important to your quality of life? *(circle a number between 1 and 5)*

Completely agree	Somewhat agree	Neutral	Somewhat disagree	Completely disagree
1	2	3	4	5

Q16. If you responded with 'somewhat disagree' or 'completely disagree,' would you like to tell us what you think the **SF-12 survey** was missing?

Supplementary Item 5 (Item S5): SF-6D domains

Level	SF-6D
	Physical Functioning
1	Your health does not limit you in *vigorous activities*
2	Your health limits you a little in *vigorous activities*
3	Your health limits you a little in *moderate activities*
4	Your health limits you a lot in *moderate activities*
5	Your health limits you *a little in bathing and dressing*
6	Your health limits you *a lot in bathing and dressing*
	Role limitations
1	You have *no* problems with your work or other regular daily activities as a result of your physical health or any emotional problems
2	You are limited in the kind of work or other activities as a result of your physical health
3	You accomplish less than you would like as a result of emotional problems
4	You are limited in the kind of work or other activities as a result of your physical health and accomplish less than you would like as a result of emotional problems
	Social functioning
1	Your health limits your social activities *none of the time*
2	Your health limits your social activities *a little of the time*
3	Your health limits your social activities *some of the time*
4	Your health limits your social activities *most of the time*
5	Your health limits your social activities *all of the time*
	Pain
1	You have *no* pain
2	You have pain but it does not interfere with your normal work (both outside the home and housework)
3	You have pain that interferes with your normal work (both outside the home and housework) *a little bit*
4	You have pain that interferes with your normal work (both outside the home and housework) *moderately*
5	You have pain that interferes with your normal work (both outside the home and housework) *quite a bit*
6	You have pain that interferes with your normal work (both outside the home and housework) *extremely*
	Mental health
1	You feel tense or downhearted and low *none of the time*
2	You feel tense or downhearted and low *a little of the time*
3	You feel tense or downhearted and low *some of the time*
4	You feel tense or downhearted and low *most of the time*
5	You feel tense or downhearted and low *all of the time*
	Vitality
1	You have a lot of energy *all of the time*
2	You have a lot of energy *most of the time*
3	You have a lot of energy *some of the time*
4	You have a lot of energy *a little of the time*
5	You have a lot of energy *none of the time*

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Health-related quality of life and wellbeing in people over 75 years of age with end-stage kidney disease managed with dialysis or comprehensive conservative care: a cross-sectional study in the UK and Australia

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Title: Health-related quality of life and wellbeing in people over 75 years of age with end-stage kidney disease managed with dialysis or comprehensive conservative care: a cross-sectional study in the UK and Australia

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ABSTRACT

Objective

To measure HRQoL and wellbeing in older people with end stage kidney disease and to determine the association between treatment type and socio-demographic characteristics on these outcome measures. In addition, to assess the convergent validity between the HRQoL and wellbeing measure and their feasibility and acceptability in this population.

Design

Prospective cross-sectional study.

Setting

3 renal units in the UK and Australia.

Participants

129 ESKD patients managed with dialysis or with an estimated glomerular filtration (eGFR)≤10ml/min/1.73m^2 and managed with comprehensive conservative, non-dialytic care.

Outcome measures

HRQoL and wellbeing were assessed using Short-Form six dimensions (SF-6D, 0-1 scale); KDQOL-36 (0-100 scale) and Investigating Choice Experiments Capability Measure–Older people (ICECAP-O, 0-1 scale). Linear regression assessed associations between treatment, HRQoL and wellbeing. Pearson's correlation coefficient assessed convergent validity between instruments.

Results

Median age of 81 years [IQR 78–85], 65% males; 83(64%) were managed with dialysis and 46(36%) with conservative care. When adjusted for treatment type and sociodemographic variables, those managed on dialysis reported lower mean SF-6D utility (-0.05, 95%CI -0.12 to 0.01); lower KDQOL Physical Component Summary score (-3.17, 95%CI -7.61 to 1.27); lower Mental Component Summary score (-2.41, 95%CI -7.66 to 2.84); lower quality of life

due to Burden (-28.59, 95%CI -41.77 to -15.42); Symptoms (-5.93, 95%CI -14.61 to 2.73), and Effects of Kidney Disease (-16.49, 95%CI -25.98 to -6.99); and lower overall ICECAP-O wellbeing (-0.07, 95%CI -0.16 to 0.02) than those managed conservatively. Correlation between ICECAP-O wellbeing and SF-6D utility scores was strong overall, 0.65 (p<0.001), but weak to moderate at domain level.

Conclusions

Older people on dialysis report significantly higher burden and effects of kidney disease than those on conservative care. Lower HRQoL and wellbeing may be associated with dialysis treatment, and should inform shared decision making about treatment options.

Trial registration

UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36).

KEYWORDS

Chronic Kidney Failure, Chronic Renal Insufficiency, Renal Dialysis, Quality Of Life, Palliative Care

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The strengths of our study include a prospective assessment of HRQoL in people over 75 years of age, and the use of a novel measure to value wellbeing.
- This information is essential for doctors to discuss the relative benefits of dialysis compared with conservative care.
- The limitation of this study is that, the sample size may not have been sufficient to detect a statistically significant difference in mean scores if one existed.
- We did not have complete data on patient's comorbid conditions that may have impacted our ability to explore the associations between comorbid conditions and HRQoL or wellbeing.
- Considering the cross-sectional nature of the data, we were unable to analyse any changes relating to individuals' HRQoL or wellbeing over time, which might be captured in a longitudinal study.

INTRODUCTION

Comprehensive conservative care services were developed for people with end-stage kidney disease (ESKD) in the UK and Australia following the substantial increase in the number of older people aged ≥75 years being referred to nephrologists for dialysis,[1]. Comprehensive conservative care includes interventions to delay the progression of kidney disease and minimise complications, as well as detailed communication, shared decision-making, advance care planning, and psychologic and family support, but does not include dialysis,[2]. For older patients who often have high levels of comorbidity (such as diabetes and heart disease) and poor functional status, the survival advantage of dialysis may be limited, and comprehensive conservative management may be considered; however, robust comparative evidence remains minimal,[2]. Considerations such as symptoms, quality of life, and hospital-free days are sometimes more important for patients and families, than expected length of survival,[2].

Traditionally, economists attempt to assist resource allocation decisions by focusing on measuring and valuing health (in its broadest sense), using health-related quality of life (HRQoL) measures and survival, in particular combined in the quality-adjusted life year (QALY),[3]. In QALY calculations, values (often referred to as utility scores) are assigned to different health states, which allows the quantification of health gains comprising both length and quality of life gains from medical interventions,[3, 4]. Utilities are preference weights, where preference can be equated with value or desirability,[5, 6]. The quality adjusted life years (QALYs) value is then calculated by combining the length of survival and the utility weights.

However, many healthcare interventions may impact more broadly on quality of life (assumed to encompass the broad range of factors that are important to people in living their lives) rather than just health (which centers on physical and mental health),[3]. These broad factors could

be related to health and non-health factors that may impact the overall quality of life of a patient,[4]. Measures that look only at health in assessing the impact of these interventions would be very likely to underestimate this impact,[3, 7].

Dialysis has a large impact on the quality of life of both patients and their families; however, traditional HRQoL measures, such as the Short Form 36 (SF-36) and Kidney Disease Quality of Life (KDQOL-36) surveys may be too narrowly focused to detect all of the critical aspects of dialysis that increase or decrease an individual's quality of life,[8]. KDQOL-36™ is a short form questionnaire that includes the SF-12, a generic quality of life questionnaire,[9, 10] plus disease-specific domains including the burden of kidney disease, symptoms/problems of kidney disease, and effects of kidney disease. For this purpose, broader HRQoL measures, often named wellbeing measures, could be used to capture more facets of peoples' lives than health status alone,[4].

New instruments have been developed that provide information across health and social care, rather than just across health,[3]. The recently developed "Investigating Choice Experiments Capability Measure (ICECAP)" family of instruments have been designed to incorporate such dimensions,[11]. These instruments have their theoretical grounding in Amartya Sen's work on the relationships between functioning and capability,[11, 12]. They seek to measure a conceptually different evaluative space through a focus on capabilities: that is, what a person is able to do and who they are able to be, rather than on functioning: what a person actually does and who they become,[13]. Capabilities refer to the potential to achieve certain states and perform certain actions,[4]. Having the capability to live life the way one desires is obviously important, also to older people, and reduction of this capability limits their wellbeing,[4, 14, 15]. The ICECAP-O instrument was specifically developed to measure capability in older

people. There is little research on how the ICECAP-O is related to other conceptualisations of wellbeing, and the relationships between the ICECAP-O and measures of health (physical, psychological, and social) remain underexplored,[16].

The aims of the study were to measure HRQoL using SF-12 questionnaire, kidney disease quality of life using KDQOL-36™ questionnaire, and wellbeing using ICECAP-O questionnaire; to determine the association between treatment type and socio-demographic characteristics on these outcome measures; to assess the convergent validity between the ICECAP-O wellbeing and the SF-6D utility (derived from SF-12 questionnaire); and to assess the feasibility and acceptability of questionnaires in older ESKD patients.

MATERIALS AND METHODS

Study design

We conducted a cross-sectional study of patients with ESKD treated with dialysis or comprehensive conservative care in the UK and Australia between 2014 and 2017. The study was performed in accordance with the Australian National Statement on Ethical Conduct in Human Research (2007), and relevant guidance in the UK. Each renal unit participating in the study obtained the approval of their Institutional Research Boards UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36). The study was reported using STROBE guidelines for observational studies (Item S1),[17]. Eligible subjects were fully informed about the purpose, benefits and risks of the study, and signed an approved participant consent form.

Setting and participants

The study was undertaken at three renal units in the UK and Australia. Included were males and females aged ≥75 years with ESKD, managed with dialysis (facility haemodialysis, home

haemodialysis, and peritoneal dialysis) or with an estimated glomerular filtration (eGFR) ≤10ml/min/1.73m^2 and managed with comprehensive conservative, non-dialytic care. The exclusion criteria comprised cognitive impairment; patients unable to read English; and patients who were legally blind. To reduce selection bias, nephrologists and clinical nurses in each participating renal unit reviewed their clinic lists for all patients that met the eligibility criteria.

Sample size calculation

As per the study protocol, a sample size of 194 patients (97 on dialysis, 97 on comprehensive conservative care) was calculated to detect a mean difference of 0.05 in the outcomes with 80% power and 95% confidence.

Patient and public involvement

The research question was developed from prior qualitative work with people with end-stage kidney disease and their carers,[18-20]. Patients were not directly involved in the design of this research study. Patients and their caregivers were informed of the study and invited to participate by the renal unit's research nurses. Participants were provided with an information sheet and consent form for them to read. If they were interested in participating they were asked to sign the consent form and then were provided with two surveys contained in the one booklet, (the ICECAP-O survey and the standard KDQOL-36^{TM}) while at their renal clinic. Patients and their caregivers were assured that participation was voluntary, that they did not have to participate and that their decision either way would not affect their clinical care.

Outcomes and variables

The key outcomes were SF-6D utilities derived from the SF-12 questions, KDQOL scores from the KDQOL-36 questions, ICECAP-O capability index derived from the ICECAP-O questions. Other outcomes were convergent validity between ICECAP-O wellbeing and the SF-6D utility instrument measured using the Pearson's correlation coefficient; and the feasibility and acceptability of the ICECAP-O and SF-12 questionnaires, assessed by response rate and specific items asking the patient whether the questionnaire was easy to complete, and whether it covered questions important to their quality of life and wellbeing.

Data sources/measurement

All eligible patients were invited to complete the KDQOL-36^{TM} (Item S2) and the five-question ICECAP-O questionnaire (Item S3) while at their renal clinic. Relevant sociodemographic details such as age, sex, country, educational attainment, private health insurance and questions assessing feasibility and acceptability of the ICECAP-O and SF-12 questionnaire were collected (Item S4). Kidney treatment type (facility haemodialysis, home haemodialysis, peritoneal dialysis, and comprehensive conservative care), dialysis status (if currently on dialysis, and time of initiation) and renal transplant status were documented.

Health related quality of life questionnaire

The KDQOL-36 has 36 items: the SF-12 version 1 and another 24 kidney specific items,[21]. The SF-12 responses on the KDQOL-36 were transformed into HRQoL weights, known as utilities, using a published SF-6D algorithm,[22]. The SF-6D is a generic preference-based single measure of health used to generate utilities from six domains: physical, role, social, pain, mental, and vital (Item S5). The SF-6D utilities generated are measured on a 0 (death) to 1 (full health) scale, and were reported with mean and standard deviations (SDs) using UK population values,[22-24].

The SF-12 section of KDQOL-36 also yields PCS (Physical Component Summary) and MCS (Mental Component Summary) scores, both of which are scored on a T-score metric (mean = 50, SD = 10, for the US general population),[21, 25]. The three kidney specific scales assess Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease. Each of these scales is scored by transforming all items to a 0 to 100 possible range and averaging across the items on each scale to create scale scores,[21]. KDQOL-36 items are all scaled so that higher scores indicate better HRQoL,[21, 26].

Wellbeing questionnaire

The ICECAP-O questionnaire measures capabilities and covers five domains of wellbeing, including attachment (love and friendship); security (thinking about the future without concern); role (doing things that make you feel valued); enjoyment (enjoyment and pleasure); and control (independence),[27]. It has four-level response options, representing four levels of capability: none, a little, a lot, and all. The responses on the ICECAP-O questions were transformed to a ICECAP-O capability index ranging from 0 (no capability) to 1 (full capability), and presented with mean and SDs using UK population weights,[3].

Quantitative variables

The SF-6D utilities, KDQOL scores, ICECAP-O capability index, and patients' age were treated as continuous, while patients' sex, treatment type (dialysis, conservative care), education (some high school or lower levels, completed high school or higher levels), private health insurance (yes, no), and health system (UK, Australia) were analysed as categorical variables. Age was also additionally dichotomised (less than or equal to, versus greater than the median age [81 years]).

Statistical methods

The analysis of data involved descriptive statistics assessing proportions and mean values of the SF-6D utilities, PCS, MCS, Burden of Kidney Disease, Symptoms of Kidney Disease, Effects of Kidney Disease scores, and the ICECAP-O capability index for the entire cohort. Hypothesis testing with a two-tailed Student's t-test was used to detect differences in the mean values of SF-6D utilities, KDQOL-36 scores, and ICECAP-O capability index for patients' treatment type and socio-demographic characteristics. We hypothesised that HRQoL and wellbeing measures in each treatment group would be equivalent.

Linear regression with multivariable models was undertaken to determine the association between treatment type and patient characteristics on SF-6D utilities, KDQOL scores and ICECAP-O capability index. In the multivariable linear regression, age, sex, treatment type, education, private health insurance, and health system were included as covariates on the basis of *a priori* knowledge of their associations with the HRQoL and wellbeing measures.

Pearson's correlation coefficient was used to determine the convergent validity of the ICECAP-O wellbeing with the SF-6D utility instrument. The correlations were assessed for the overall ICECAP-O and SF-6D utility scores and their domains. We hypothesised, moderate to strong positive correlations because both these instruments measures some similar facets of quality of life. Correlations above 0.5 were considered strong, between 0.3 and 0.5 as moderate, and below 0.3 as weak,[16].

Complete case analysis was performed for all outcomes. All statistical analyses were performed with SAS Version 9.4 (SAS Institute, Cary, NC). A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 129 patients were recruited, including 83 (64%) managed with dialysis and 46 (36%) patients managed with comprehensive conservative care. The majority of conservatively treated patients were from Australia (n = 37), and most treated with dialysis were from the UK (n = 58). Overall, 65% were male, and the median age of the entire cohort was 81 years [IQR 78–85]. Patient characteristics are shown in Table 1.

Health-related quality of life SF-6D utilities

Of 129 patients, the mean utility for 116 patients with complete data was 0.62 (SD 0.14) (n =13 missing values). The mean SF-6D utilities for the dialysis group were 0.61 (SD 0.13), and 0.65 (SD 0.15) for the conservative care group (Table S1). The "vitality" domain reported the highest average score, and was responsible for the highest decrement in utilities in both treatment groups (Table S2).

The mean SF-6D utilities were 0.07 (SD 0.14) lower for females than for males (p = 0.006); 0.06 (SD 0.14) lower for patients residing in the UK compared with those residing in Australia (p = 0.03); and 0.07 (SD 0.14) lower for patients without a private health insurance compared to patients with a private health insurance (p = 0.03) (Table S1). When adjusted for all variables, the mean SF-6D utilities were 0.09 lower for females compared to males (95 % lower CI = -0.14 and upper CI = -0.03, p = 0.002). There was no significant difference in the mean utilities observed between two treatments when adjusted for other variables (Table 2).

KDQOL scores

The mean KDQOL scores on the five domains for patients with complete data were as follows: PCS score of 32.41 (n = 115, SD 9.68); MCS score of 47.25 (n = 115, SD 11.34); Burden of Kidney Disease score of 44.46 (n = 127, SD 31.28); Symptom/Problems of Kidney Disease score of 72.78 (n = 125, SD 19.03); and Effects of Kidney Disease score of 70.24 (n = 127, SD 22.35).

In univariate analysis the PCS score was 5.46 points lower in females than males (p = 0.004) (i.e. lower physical health); the MCS score was 4.63 points lower in Australian versus UK patients (p = 0.03) (i.e. lower mental health) table S1 and table S3. The Burden of Kidney Disease score was 28.12 points lower in the dialysis group than the conservative care group (p < 0.001) (indicating a higher burden of disease and lower quality of life) (Figure 1 and Figure 2); 14.06 points lower in UK versus Australian patients (p = 0.01) (indicating higher burden of disease); 13.70 points lower in patients without private health insurance compared to those with private health insurance (p = 0.04) (indicating a higher burden of disease). The Effects of Kidney Disease score was 17.11 points lower in the dialysis group compared to the conservative care group (p < 0.001) (indicating higher effects of the disease and lower quality of life) (Figure 3, Figure 4); 8.35 points lower in UK versus Australian patients (p = 0.03) (indicating higher effects of the disease).

The dialysis group reported a higher MCS score (47.67 vs 46.56), indicating marginally better mental health than the conservative care group. (Table S2).

When adjusted for other variables, the mean score for the Burden of Kidney Disease sub-scale was 28.59 lower (i.e. more burdensome) for patients on dialysis compared with patients on conservative care (p<0.001) (Table 2). The mean score for Effects of Kidney Disease when adjusted for all the other variables, was 16.49 lower (i.e. higher disease related effects) for patients on dialysis compared with patients on comprehensive conservative care (p<0.001) (Table 2). Adjusted scores were lower but not statistically, significantly different for PCS, MCS and Symptoms of Kidney Disease between the two treatment groups.

ICECAP-O capability index

The mean ICECAP-O capability index for 126 patients with complete data was 0.72 (SD 0.19) (n=3 missing values). In the dialysis group, the mean capability index was 0.71 (SD 0.19), and 0.76 (SD 0.20) for the conservative care group (Table S1), but not significantly different. Overall, the dialysis treatment group reported a lower wellbeing score on all five domains compared to the conservative care group. The "attachment" domain showed the highest average score, and was responsible for the highest contribution to capabilities in both treatment groups (Table S2). When adjusted for other variables, there were no significant differences in the mean capability index observed between the two treatments (Table 2).

Convergent validity

For 114 observations the SF-6D utilities score and the pain domain of the SF-6D were strongly correlated with the overall ICECAP-O capability index with a Pearson's coefficient of 0.65 (p<0.001) and 0.56 (p<0.001) respectively. At the domain level, the role and control domains of the ICECAP-O questionnaire were strongly correlated with the pain domain of the SF-6D, with a Pearson's coefficient of 0.51 (p<0.001) and 0.53 (p<0.001) respectively. All other

domains of the ICECAP-O were weakly or moderately correlated with SF-6D domains, values ranging from 0.02 to 0.49 (Table 3).

Feasibility and acceptability

115 of 129 patients completed the questionnaire, with 14 patients missing items for the ICECAP-O and 10 patients missing items for the SF-12. Overall, patients found both questionnaires easy to use and relevant to assessing their wellbeing. They responded with an average score of 1.78 out of 5 (1 = strongly agree, 5 = completely disagree) on questions assessing ease of use; and with an average score 1.77 and 1.79 out of 5 on the questions assessing the relevance of ICECAP-O and the SF-12 questions respectively.

DISCUSSION

This prospective cross-sectional study determined the mean SF-6D utilities, KDQOL scores and ICECAP-O capability index for patients with ESKD according to treatment, and socio-demographic variables. Our findings suggest females compared with males, patients residing in the UK compared with those residing in Australia, and patients without private health insurance compared with those with private health insurance have significantly lower SF-6D utilities. However, when adjusted for the other variables, only females reported significantly lower utilities compared with males. Furthermore, the study determined the convergent validity between the ICECAP-O wellbeing and SF-6D utility instrument and assessed the feasibility and acceptability of the ICECAP-O wellbeing and SF-12 questionnaire in older people with ESKD.

The dialysis group reported 0.05 lower SF-6D utilities compared with the conservative care group reflecting a potentially clinically meaningful difference related to treatment, however,

this difference was not statistically significant. Meaningful differences or the minimal important difference (MID) in utility-based HRQoL reported in 11 studies using the SF-6D utilities ranged from 0.011 to 0.097, with a mean MID of 0.041,[28]. It is therefore likely our study has detected a meaningful difference. In addition, a 0.05 difference in ICECAP-O wellbeing for dialysis patients may also represent a clinically meaningful difference, however, MIDs for ICECAP-O have not yet been published. Similarly, the KDQOL-36^{TM} instrument identified a higher burden of disease, and greater effects of the disease for those on dialysis. This finding needs to be explored further in a larger sample size to investigate the potential detrimental effects of dialysis on HRQoL.

In our study, with the exception of a strong correlation between the "control" and "role" domain of the ICECAP-O with the "pain" domain on the SF-6D, most of the ICECAP-O domains were found to have weak to moderate correlations with the SF-6D corresponding domains. This indicates the newly developed capability instrument does measure different aspects of quality of life or wellbeing, and offers additional information when compared to measures of health, such as the SF-6D used in the conventional QALY approach. In addition, we observed a higher score for the feasibility and acceptability of the ICECAP-O questions indicating it to be acceptable and as relevant as SF-12 (an established HRQoL measure).

There is debate in the health economics literature concerning the ways to apply the capability approach in economic evaluations with some suggesting that QALYs alone are adequate, while others argue this approach is too narrow, and that direct measures of capability or wellbeing provide a more extensive application of Sen's paradigm,[29]. Capability is empirically distinct from functioning and the content of capability instruments is not subsumed by the content of instruments used to capture changes in HRQoL for QALYs,[29].

Health economic analyses would benefit from the inclusion of individual capability measures; whether the focus should be only upon people's *achievements*—their "functioning"—or people's *capability to achieve* is contested,[29]. Sen's example of the fasting man versus the starving man serves as a key example for focusing on capability: two people, one of whom is starving and the other, who is fasting, have comparable functioning in terms of nourishment, but their capabilities to be nourished are notably different,[29]. The argument is that focusing on functioning alone would miss important distinctions, such as differences in freedom and choice between individuals,[29].

There are some limitations to this study. First, we were only able to recruit 129 of the 194 patients outlined in the protocol sample size, as some of the study sites were unable to participate. Hence, the sample size may not have been sufficient to detect a statistically significant difference in mean scores if one existed. Second, our observational study of older patients with end-stage kidney disease may not have perfectly matched the two groups with respect to co-morbid conditions or rate of renal decline. We did not have complete data on comorbidities and this may have impacted our ability to explore the associations between treatment type, HRQoL or wellbeing. Third, considering the cross-sectional nature of the data, we were unable to analyse any changes relating to individuals' HRQoL or wellbeing over time, which might be captured in a longitudinal study. The strengths of our study include a prospective assessment of HRQoL in people over 75 years of age, and the use of a novel measure to value wellbeing. This information is essential for doctors to discuss the relative benefits of dialysis compared with conservative care.

In conclusion, we observed lower quality of life and wellbeing for older patients with ESKD managed on dialysis compared to comprehensive conservative care. Furthermore, measuring wellbeing using a capability index provides additional insights into the impact of dialysis on older people than HRQoL measurement alone and has potential to improve the economic evaluation of treatment for ESKD.

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Authors' Contributions

Authors FM, KM, SC, AB, and RM designed the study. RM, SC and AB led the data collection. KS conducted the analysis and drafted the first version of the manuscript. RM, AT and KM supported the data analysis and interpretation of the results, and all authors revised the final version of the manuscript.

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Competing interests

None of the authors declare a conflict of interest. The results presented in this paper have not been published previously elsewhere, either in whole or part, except in abstract format.

Ethics approval

The study was performed in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (Commonwealth of Australia, 2007), and relevant guidance in the

UK. Each renal unit participating in the study obtained the approval of the Institutional Health Research Ethics Committee to conduct the study. The study approval numbers are as follow: UK (IRAS project ID: 134360 & REC reference 14/LO/0291) and Australia (R20140203 HREC/14/RAH/36).

Data sharing statement

Data for the study can be provided for specific research questions that are available from the corresponding author on request.

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Table 1: Patients characteristics according to treatment group

Patient Characteristics	Dialysis	Conservative Care	Total
	n = 83	n = 46	n = 129
	n (%)	n (%)	n (%)
Dialysis			
Facility Haemodialysis	68 (82%)	-	68 (53%)
Home Haemodialysis	2 (2%)	-	2 (2%)
Peritoneal Dialysis	13 (16%)	-	13 (10%)
Median age (y)	81 [78-84]	83 [81-87]	81 [78-85]
Age group			
≤81 years	50 (60%)	19 (41%)	69 (53%)
>81 years	33 (40%)	27 (59%)	60 (47%)
Sex			
Males	57 (69%)	27 (59%)	84 (65%)
Females	26 (31%)	19 (41%)	45 (35%)
Country			
United Kingdom	58 (70%)	9 (20%)	67 (52%)
Australia	25 (30%)	37 (80%)	62 (48%)
Education			
Primary school	26 (31%)	19 (41%)	45 (35%)
Some high school	35 (42%)	17 (37%)	52 (40%)
Completed high school	8 (10%)	3 (7%)	11 (9%)
Completed diploma	6 (7%)	3 (7%)	9 (7%)
Completed university degree	7 (8%)	3 (7%)	10 (8%)
Private Health Insurance			
Yes	15 (18%)	14 (30%)	29 (22%)
No	65 (78%)	29 (63%)	94 (73%)
Unknown	1 (1%)	1 (2%)	2 (2%)

Table 2: Adjusted Difference in SF-6D utilities, KDQOL-36 scores, and ICECAP-O capability index for dialysis compared with conservative care (fully adjusted)

	Differences†	95 % Lower CI	95 % Upper CI	p value
SF-6D utilities	-0.05	-0.12	0.01	0.12
KDQOL-PCS	-3.17	-7.61	1.27	0.16
KDQOL-MCS	-2.41	-7.66	2.84	0.37
KDQOL-Burden of Disease	-28.59	-41.77	-15.42	<0.001*
KDQOL-Symptoms of Disease	-5.93	-14.61	2.73	0.18
KDQOL-Effects of Disease	-16.49	-25.98	-6.99	<0.001*
ICECAP-O capability index	-0.07	-0.16	0.02	0.12

† Difference in scores adjusted for age, gender, country, education, and health insurance status. * $p < 0.001$, statistical significance. CI - Confidence interval. KDQOL-36 - Kidney disease quality of life with 36 items. PCS - Physical Component Summary. MCS -Mental Component Summary.

Table 3: Convergent validity between ICECAP-O and SF-6D measures (n = 114)† using Pearson's correlation coefficient

	ICECAP-O overall	ICECAP-O domain				
		Attachment	Security	Role	Enjoyment	Control
SF-6D overall	0.65**	-	-	-	-	-
SF-6D domain						
Physical health	0.43**	0.08	0.31*	0.40**	0.32*	0.40**
Role limitations	0.30*	0.05	0.21*	0.28*	0.14	0.31*
Social functioning	0.41**	0.18	0.25*	0.34*	0.30*	0.35*
Pain	**0.56****	0.17	0.29*	**0.51****	0.43**	**0.53****
Mental health	0.39**	0.19*	0.35*	0.30*	0.27*	0.27*
Vitality	0.44**	0.17	0.21*	0.41**	0.28*	0.42**

† Observations with missing values on either SF-12 or ICECAP-O questions were removed from the analysis (n = 15). * $p < 0.05$, statistical significance. ** $p < 0.001$, statistical significance.

Figure Legends

Figure 1- *Title:* KDQOL-36 Burden of Kidney Disease score for Dialysis group (n = 83).

Explanatory text: A higher score indicates lower burden of disease and better quality of life.

Figure 2- Title: KDQOL-36 Burden of Kidney Disease score for Conservative Care group (n = 44).

Explanatory text: A higher score indicates lower burden of disease and better quality of life.

Figure 3- *Title:* KDQOL-36 Effects of Kidney Disease score for Dialysis group (n = 82).

Explanatory text: A higher score indicates lower effects of disease and better quality of life.

Figure 4- Title*:* KDQOL-36 Effects of Kidney Disease score for Conservative Care group (n = 45).

Explanatory text: A higher score indicates lower effects of disease and better quality of life.

Supplementary Material

Supplementary Table 1 (Table S1): SF-6D utilities, SF-12 PCS and MCS scores, and ICECAP-O capability index according to patient characteristics

Supplementary Table 2 (Table S2): Mean scores and weights of SF-6D, KDQOL-36 and ICECAP-O according to treatment group

Supplementary Table 3 (Table S3): KDQOL-36 Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease scores according to patient characteristics

Supplementary Item 1 (Item S1): STROBE Statement: checklist of items that should be included in reports of observational studies

Supplementary Item 2 (Item S2): KDQOL-36 Questionnaire (SF-12: Questions 1 – 12 (converted to SF-utilities), KDQOL scores (PCS and MCS scores: Questions 1 – 12, burden of kidney disease: Questions 13 – 16, effects of kidney disease: Questions 17 – 28, symptoms of kidney disease: Questions 29 – 36)

Supplementary Item 3 (Item S3): ICECAP-O Questionnaire

Supplementary Item 4 (Item S4): Background Questions

Supplementary Item 5 (Item S5): SF-6D domains

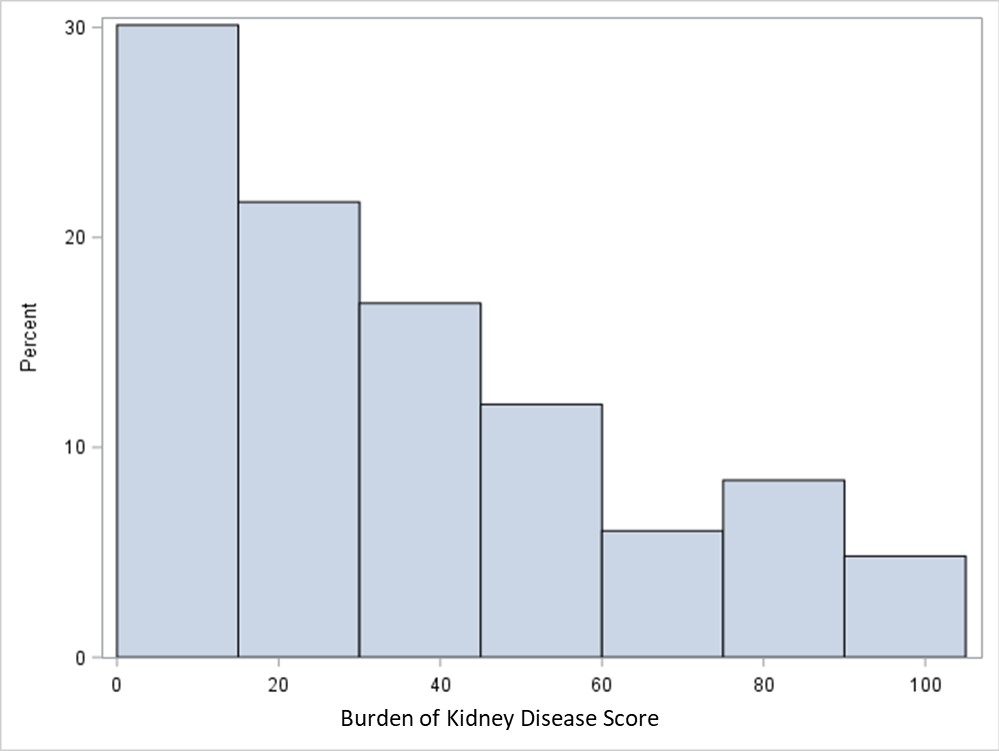

Figure 1: KDQOL-36 Burden of Kidney Disease score for Dialysis group (n = 83). A higher score indicates lower burden of disease and better quality of life.

84x63mm (300 x 300 DPI)

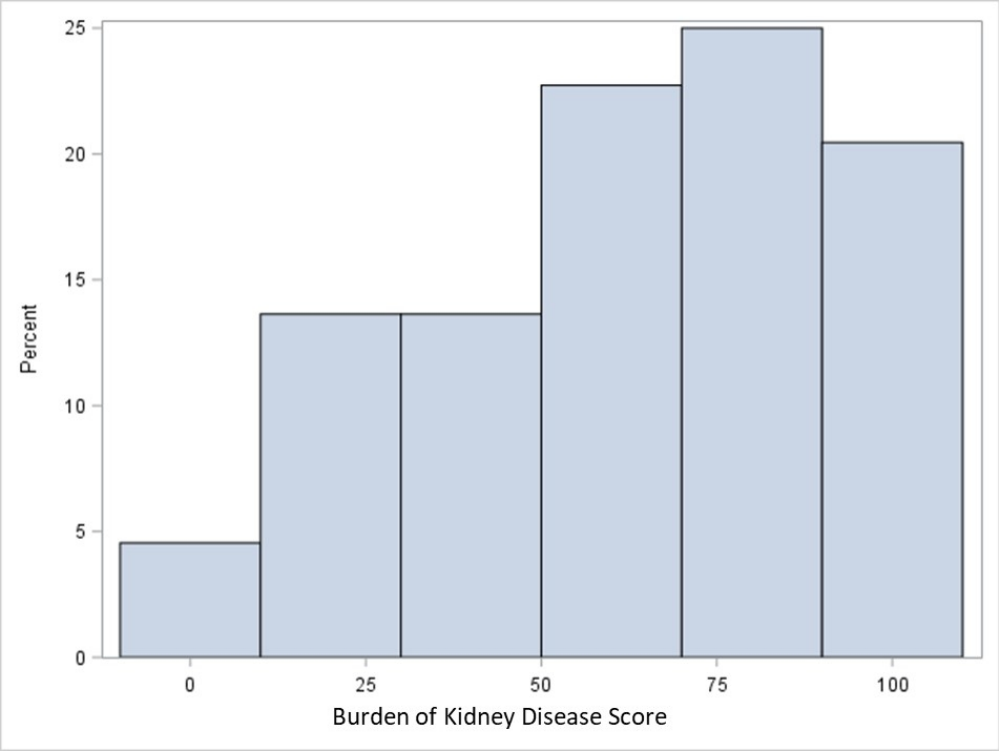

Figure 2: KDQOL-36 Burden of Kidney Disease score for Conservative Care group (n = 44). A higher score indicates lower burden of disease and better quality of life.

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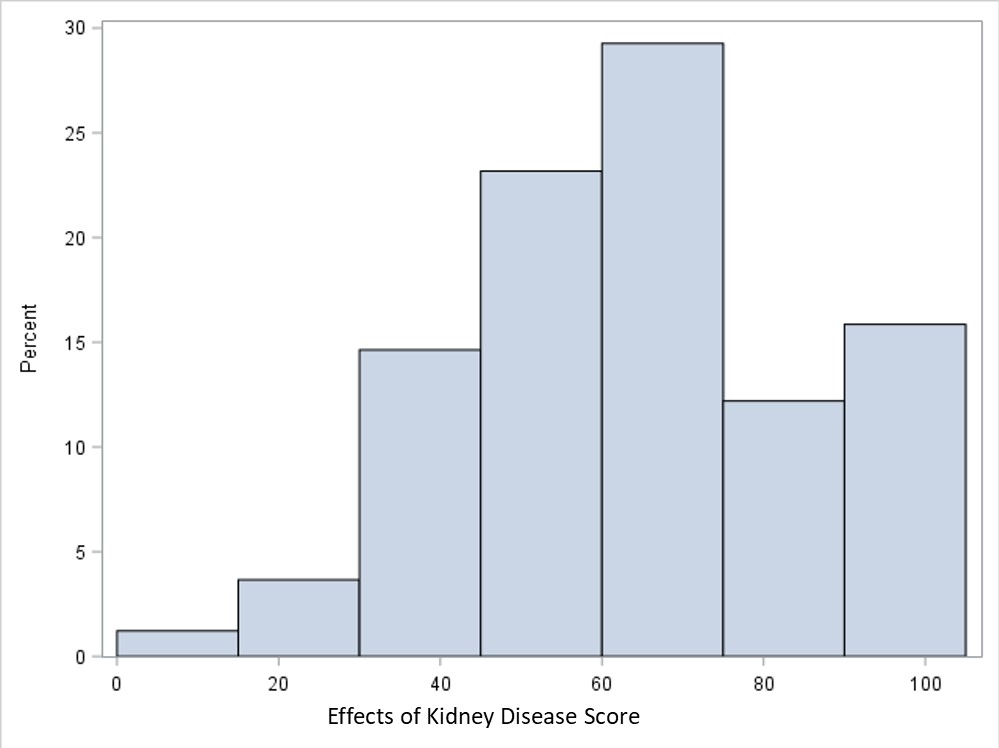

Figure 3: KDQOL-36 Effects of Kidney Disease score for Dialysis group (n = 82). A higher score indicates lower effects of disease and better quality of life.

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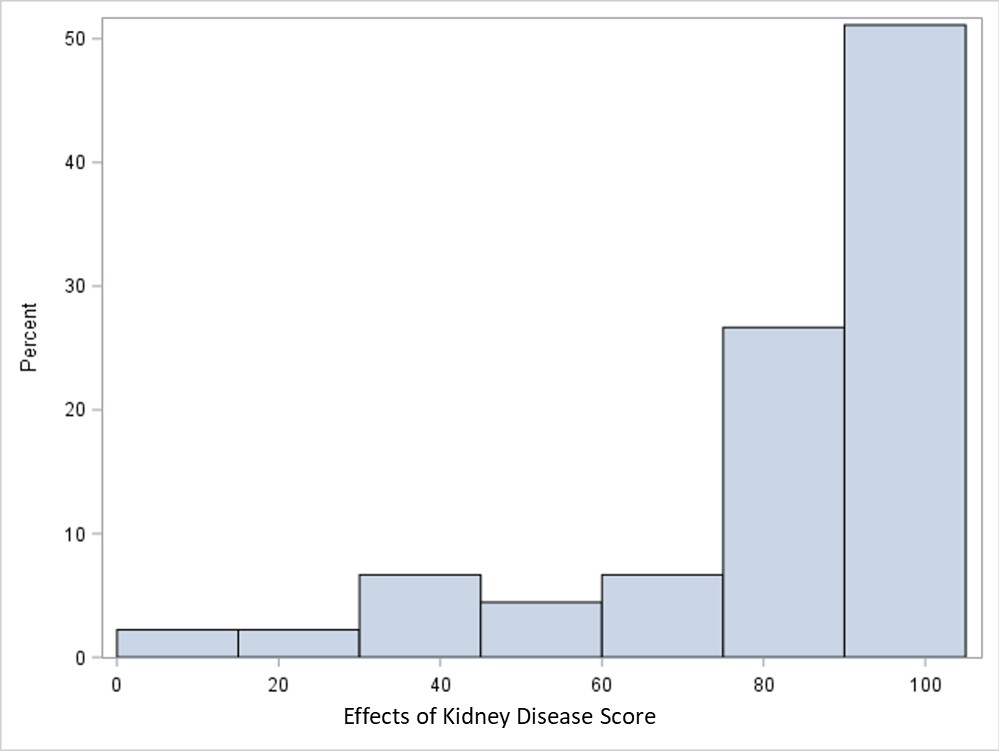

Figure 4: KDQOL-36 Effects of Kidney Disease score for Conservative Care group (n = 45). A higher score indicates lower effects of disease and better quality of life.

84x63mm (300 x 300 DPI)

Supplementary Table 1 (Table S3): SF-6D utilities, SF-12 PCS and MCS scores, and ICECAP-O capability index according to patient characteristics

Characteristics	SF-6D (n = 116)†	PCS (n = 115)††	MCS (n = 115)‡	ICECAP-O (n = 126)‡‡
	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)
Age				
≤81 years	0.63 (0.60-0.67)	32.71 (30.31-35.10)	48.35 (45.51-51.19)	0.73 (0.69-0.78)
>81 years	0.62 (0.58-0.65)	32.08 (29.33-34.84)	46.04 (42.89-49.20)	0.72 (0.67-0.77)
Gender				
Males	0.65 (0.62-0.68)*	34.31 (32.00-36.62)*	47.92 (45.44-50.40)	0.73 (0.68-0.77)
Females	0.58 (0.53-0.62)*	28.85 (26.31-31.39)*	45.98 (42.03-49.93)	0.72 (0.67-0.78)
Treatment**				
Dialysis	0.61 (0.57-0.64)	31.22 (29.02-33.43)	47.67 (45.03-50.30)	0.71 (0.66-0.75)
Conservative Care	0.65 (0.61-0.70)	34.32 (31.27-37.38)	46.56 (42.98-50.15)	0.76 (0.70-0.82)
Country				
United Kingdom	0.60 (0.56-0.63)*	30.76 (28.30-33.22)	49.62 (46.66-52.58)*	0.72 (0.67-0.76)
Australia	0.65 (0.61-0.69)*	33.98 (31.38-36.57)	44.99 (42.06-47.92)*	0.73 (0.68-0.79)
Education §				
Attended some high school	0.62 (0.59-0.65)	31.87 (29.84-33.91)	46.98 (44.43-49.53)	0.72 (0.68-0.76)
Completed high school or tertiary education	0.63 (0.58-0.69)	34.19 (30.22-38.17)	48.09 (44.21-51.97)	0.73 (0.66-0.80)
Private Health Insurance ¶				
Yes	0.68 (0.62-0.73)*	33.03 (29.55-36.50)	49.50 (44.82-54.18)	0.79 (0.73-0.85)
No/Unknown	0.61 (0.58-0.64)*	32.25 (30.09-34.40)	46.77 (44.40-49.13)	0.71 (0.67-0.75)

† Specific SF-6D algorithms were used to convert the SF-12 scores to preference based SF-6D utilities for the UK and the Australian population. 13 out of 129 observations had missing values on SF-12 questionnaire and their SF-6D utilities were not calculated; the remaining had 2 observations missing value for education variable; 3 observations missing value for health insurance variable. †† 14 out of 129 observations had missing values on SF-12 questionnaire and their PCS score were not calculated; the remaining had 1 observation missing value for education variable; 2 observations missing value for health insurance variable. ‡ 14 out of 129 observations had missing values on SF-12 and their MCS score were not calculated; the remaining had 1 observation missing value for education variable; 2 observations missing value for health insurance variable. ‡‡ 3 out of 129 observations had missing values on ICECAP-O questionnaire and their capability index were not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. * $p < 0.05$, statistical significance. ** The dialysis group consist of Facility Haemodialysis, Home Haemodialysis and Peritoneal dialysis. § Individual responses to Primary school/Some high school were merged into one category as "Attended some high school" and the responses to GCSEs/Completed high school/Diploma/TAFE/ Completed A- levels/ University degree were merged into one category as "Completed high school or tertiary education". ¶ Individual responses to "No" and "Unknown" were merged into one category as "No/Unknown". CI - Confidence interval. SF-12 - Short form survey with 12 items. PCS - Physical Component Summary. MCS - Mental Component Summary.

Supplementary Table 2 (Table S2): Mean scores and weights of SF-6D, KDQOL-36 and ICECAP-O according to treatment group

Instrument	Score Mean (SD)	Weights Mean (SD)	Score Mean (SD)	Weights Mean (SD)
SF-6D‡				
Physical functioning	2.47 (1.04)	-0.02 (0.02)	2.26 (0.68)	-0.018 (0.02)
Role limitations	3.22 (1.44)	-0.06 (0.02)	2.84 (1.28)	-0.05 (0.03)
Social functioning	3.33 (1.62)	-0.06 (0.03)	2.65 (1.25)	-0.06 (0.03)
Pain	3.29 (2.13)	-0.05 (0.05)	2.60 (1.37)	-0.04 (0.05)
Mental health	2.90 (1.92)	-0.05 (0.04)	2.33 (1.10)	-0.05 (0.04)
Vitality	3.86 (1.72)	-0.09 (0.02)	3.57 (1.13)	-0.09 (0.01)
KDQOL-36				
Physical Component Summary (PCS)	31.22 (9.32)	-	34.32 (10.05)	-
Mental Component Summary (MCS)	47.67 (11.12)	-	46.56 (11.78)	-
Burden of Kidney Disease	34.71 (27.77)	-	62.83 (29.45)	-
Symptom of Kidney Disease	70.71 (18.74)	-	76.61 (19.18)	-
Effects of Kidney Disease	64.18 (20.27)	-	81.29 (21.92)	-
ICECAP-O‡‡				
Attachment (love and friendship)	3.25 (0.87)	0.22 (0.06)	3.27 (0.81)	0.22 (0.05)
Security (thinking about future without concern)	2.42 (0.99)	0.09 (0.05)	2.71 (0.92)	0.10 (0.05)
Role (doing things that make you feel valued)	2.51 (0.82)	0.15 (0.04)	2.69 (0.85)	0.15 (0.05)
Enjoyment (enjoyment and pleasure)	2.52 (0.94)	0.13 (0.04)	2.80 (0.97)	0.14 (0.04)
Control (independence)	2.51 (0.94)	0.13 (0.08)	2.82 (1.01)	0.15 (0.09)

† 6 observations missing values on SF-6D Role limitation domain; 12 observations missing PCS and MCS score; 2 observations missing Symptoms of Kidney Disease score; 1 observations missing Effects of Kidney Disease score; 2 observations missing values on ICECAP-O Attachment domain. †† 1 observation missing value on SF-6D Role limitation domain; 2 observations missing KDQOL-36 PCS, MCS, Burden of Kidney Disease, and Symptoms of Kidney Disease score; 1 observation missing KDQOL-36 Effects of Kidney Disease score; 1 observation missing value on all ICECAP-O domains. ‡ SF-6D domain scores are weighted decrements. ‡‡ ICECAP-O domain scores are weighted increments. SD - Standard deviation. KDQOL-36 - Kidney disease quality of life with 36 items.

Supplementary Table 3 (Table S3): KDQOL-36 Burden of Kidney Disease, Symptoms of Kidney Disease, and Effects of Kidney Disease scores according to patient characteristics

Characteristics	Burden of Kidney Disease (n = 127)†	Symptoms of Kidney Disease (n = 125)††	Effects of Kidney Disease (n = 127)‡
	Mean (95 % CI)	Mean (95 % CI)	Mean (95 % CI)
Age			
≤81 years	41.80 (34.47-49.12)	72.21 (67.15-77.27)	69.15 (63.05-75.25)
>81 years	47.16 (38.81-55.50)	73.35 (68.76-77.95)	71.35 (66.26-76.43)
Gender			
Males	44.43 (37.70-51.15)	74.00 (70.01-78.00)	71.48 (66.72-76.23)
Females	44.51 (34.62-54.39)	70.46 (64.13-76.79)	67.91 (60.77-75.05)
Treatment**			
Dialysis	34.71 (28.65-40.78)*	70.71 (66.56-74.85)	64.18 (59.72-68.63)*
Conservative Care	62.83 (53.88-71.78)*	76.61 (70.78-82.44)	81.29 (74.70-87.88)*
Country			
United Kingdom	37.81 (30.68-44.94)*	71.97 (67.37-76.58)	66.29 (61.31-71.28)*
Australia	51.88 (43.59-60.16)*	73.72 (68.64-78.81)	74.65 (68.52-80.77)*
Education§			
Attended some high school	45.32 (38.85-51.79)	71.42 (67.21-75.63)	70.93 (66.29-75.57)
Completed high school or tertiary education	43.53 (32.44-54.61)	76.87 (72.15-81.59)	68.92 (61.06-76.79)
Private Health Insurance¶			
Yes	55.32 (41.82-68.83)*	73.33 (65.11-81.54)	75.85 (67.67-84.02)
No/Unknown	41.62 (35.62-47.63)*	72.88 (69.03-76.73)	69.32 (64.80-73.84)

† 2 out of 129 observations had missing values on burden of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. †† 4 out of 129 observations had missing values on symptoms of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. ‡ 2 out of 129 observations had missing values on effects of disease questions and their score was not calculated; the remaining had 2 observations missing value for education variable; 4 observations missing value for health insurance variable. * $p < 0.05$, statistical significance. ** The dialysis group consist of Facility Haemodialysis, Home Haemodialysis and Peritoneal dialysis. § Individual responses to Primary school/Some high school were merged into one category as "Attended some high school" and the responses to GCSEs/Completed high school/Diploma/TAFE/ Completed A- levels/ University degree were merged into one category as "Completed high school or tertiary education". ¶ Individual responses to "No" and "Unknown" were merged into one category as "No/Unknown". CI - Confidence interval. KDQOL-36 - Kidney disease quality of life with 36 items.

Supplementary Item 1 (Item S1): STROBE Statement: checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Yes/No/NA, Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Yes, page 1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes, Page 2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Yes, Page 4-7
Objectives	3	State specific objectives, including any pre-specified hypotheses	Yes, Page 7
Methods			
Study design	4	Present key elements of study design early in the paper	Yes, Page 7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Yes, Page 7-8
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Yes, Page 7-8

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes, Page 8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes, Page 9-10
Bias	9	Describe any efforts to address potential sources of bias	Yes, Page 8
Study size	10	Explain how the study size was arrived at	Yes, Protocol Page 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes, Page 10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Yes, Page 10-11
		(*b*) Describe any methods used to examine subgroups and interactions	Yes, Page 10-11
		(*c*) Explain how missing data were addressed	Yes, Page 10-11
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	NA

		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	No – screening logs at each site were not available
		(b) Give reasons for non-participation at each stage	No
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders	Yes, Page 7-8, 22
		(b) Indicate number of participants with missing data for each variable of interest	Yes, Page 12-14, 24
		(c) *Cohort study*—Summarise follow-up time (e.g., average and total amount)	NA
Outcome data	15*	*Cross-sectional study*—Report numbers of outcome events or summary measures	Yes, Page 11-14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes, Page 11-14, 23-24

		(*b*) Report category boundaries when continuous variables were categorised	Yes, Page 11-14, 23-24
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Yes, Page 11-14
Discussion			
Key results	18	Summarise key results with reference to study objectives	Yes, Page 15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Yes, Page 17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes, Page 17
Generalisability	21	Discuss the generalisability (external validity) of the study results	Yes, Page 17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes, Page 18

Supplementary Item 2 (Item S2): KDQOL-36 Questionnaire (SF-12: Questions 1 – 12 (converted to SF-utilities), KDQOL scores (PCS and MCS scores: Questions 1 – 12, burden of kidney disease: Questions 13 – 16, effects of kidney disease: Questions 17 – 28, symptoms of kidney disease: Questions 29 – 36)

Your Health

– and –

Well-Being

Kidney Disease and Quality of Life (KDQOL™-36)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Thank you for completing these questions!

Your Health

This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.

1. In general, would you say your health is: [Mark an ☒ in the one box that best describes your answer.]

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [Mark an ☒ in a box on each line.]

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
3. Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐ 1	☐ 2
5. Were limited in the kind of work or other activities	☐ 1	☐ 2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐ 1	☐ 2
7. Didn't do work or other activities as carefully as usual	☐ 1	☐ 2

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Your Kidney Disease

How true or false is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
13. My kidney disease interferes too much with my life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. Too much of my time is spent dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. I feel frustrated dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. I feel like a burden on my family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the <u>past 4 weeks</u>, to what extent were you bothered by each of the following?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
17. Soreness in your muscles?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18. Chest pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19. Cramps?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. Itchy skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. Dry skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22. Shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
23. Faintness or dizziness?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24. Lack of appetite?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25. Washed out or drained?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26. Numbness in hands or feet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27. Nausea or upset stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[a]. (Hemodialysis patient only) Problems with your access site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[b]. (Peritoneal dialysis patient only) Problems with your catheter site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Effects of Kidney Disease on Your Daily Life

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease bother you in each of the following areas?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
29. Fluid restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30. Dietary restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31. Your ability to work around the house?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32. Your ability to travel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33. Being dependent on doctors and other medical staff?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34. Stress or worries caused by kidney disease?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35. Your sex life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36. Your personal appearance?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Supplementary Item 3 (Item S3): ICECAP-O Questionnaire

ABOUT YOUR QUALITY OF LIFE

By placing a tick (✓) in ONE box in EACH group below, please indicate which statement best describes your quality of life at the moment.

1. Love and Friendship

I can have all of the love and friendship that I want	4
I can have a lot of the love and friendship that I want	3
I can have a little of the love and friendship that I want	2
I cannot have any of the love and friendship that I want	1

2. Thinking about the future

I can think about the future without any concern	4
I can think about the future with only a little concern	3
I can only think about the future with some concern	2
I can only think about the future with a lot of concern	1

3. Doing things that make you feel valued

I am able to do all of the things that make me feel valued	4
I am able to do many of the things that make me feel valued	3
I am able to do a few of the things that make me feel valued	2
I am unable to do any of the things that make me feel valued	1

4. Enjoyment and pleasure

I can have all of the enjoyment and pleasure that I want	4
I can have a lot of the enjoyment and pleasure that I want	3
I can have a little of the enjoyment and pleasure that I want	2
I cannot have any of the enjoyment and pleasure that I want	1

5. Independence

I am able to be completely independent	4
I am able to be independent in many things	3
I am able to be independent in a few things	2
I am unable to be at all independent	1

Tick one box only in each section

Supplementary Item 4 (Item S4): Background Questions

Q1. What is your full name? _____

Q2. What is your date of birth? _____ (*dd/mm/yyyy*)

Q3. Gender (*please tick one*)

Male □

Female □

Q4. What is your main residential postcode? _____

Q5. What was your country of birth? _____

Q6. What is the highest level of education you have completed? (*please tick the box that best describes you*)

Primary school □

Some high school □

Completed high school □

Completed Diploma/ TAFE course □

Completed University Degree □

Q7. Do you have private health insurance? (*please tick one*)

Yes □

No □

Don't know □

Q8. What type of kidney treatment are you ***currently*** having? (*please tick one*)

Hemodialysis (satellite or hospital) □

Hemodialysis at home □

Peritoneal dialysis □

Non-dialysis renal supportive care □

Q9. If you are currently on dialysis when did you first start dialysis?

_____ *(*mm/yyyy)

Q10. Have you ever had a kidney transplant before? (*please tick one*)

Yes □ No □

Q11. The next two questions are about the **ICECAP-O survey.** On the scale below please rate how <u>easy</u> this survey was to complete *(circle a number between 1 and 5)*

Very easy	Somewhat easy	Neutral	Somewhat difficult	Very difficult
1	2	3	4	5

Q12. Did this survey measure the things that you consider <u>important</u> to your quality of life? *(circle a number between 1 and 5)*

Completely agree	Somewhat agree	Neutral	Somewhat disagree	Completely disagree
1	2	3	4	5

Q13. If you responded with 'somewhat disagree' or 'completely disagree,' would you like to tell us what you think the **ICECAP-O survey** was missing?

_____

_____

_____

_____

_____

Q14. The next two questions are about the **SF-12 survey.** On the scale below please rate how easy this survey was to complete *(circle a number between 1 and 5)*

Very easy	Somewhat easy	Neutral	Somewhat difficult	Very difficult
1	2	3	4	5

Q15. Did this survey measure the things that you consider important to your quality of life? *(circle a number between 1 and 5)*

Completely agree	Somewhat agree	Neutral	Somewhat disagree	Completely disagree
1	2	3	4	5

Q16. If you responded with 'somewhat disagree' or 'completely disagree,' would you like to tell us what you think the **SF-12 survey** was missing?

Supplementary Item 5 (Item S5): SF-6D domains

Level	SF-6D
	Physical Functioning
1	Your health does not limit you in *vigorous activities*
2	Your health limits you a little in *vigorous activities*
3	Your health limits you a little in *moderate activities*
4	Your health limits you a lot in *moderate activities*
5	Your health limits you *a little in bathing and dressing*
6	Your health limits you *a lot in bathing and dressing*
	Role limitations
1	You have *no* problems with your work or other regular daily activities as a result of your physical health or any emotional problems
2	You are limited in the kind of work or other activities as a result of your physical health
3	You accomplish less than you would like as a result of emotional problems
4	You are limited in the kind of work or other activities as a result of your physical health and accomplish less than you would like as a result of emotional problems
	Social functioning
1	Your health limits your social activities *none of the time*
2	Your health limits your social activities *a little of the time*
3	Your health limits your social activities *some of the time*
4	Your health limits your social activities *most of the time*
5	Your health limits your social activities *all of the time*
	Pain
1	You have *no* pain
2	You have pain but it does not interfere with your normal work (both outside the home and housework)
3	You have pain that interferes with your normal work (both outside the home and housework) *a little bit*
4	You have pain that interferes with your normal work (both outside the home and housework) *moderately*
5	You have pain that interferes with your normal work (both outside the home and housework) *quite a bit*
6	You have pain that interferes with your normal work (both outside the home and housework) *extremely*
	Mental health
1	You feel tense or downhearted and low *none of the time*
2	You feel tense or downhearted and low *a little of the time*
3	You feel tense or downhearted and low *some of the time*
4	You feel tense or downhearted and low *most of the time*
5	You feel tense or downhearted and low *all of the time*
	Vitality
1	You have a lot of energy *all of the time*
2	You have a lot of energy *most of the time*
3	You have a lot of energy *some of the time*
4	You have a lot of energy *a little of the time*
5	You have a lot of energy *none of the time*