Quality of life in patients starting dialysis and their partners

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in the Faculty of Biology, Medicine and Health

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Thesis Abstract

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in January 2020.
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Patients with established renal failure (ERF) and their partners prioritise quality of life (QOL), especially as the patient prepares to start dialysis. However, limited research exists which examines QOL in patient-partner couples around the start of dialysis. Patients and their partners form a unique social unit, or dyad, who influence each other and may be mutually or individually affected by illness or its treatment. Examining QOL in patient-partner dyads may provide new insight into the psychological or relationship factors related to QOL.

The thesis comprises a literature review and three empirical studies which are described across four chapters: 1) a narrative literature review exploring QOL in ERF patients and their partners (Chapter 3), 2) a qualitative study using dyadic thematic analysis to examine the impact of dialysis on the dyadic relationship between male patients and their female partners (Chapter 4), 3) a multi-phase study to develop a measure to assess psychological and interpersonal factors related to QOL (Chapter 5), and 4) a longitudinal, quantitative questionnaire-based study to describe changes in QOL in patient-partner dyads over the transition onto dialysis (Chapter 6).

The literature review is the first to focus on QOL in ERF patients and their partners. It identified 14 studies (8 qualitative, 4 quantitative and 2 mixed methods). A narrative review of quantitative results and a narrative synthesis of qualitative findings suggested that ERF and dialysis significantly affect QOL. Both patients and their partners described impairments in their QOL, most notably in their psychological QOL.

Semi-structured interviews were conducted with 20 dyads (male patients and their female partners) who were in the early phases of dialysis (pre-dialysis to first 16 months on dialysis). Dyadic thematic analysis highlighted the substantial ways dialysis impacted their lives and were captured by the themes “Prioritising the patient,” “Carrying the burden” and “Changing identities.” Despite these changes, dyads who worked together and found ways to be positive, accepting of or normalised dialysis minimised negative effects on their relationship. Further analysis of the findings suggested that dialysis expectations, accepting dialysis and features of the dyadic relationship relate to QOL. A measure, the Starting Dialysis Questionnaire (SDQ), was developed to assess these constructs. Cognitive interviews and preliminary psychometric evaluations indicate that the SDQ has good face validity and overall performance.

A longitudinal, quantitative study measured changes in QOL from pre-dialysis (83 dyads), at 6 weeks (42 dyads) and 12 weeks (39 dyads) after starting dialysis. Patients’ general and physical QOL improved from poor to good QOL. For partners, QOL was good overall despite it worsening at 6 weeks after the patient started dialysis.

The thesis makes a novel contribution to the ERF literature by focusing on patient-partner dyads over a critical time period in the illness trajectory and using methods which better our understanding of the wider interpersonal context in which dialysis occurs.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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Six trees have been planted by the UK National Forest
to off-set the wasted paper created over the course of this PhD.

Disclosure: Copious amounts of chocolate and coffee have been consumed in the writing up of the thesis.

The Author

Born and raised in the USA, Currie Moore received a Bachelor of Science degree in Psychology from Furman University in 2006. Then moved to Thailand to teach English, and where she met her future husband, Paul. They then moved to Christchurch, New Zealand where she worked in sales and marketing while he pursued his PhD. After an unsettling earthquake in NZ, they relocated to the UK. With the hope of re-starting her career and pursuing her life-long ambition of working with people with chronic illnesses, she earned a Masters of Research in Psychological Sciences at the University of Manchester in 2013. Her dissertation topic was on the lived experiences of male home haemodialysis patients and how they came to terms with a particular form of self-care essential for home dialysis, self-cannulation. In January 2014, she was awarded a PhD studentship through the Medical Research Council UK’s doctoral training partnership and additional funding from the President’s Doctoral Scholar programme (University of Manchester).

Chapter 1: Introduction

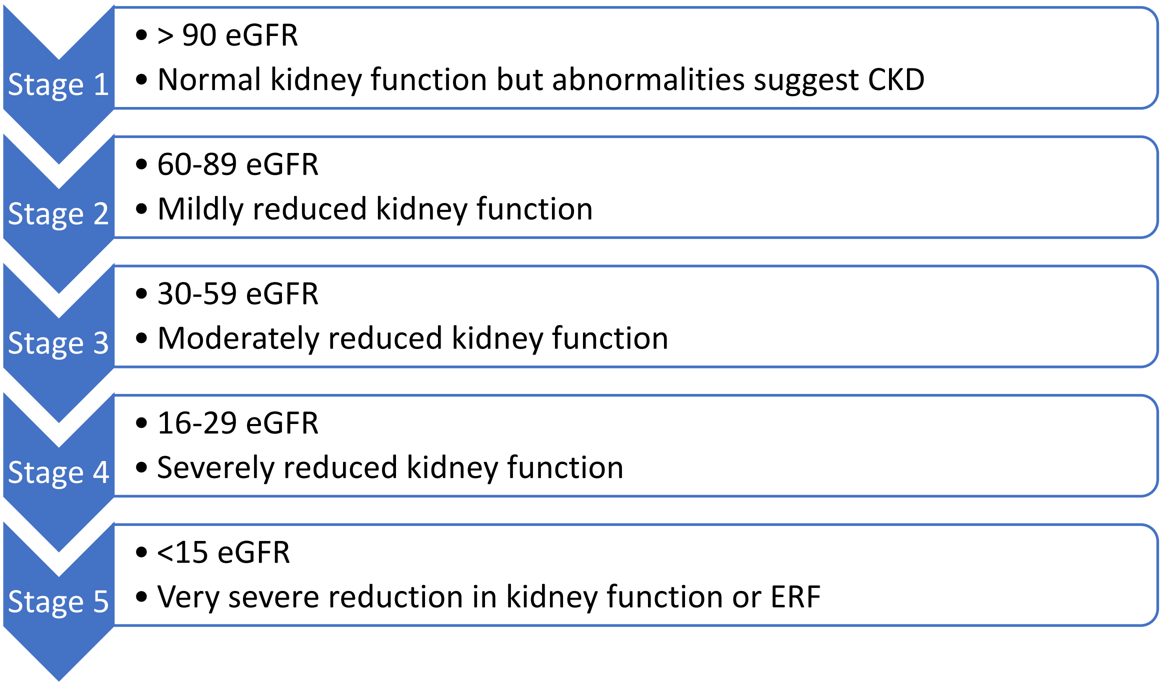
1.1 Introduction and overview

The primary aim of this thesis was to examine and describe the quality of life (QOL) in patients starting dialysis and their partners. The participants in the studies reported here were recruited as couples, or dyads, and the non-patient member of the couple was the primary caregiver. A secondary aim was to explore the effects of dialysis on the dyadic relationship and to identify psychological or relationship factors related to QOL during the period when the patient started dialysis. Additionally, the researcher aimed for the programme of research to be patient-centred, to this end a patient and public renal research group were consulted and provided feedback throughout the research process.

The present chapter sets out the context for this programme of research and demonstrates the need for research on QOL in ERF patient-partner dyads. It opens with an introduction to established renal failure (ERF) and dialysis. Next, it establishes the importance attached to QOL in the field of renal medicine. There then follows an overview of existing QOL research in patients with ERF and their partners. Finally, the aims of this programme of research and how they will be addressed in this thesis are presented.

1.2 Established renal failure

Chronic kidney disease (CKD) is the term used to denote abnormal functioning of the kidneys and is a progressive disease which is conceptualised as consisting of five stages (see Figure 1.1). The continuum begins with a worsening of kidney functioning, which at that stage may be asymptomatic, and culminates in the final stage where irreversible loss of kidney function occurs (KDIGO, 2013). In the UK, people are referred to nephrologists at Stage 3 when their kidneys are only able to clear <30% of the toxins in the body (NICE, 2014). The measure indicating clearance of toxins from the body is the glomerular filtration rate (GFR), often estimated from other parameters (eGFR). Established renal failure (ERF) is the last stage of in CKD (CKD stage 5) whereby the kidneys are no longer able to clear the toxins in the blood adequately to sustain life. At this stage, alternative methods of cleaning the blood may be used to sustain the individual's life (NICE, 2018). People with ERF rely on renal replacement therapies (RRT) such as kidney transplantation and dialysis to sustain their lives.



Stage 1
- > 90 eGFR
- Normal kidney function but abnormalities suggest CKD

Stage 2
- 60-89 eGFR
- Mildly reduced kidney function

Stage 3
- 30-59 eGFR
- Moderately reduced kidney function

Stage 4
- 16-29 eGFR
- Severely reduced kidney function

Stage 5
- <15 eGFR
- Very severe reduction in kidney function or ERF

Figure 1.1. Stages of Chronic Kidney Disease (CKD).
Adapted from "KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease," by the Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group, 2013, *Kidney International* Suppl. 3, p.6.
Key. CKD: chronic kidney disease; eGFR: estimated Glomerular Filtration Rate which measures the body's ability to eliminate toxins.

In the UK, approximately 64,900 people are on a form of RRT, or 983 per million of the population. In 2017, 8000 people started on RRT, which reflects an increase of 2.6% from the prior year. ERF presents a growing public health concern. Increasing incidence rates of ERF are associated with increased rates of risk factors such as diabetes, hypertension and obesity (Robinson et al., 2016). Furthermore, ERF requires sophisticated and costly treatments which are funded in the UK through the National Health Service (NHS). In 2010, £1 of every £77 spent by the NHS went towards renal care services, equating to a total of £1.45 billion (Kerr, 2012). There are many known complications of renal failure, the most important one being cardiovascular disease which is the major cause of death in these patients. Given the impact and costliness of ERF, its treatment and its complications, and the rising rate of patients requiring RRT, it is important to ensure that RRTs address patients' needs, such as maintaining their QOL.

1.3 Renal replacement therapies

The three central methods of RRT are renal transplants, haemodialysis (HD) and peritoneal dialysis (PD). Kidney transplantation requires meeting stringent criteria for eligibility and receiving an organ donation from a live or cadaveric source. In haemodialysis (HD), the individual's blood is circulated through a machine which filters out the toxins and excess fluid before returning the "cleaned" blood to the body. The patient's blood supply is connected to the machine via vascular access points (most commonly an arteriovenous fistula or a neck catheter). Haemodialysis treatment may be administered in renal units within hospitals, in out-patient renal facilities (referred to as satellite dialysis centres) or in the patient's home. The duration and timing of each HD treatment session is dependent on the modality selected; however clinical recommendations are that HD should be undertaken at least 3 days a week for a minimum of 4 hours, commonly referred to as ‘conventional’ HD. In PD, the blood is filtered by a different method. A cleaning solution, or dialysate, is introduced into the body via an abdominal catheter inserted into the peritoneum, or the lining of the abdominal cavity. The peritoneum acts as a membrane through which the dialysate draws water from the blood, at the same time collecting the accumulated toxins. The toxin-rich fluid should be exchanged for new dialysis solutions every 24 hours. The two main forms of PD are continuous ambulatory peritoneal dialysis (CAPD) which is typically conducted over four 40-minute sessions per day and automated (APD) which is done for eight-nine hours overnight while the patient sleeps. Peritoneal dialysis is most often conducted in the patient’s home rather than in clinical settings due to the frequency and duration of the exchanges. Determining which mode of dialysis best suits patients is a complex one and the decision-making process between patients and their renal care teams take into account the patients’ health and physiological parameters, lifestyle objectives, resources (e.g., housing, social support) and feasibility.

Those starting RRT for the first time tend to start on a form of dialysis, HD or PD, with less than 10% of patients receiving a transplant as their first form of RRT. The percentage of patients who utilise each modality at the start of RRT is presented in Figure 1.2. Over time the percentage utilising each RRT shifts, with more than half of people receiving a transplant (54%) and the rest on dialysis (conventional HD 38%, PD 6% and home HD 2%) (Registry, 2019). With nearly half the RRT population reliant on dialysis for long-term treatment, there has been an impetus in HD and PD research to assess patient-centred outcomes with the aim of better understanding the effects of this invasive treatment on their overall health and QOL (Finkelstein, Arsenault, Taveras, Awuah, & Finkelstein, 2012).

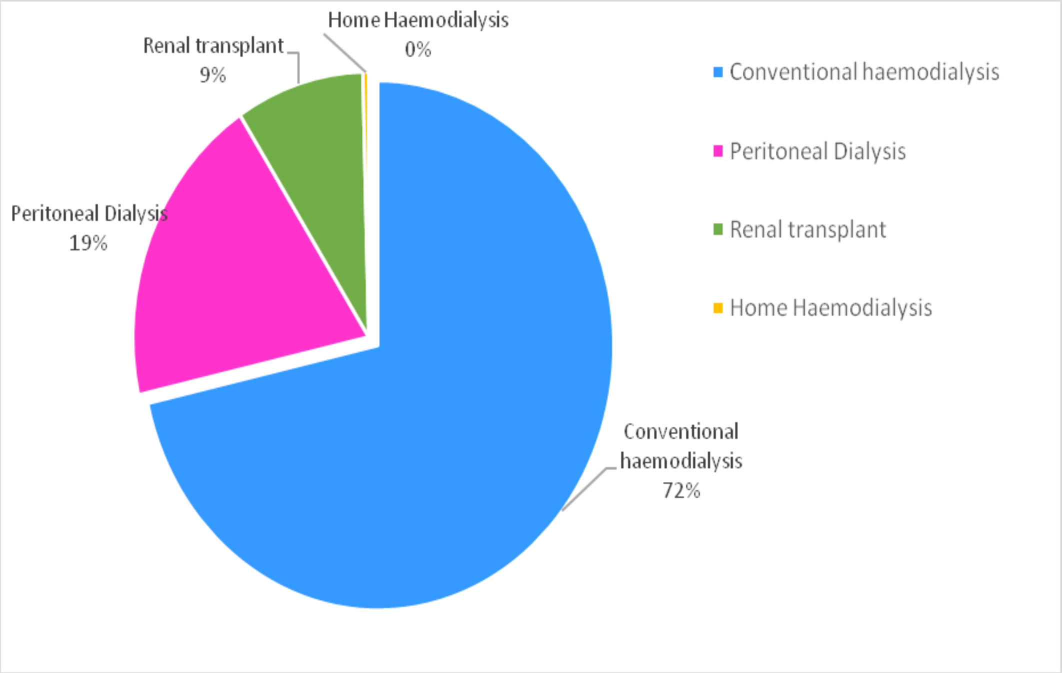


Figure 1.2. Renal replacement therapies utilised by patients when starting. Taken from “Adults starting RRT for ESKD in the UK in 2017,” by the UK Renal Registry, 2019, UKRR 21st Annual Report.

1.4 Phases of dialysis

The programme of research described in this thesis is predominantly focused on the early phases of dialysis. The dialysis “journey” is often conceptualised as pre-dialysis, starting dialysis and being established on dialysis. The early phases of pre- and starting-dialysis are considered key points in ERF patients’ illness trajectory (Jablonski, 2004) yet are under-researched. This is despite calls for more studies to examine these crucial phases of the trajectory (Kutner, Zhang, Barnhart, & Collins, 2005; Wu et al., 2004).

Pre-dialysis refers to the period of time when the patient is under the care of a nephrologist for the treatment and management of ERF. In the pre-dialysis phase, patients are not necessarily preparing for dialysis but considering their RRT options should their kidneys continue to decline in function. Physicians in the UK follow a structured pre-dialysis pathway whereby patients are monitored regularly. The aim of the structured pathway is to facilitate patients to start dialysis in a planned manner (i.e., in HD patients, a fistula will be fitted at least 6 months before it is anticipated that dialysis will start). A recent report has shown that approximately 70% of patients in the UK receive pre-dialysis care for more than four months before starting dialysis (Robinson et al., 2016). However, research indicates that improving access to renal support services, such as counselling and social services, and optimising the delivery of education and informational material, is needed to meet the growing demands of the ERF population (Combes, Sein, & Allen, 2017; Seekles et al., 2017).

Before starting dialysis, the renal care teams should have discussed with patients and their family members and/or carers the different RRT options, including conservative management (i.e., managing kidney function through diet, medication and exercise, but with a recognition that kidney function will continue to decline eventually leading to death). The decision to start dialysis should be made jointly with the patient and should take account of the patient’s clinical indicators (e.g., eGFR) and the effect of symptoms on daily life (NICE, 2018).

Renal teams endeavour to provide continuity of care as patients transition onto dialysis, which may be done through formal handover reports or informal communication between staff. After starting dialysis, patients are monitored at dialysis sessions (HD) or by their renal care teams at their homes or at clinic appointments (PD and HHD). Patients usually have routine appointments with their lead consultant nephrologist approximately once every 2 months.

1.5 Quality of life

In the programme of research described here, QOL is conceptualised in accordance with the World Health Organization's (WHO) definition which is stated as "*an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns*" (The WHOQOL Group, 1994, p. 43). The WHOQOL definition matches the aims of this programme of research which seeks to capture the views and experiences of patients and their partners as they prepare for and begin dialysis, and the impact this treatment has on the many facets of their lives which contribute to their QOL.

Although 'QOL' research has burgeoned in the ERF field over the last two decades (Moreiras-Plaza, Blanco-Garcia, Cossio-Aranibar, & Rodriguez-Goyanes, 2011), an issue in this research is that the term 'QOL' has often been conflated with the constructs of health status and functioning and has often been measured by instruments such as the SF-36 (Ware & Sherbourne, 1992), SF-12 (Ware, Kosinski, & Keller, 1996)and Karnofsky performance status (Karnofsky & Burchenal, 1949). This issue of the definition and meaning of QOL is not limited to ERF research and occurs in wider medical and clinical research. Health status/functioning refers to what a patient is able to do (e.g. walking, bathing, taking part in social or work activities). Quality of life researchers would argue that health status/functioning and QOL are two separate concepts and that conflating them implies that good physical health equates to good QOL (Moons, Budts, & De Geest, 2006). This narrow view of health status as an indicator of QOL fails to capture the full of experiences of people or to take into account the fact that people with chronic illnesses may rate their QOL as good despite quite marked physical or mental limitations (Moons et al., 2006). Therefore, research which draws on broader conceptualisations of QOL is needed to better understand QOL in ERF patients and their partners.

1.6 Quality of life in ERF and dialysis patients

Considerable research in ERF patients includes measures of health status as the primary outcome measure in relation to clinical markers (e.g., eGFR, serum albumin, haemoglobin). Recently, there has been a call to re-adjust the focus onto to outcomes that are important to patients (Kliger, Fishbane, & Finkelstein, 2012; Nissenson, 2013; Tong et al., 2015). Research conducted to assess patients' priorities has found QOL and well-being to be their top concerns rather than clinical indicators (Janssen et al., 2015; Nissenson, 2013). Consistent with this, studies conducted with patients on HD, which used individualised assessments where patients list the areas important to their QOL, have reported that health/well-being, family, financial/work status and leisure are most important to their QOL (Abdel-Kader et al., 2009; Matlabi & Ahmadzadeh, 2017).

Quality of life is a broad field with a multitude of scales to measure QOL and factors relating to it. Although patients and partners state QOL is a primary concern (Morton, Tong, Webster, Snelling, & Howard, 2011; Morton, Tong, Howard, Snelling, & Webster, 2010), it is not included as a core outcome measure in HD and PD clinical trials as it was considered too broad of concept and difficult to define (Evangelidis et al., 2017). With no consensus on how to best measure QOL in renal research, a QOL measure which directly addresses QOL and includes areas related to QOL, such as those highlighted as important by HD and PD patients (e.g., physical and emotional health, social support, ability to work) (Manera et al., 2019; Urquhart-Secord et al., 2016), may be best suited to fill this gap.

One such measure is the World Health Organization’s WHOQOL-BREF questionnaire (Skevington, Lotfy, & O'Connell, 2004) which was created by an international collaboration, using an inductively-driven process, with the specific aim of designing a scale to measure QOL across all types of chronic illnesses and healthy people (Skevington & McCrate, 2012). It is a 26-item measure which includes a general QOL facet and four QOL domains (physical, psychological, social and environment). Participants rate their responses to each item on a five-point Likert scale, where higher scores indicate better QOL. The WHOQOL general QOL facet includes an item on overall QOL (How would you rate your quality of life? 1=Very poor, 2=Poor, 3=Neither good nor poor, 4=Good, 5=Very good) and an item on health-related QOL (How satisfied are you with your health? 1=Very dissatisfied, 2=Dissatisfied, 3=Neither satisfied or dissatisfied, 4=Satisfied, 5=Very satisfied). The WHOQOL-BREF domain scores are transformed onto a scale from 0-100 to facilitate comparisons between domains with unequal item numbers. Domain scores less than 50 indicate poor or very poor QOL. The WHOQOL-BREF, which assesses QOL in its broader conceptualisation and includes items related to topics important to ERF patients, may therefore further understanding of QOL experiences in dialysis patients.

In the existing ERF literature that focuses on patients, and particularly dialysis patients, studies report their health status to be significantly lower before starting dialysis and after one year of treatment than that the general population (Fan, Sathick, McKitty, & Punzalan, 2008). ERF research is dominated by studies attempting to draw distinctions between RRT on the basis of health status, with renal transplant patients consistently found to have better physical and mental functioning than HD or PD patients (Liem, Bosch, Arends, Heijenbrok-Kal, & Hunink, 2007).

Similarly, studies with HD and PD patients have sought to highlight the benefits and disadvantages of each of these modes on health status and QOL (Boateng & East, 2011). In a systematic review conducted by Boateng & East (2011) to examine QOL between HD and PD patients, only 4 of the 26 studies included in the review measured QOL. Boateng & East (2011) reported no significant differences between QOL in PD and HD patients.

Cross-sectional studies which examined QOL, in its broader conceptualisation using the WHOQOL-BREF, in ERF patients at pre-dialysis have found that patients reported their QOL to be good across the physical, psychological, social and environment domains but that overall QOL was rated as poor (Lee, Kim, Cho, & Kim, 2013). Studies in patients established on dialysis have also reported QOL as good across the domains of the WHOQOL-BREF (Ginieri-Coccossis, Theofilou, Synodinou, Tomaras, & Soldatos, 2008; Griva, Kang, et al., 2014; Griva, Yu, et al., 2014). Differences in physical QOL were found in older vs. younger PD patients, with older patients reporting poorer QOL (Griva, Yu, et al., 2014), and also between PD and HD patients, with PD patients reporting poorer QOL (Griva, Kang, et al., 2014).

In a longitudinal study assessing changes that occur in PD and HD patients over the first year on dialysis (Wu et al., 2004), patients completed the CHEQ questionnaire (comprised of the SF-36 and a 14-domain dialysis module, which includes a 2-item domain on global QOL, Wu et al., 2001) before starting dialysis and again 12 months later. Overall there were no differences between HD and PD patients; however, the raw scores (unadjusted for differences between the groups such as age, gender, education and baseline clinical variables) indicated that HD patients reported greater improvement in their QOL than PD patients. These findings, taken together, suggest that patient characteristics (e.g. age, gender, clinical factors) and phase in the journey (i.e., just starting dialysis vs. long-term dialysis patients) may explain some of variations in QOL reported in the literature. As this overview of the existing literature on ERF patients' QOL has demonstrated, limited research exists which considers QOL in its broader conceptualisation or examines it using longitudinal designs. Furthermore, these studies do not consider the effects of the illness or treatment on the patients' QOL in its wider interpersonal context and do not take account of the impact of ERF on their personal relationships or on their partners.

1.7 Quality of life in partners

In the programme of research described here, the term *partner* refers to a person who is in a spousal-type relationship with the patient. This means that both members of the couple identify as a 'couple' and includes spouses, civil partners, boyfriends or girlfriends. Usually the partner is also the person who provides the most informal care in the form of physical, treatment-related, or emotional support to an ERF patient (Revenson et al., 2016a). Although the terms ‘caregiver’ and ‘carer’ are often used to describe patients’ family members, these terms may be better suited for people who provide formal instrumental care (Revenson et al., 2016b). During the course of this research, consultations were held with a patient and public renal research group, who provided valuable feedback throughout. This group recommended the use of the term ‘partners’ rather than carers.

Research is lacking which investigates QOL, as opposed to other outcomes, in the partners of ERF patients. The majority of the research which is about partners assesses burden, health status or depression (Gilbertson et al., 2019), rather than QOL. In a review of the literature, which included 61 papers, Gilbertson and colleagues concluded that partners of HD patients had poorer health status, more burden and slightly higher levels of depression in comparison to the general population. Within this review, they identified a subset of studies (n= 25) which provided data for both partners and patients and found that partners tended to show less depression (assessed using BDI) and better functioning (using SF-36, Ware & Sherboune, 1992) compared to patients. However, in reviewing the supplementary material related to this review, only 8 studies, out of the 61 studies in the entire review, were identified which assessed QOL using a recognised measure. Although the findings of the QOL studies were not summarised, an inspection of each study’s findings indicated that dialysis affects QOL variously, with some partners rating their QOL as good and other rating it as poor. Despite a growing body of research on the partners of dialysis patients, research remains limited which focuses on QOL, rather than burden, health functioning or depression, in partners.

One study which compared the health status of partners across the different types of RRT (transplant, HD and PD) found that the partners of transplant patients reported their health functioning better than partners of HD or PD patients (Lindqvist, Carlsson, & Sjoden, 2000). Moreover, the review by Gilbertson et al. (2019) did not find significant differences in burden, health status or depression in the partners of HD patients compared to PD patients.

Recently, the WHOQOL-BREF has been used to assess changes in QOL, alongside burden and affect, in partners of patients established on PD at a baseline assessment point and then at a one-year follow-up (Kang, Yu, Foo, Chan, & Griva, 2019). In this study, partners reported their QOL to be good over the study duration; however, despite a reduction in some of their caring activities , their sense of burden and their psychological QOL worsened over the year, suggesting that continued caregiving over a long period of time was taking a psychological toll.

1.8 Quality of life in patient-partner dyads

Although it is important to assess QOL and its unique effects on patients and partners at the individual level, it must also be acknowledged that patients and their partners do not exist in isolation of each other and their characteristics affect each other (Revenson et al., 2016b). Research in ERF has begun to recognise the unique influences of patients and their partners, in a dyad, on constructs such as QOL, depression and health outcomes. A recent cross-sectional study (Al-Rawashdeh, Alshraifeen, Rababa, & Ashour, 2020), conducted in Jordan, included

123 patient-partner dyads and assessed within dyad effects of hope on QOL, as measured by the WHOQOL-BREF, using the actor-partner interdependence model. They found that patients and partners own hope was significantly associated with their own QOL (i.e., actor effects). The only partner effect (i.e., that a variable measured in one member of the dyad is related to an outcome variable in the other member of the dyad) identified was an association between patients' hope and partners' QOL in the environment domain. The authors suggest that the more hopeful the patient is the better the partner perceives environmental factors such as opportunities for travel and leisure, finances and access to healthcare. This emerging research highlights the need for research which unpicks the complex dynamics occurring within ERF patient-partner dyads.

A longitudinal study which investigated actor-partner effects in HD patients and their partners found that partners' level of burden was positively associated with their own and patients' negative affect (Wilson-Genderson, Pruchno, & Cartwright, 2009). Studies in the wider field of ERF have found that if one member of the dyad showed depressive symptoms the other was more likely to be depressed as well (Daneker, Kimmel, Ranich, & Peterson, 2001). Further to this, in a study with HD patients, higher levels of depression were linked to negative assessments of their dyadic satisfaction and adjustment. Those who reported higher levels of dyadic satisfaction, particularly women, and less dyadic conflict had decreased mortality risk (Kimmel et al., 2000). These studies show highlight the impact dialysis may have on both members of the dyad and that the dyadic relationship itself may affect patients' health outcomes. Thus, examining how ERF and dialysis impacts the QOL in both members of the dyad may be crucial to the long-term success of dialysis.

1.9 Summary of limitations of current research on QOL in ERF patients and partners

To summarise the limitations of the current body of research on QOL in ERF patients and their partners, there are five main issues. First, there is an issue around the conceptualisation and measurement of QOL which is often conflated with health status and assessed using measures of functioning that do not tap into the wider construct of QOL. Second, the lack of consensus over what QOL is, and how to measure it, has led to a very disparate literature in which many different measures have been used, with very few studies actually measuring QOL. Third, even though the time both before and after starting dialysis are regarded as particularly difficult, and possibly critical in its impact on QOL (Jablonski, 2004), the majority of the research to date has been conducted with HD patients who are established on dialysis. Fourth, while research including partners of ERF patients is growing, it tends to examine factors related to QOL, rather than QOL itself. Finally, research is lacking which includes both ERF patients and their partners and which examines QOL and the effects of ERF or dialysis on the couple as well as on each member of the dyad.

1.10 Aims of the thesis

The aims of this programme of research were to address the following research questions:

- *What do we know from the existing quantitative research about QOL in ERF patients and their partners?*

- *What do we know from the existing qualitative studies about the experiences of ERF patients and their partners and how their experiences may relate to QOL?*
- *Are there differences in QOL between ERF patients and their partners?*
- *What is the impact of early dialysis on the dyadic relationship between patients and their partners?*
- *Drawing on their experience, what psychological and interpersonal factors do patients and partners relate to QOL during the early phases of dialysis?*
- *Can we develop a measure to assess these factors (the Starting Dialysis Questionnaire; SDQ)?*
    - *If so, does the SDQ have good acceptability and psychometric properties?*
- *Does QOL change in patients and their partners as they transition from pre-dialysis to 12 weeks after starting dialysis?*
- *Are there differences between patients' and partners' QOL over this transition period?*

1.11 Overview of the thesis

The thesis comprises a literature review and three empirical studies which are described across four chapters:

- Chapter 3 is a narrative literature review of QOL in ERF patients and their partners.

    - Chapter 4 presents the findings of a dyadic thematic analysis of semi-structured interviews with 20 male patients and their female partners on the impact of dialysis on the dyadic relationship.
    - Chapter 5 describes the development of a patient- and partner-centred measure, the SDQ, which was derived from a secondary analysis of the semi-structured interview data (Chapter 4), then assessed using cognitive interviews, and the preliminary psychometric properties evaluated with data drawn from the study presented in Chapter 6.
    - Chapter 6 is a longitudinal, panel, questionnaire-based quantitative study which examines QOL in patients starting dialysis and their partners, from pre-dialysis to 12 weeks after starting dialysis.

1.12 How programme of research address overall research questions

The programme of research presented in this thesis address the research questions as follows:

- Chapter 3, Study 1 (Literature review) answered the research questions:
    - *What do we know from the existing quantitative research about QOL in ERF patients and their partners?*
    - *What do we know from the existing qualitative studies about the experiences of ERF patients and their partners and how their experiences may relate to QOL?*
    - *Are there differences in QOL between ERF patients and their partners?*

- Chapter 4, Study 2 (Qualitative methods and dyadic thematic analysis) answered the research question:
    - *What is the impact of early dialysis on the dyadic relationship between patients and their partners?*
- Chapter 5, Study 3 (Development of the SDQ) answered the following specific research questions:
    - *Drawing on their experience, what psychological and interpersonal factors relate to QOL during the early phases of dialysis?*
    - *Can we develop a measure to assess these factors (the SDQ)?*
        - *If so, does the SDQ have good acceptability and psychometric properties?*
- Chapter 6, Study 4 (Longitudinal changes in QOL) addressed the last two research questions:
    - *Does QOL change in patients and their partners as they transition from pre-dialysis to 12 weeks after starting dialysis?*
    - *Are there differences between patients' and partners' QOL over this transition period?*

1.13 Personal contribution

The personal contribution of the PhD researcher to this programme of research is outlined in the preface for each of the four papers included this thesis.

Chapter 2: Methodology

2.1 Introductory statement

In this chapter, a detailed description of the methods in this programme of research is outlined. It begins with a brief rationale for using a mixed methods approach and then outlines the methods for each study included in the thesis in turn. Within each study, the research questions will be stated and the justification for the approach taken in comparison to other potential methods will be discussed.

2.2 Mixed method research

A mixed methods approach was chosen to address the programme of research described in this thesis as QOL in patient-partner dyads starting dialysis is an emerging area of research (Creswell & Plano Clark, 2011). Mixed methods research means integrating, or building upon, data generated by quantitative and qualitative methods in order to provide a better understanding of a research topic. In order to address the research topic of this thesis, we chose an exploratory sequential design whereby qualitative methods were utilised to identify and explore issues relating to QOL in patient-partner dyads and then hypotheses developed during the qualitative phase were tested using quantitative methods. The findings of the studies in the thesis were given equal value and combined to complement each other, an approach known as complementarity (Adamson, 2005). Complementarity means that the insights obtained in each strand of the research may offer value or enhancement to the overall understanding of the research topic, QOL in couples where one member of the dyad is starting or undergoing dialysis (Creswell & Plano Clark, 2011).

2.2.1 Philosophical assumptions

As mixed methods means combining quantitative and qualitative methodologies, which are paradigms with different epistemological underpinnings, an important aspect of mixed methods research entails addressing the philosophical assumptions guiding each aspect of the research (Creswell & Plano Clark, 2011). Quantitative methods are associated with positivism where variables are thought to be objective reflections of the world and required to be observable (Creswell & Plano Clark, 2011). This means that variables are often reduced to their simplest form. The relationship between variables is typically assessed firstly by observations or measurements, sometimes under controlled conditions, followed by the analysis (usually statistical) of how the variables relate to each other (Creswell & Plano Clark, 2011). Positivist approaches value replication, deductive reasoning and hypothesis testing to test and refine theories. Qualitative methods are associated with views of the world such as constructivism which recognise that data obtained from asking people about their experiences may have multiple meanings and interpretations, and that it may be inappropriate to act as though there is an objective reality (Creswell & Plano Clark, 2011). The social and interpersonal processes which shape participants' views are particularly important in qualitative methodologies, although interpersonal processes can also be studied from a quantitative perspective. In quantitative methods, the researcher is considered to be an impartial observer whereas in qualitative methods the researcher's role in interpreting data and influence on the research process is recognised (Creswell & Plano Clark, 2011).

Another distinction between quantitative and qualitative methods is that qualitative tends to build theories from the data or ‘ground up,’ known as inductive reasoning whereas quantitative methods generally take a ‘top down,’ or deductive approach (Creswell & Plano Clark, 2011). In deductive approaches, a hypothesis is derived from an existing theory and is then tested through observation in order to form a specific conclusion about whether the observations support or disprove the hypothesis (and ultimately the theory). However, between these somewhat divergent sets of philosophical assumptions lie approaches which address how quantitative and qualitative methods can be combined. One such approach is pragmatism which recognizes the usefulness of both deductive and inductive reasoning to address problems occurring within the research design (Creswell & Plano Clark, 2011).

In this thesis, the researcher adopted a pragmatic view of mixed methods research by focusing on the research question in each study and applying methods that suited the question. In line with a pragmatic view, she approached the research with an ontological position, or how we consider knowledge or truth, of critical realism. In critical realism, researchers can assess and observe reality but only through, and acknowledging, their perspectives and social context (Braun & Clarke, 2013; Creswell & Plano Clark, 2011). Contextualism was the epistemological (what is considered knowledge) view which guided analyses. In contextualism participants’ representations of themselves or experiences, whether in interviews or through questionnaire responses, are considered to represent a truth which is interpreted through the contextual lens of the researcher (Braun & Clarke, 2006, 2013).

2.3 Mixed methods in this programme of research

Within this programme of research, some research questions were better answered using solely qualitative or quantitative methods. For example, qualitative methods (semi-structured interviews) were used in Chapter 4: Study 2 to explore participants' experiences in early dialysis and their relationship with their partner. Qualitative methods were able to provide a much more detailed, nuanced and meaningful insight into the impact of dialysis than if participants had completed a marital satisfaction questionnaire, for example. However, a combination of qualitative and quantitative methods provided the best solution for some research questions, as demonstrated in Chapter 5: Study 3 (a multi-phase study to develop a measure to assess psychological and interpersonal factors in couples). In this study, qualitative methods were used to decide which issues were of importance to patients and their partners. Then after generating the items, potential responses were quantified on scales and initially tested using cognitive interviews. In the third phase, quantitative methods were then needed to examine the preliminary psychometric properties of those items. The methods which contributed to each study are presented in Figure 2.1.

The programme of research began with a literature review which was conducted to inform the design of a subsequent qualitative study. The literature review used qualitative analysis techniques (narrative review and synthesis) to describe QOL in ERF patients and their partners. Then qualitative methods (semi-structured interviews) were used to explore of the effects of early dialysis

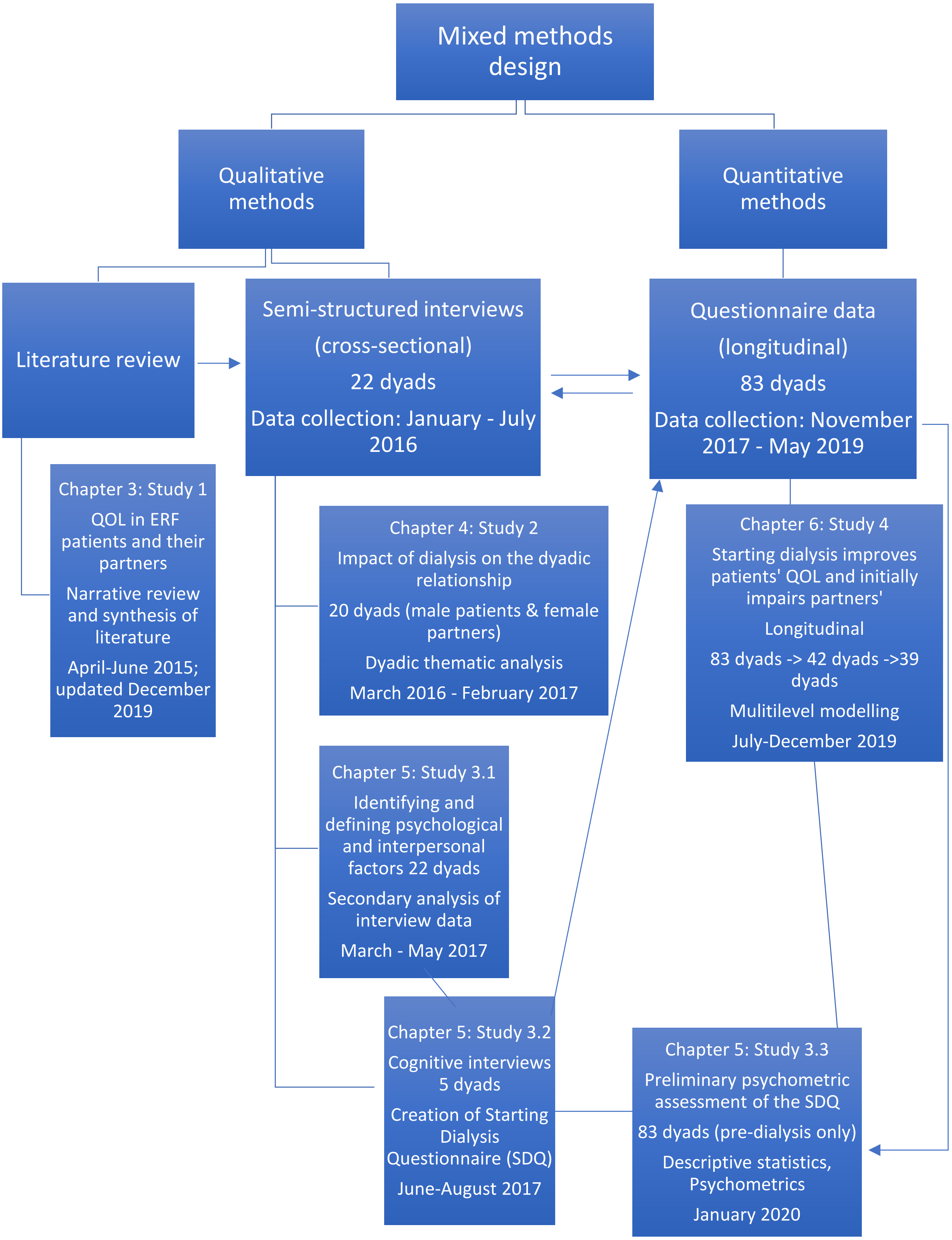


Figure 2.1. *Diagram of the exploratory sequential mixed methods design in this thesis*

on ERF patients and their partners. The primary analysis of this data were conducted using dyadic thematic analysis. The findings from this analysis form Chapter 4: Study 2: The impact of dialysis on the dyadic relationship with male patients and their female partners.

After the preliminary analysis of this data, a secondary analysis of the semi-structured interviews was carried out using theoretical thematic analysis with the aim of identifying and defining the psychological and interpersonal factors in patients and their partners that relate to QOL. This analysis yielded three themes, namely dialysis expectations, accepting dialysis and dyadic relationship characteristics (presented in Chapter 5: Study 3.1). Questions related to these themes were designed on the basis of the insights gained from the semi-structured interviews and compiled into a draft version of the Starting Dialysis Questionnaire (SDQ). In order to assess the comprehensibility and acceptability of the measure, cognitive interviews were conducted with a sub-set of dyads who had participated in the semi-structured interviews. The questions were refined on the basis of their feedback and formed the SDQ, an instrument which would provide quantitative measures of the constructs of interest (Chapter 5: Study 3.2). The findings from the three qualitative strands informed the design of the quantitative strand.

Following this, a quantitative, multi-centre, longitudinal study was conducted with ERF patients preparing to start dialysis and their partners. Measures on QOL and factors related to QOL were completed by each member of the dyad at pre-dialysis, 6 weeks and 12 weeks after starting dialysis. Multilevel modelling was used to analyse the changes in QOL within and between patients and their partners, which forms Chapter 6: Study 4. Descriptive statistics and preliminary psychometric analysis of the SDQ are described and presented in Chapter 5: Study 3.3.

The interpretations gleaned from the qualitative studies guided the design of subsequent studies (i.e., the literature review informed the semi-structured interview study, the dyadic thematic analysis indicated a secondary analysis may highlight factors related to QOL in this population which could be measured in the quantitative strand). The preliminary psychometric assessment of the SDQ provides an indication of the reliability and validity of the overall interpretation, which was drawn from all strands of the programme of research.

2.4 Patient and public involvement in research

The importance of involving in research both people who are actively using health services and the wider public has become increasingly recognised in recent years, as the process ensures that all those who have an interest in the research ("stakeholders") can also have some influence on the research agenda and the conduct of research. The term which is commonly used to refer to the inclusion of patients and public as stakeholders or partners in research is "patient and public involvement" (PPI) (INVOLVE, 2012). Patient and public involvement gives those who require health services a voice in the topics researched, thus better ensuring that the research is relevant to the target population (INVOLVE, 2012).

Three main approaches to PPI are 1) consultation - where PPI partners give their views on aspects of the research, 2) collaboration - meaning partners work with the research team to design, conduct or disseminate the research and 3) user-controlled - meaning partners actively steer and manage the research (INVOLVE, 2012). In collaborative and user-controlled approaches, PPI partners are active in the research; this partnership can foster new ideas and ensure the research is focused on topics important to all stakeholders. However, these approaches often require additional resources such as training, funding and time commitments from PPI partners and researchers. Due to a lack of additional resources in the current programme of research, a consultation approach was utilised.

Two patient and public renal groups associated with Manchester Royal Infirmary (MRI, the MRI Patient & Public Renal Research Advisory Group and the MRI Kidney Patient Association) were consulted and provided feedback throughout the programme of research. Both groups consisted of 5-10 patients with ERF with an interest in research and promoting the welfare of renal patients. They held regular meetings and invited the researcher to attend these.

Consultations were held with the PPI groups in the design phase of the qualitative and quantitative strands of the research to ensure their feedback informed the studies as early as possible. In the consultations about the qualitative strand, PPI partners provided valuable insight as to the time frame of the research (i.e., they encouraged the researcher to include people recently diagnosed with ERF as the impact on their lives may start earlier than the literature suggests). This feedback instigated a change in the researcher’s overall mixed methods design (originally conceived as an embedded design and became an exploratory sequential design) which would better permit the exploration of experiences of patients and partners in the pre-dialysis stage. During consultations for the quantitative strand, the PPI groups reviewed the measures and recommended changes (e.g., phrasing, adding a question, selecting a logo), which were acted upon.

In consultation approaches PPI partners may have a limited view of the topic or may have negative experiences of their input not being incorporated (INVOLVE, 2012). To mitigate these potentially negative effects, the researcher consulted two groups. Within the groups, the partners in attendance changed between consultations so a variety of views were attained (the MRI Renal Research Advisory Group also included health care professionals and external renal researchers). Furthermore, the researcher maintained contact with the groups by informing them of the outcomes of the studies and how their feedback had been integrated.

2.5 Conducting research with dyads

In this programme of research, the primary objective was to better understand the experiences of patients with ERF and their partners. This couple forms a unique social unit, or dyad. Dyadic research recognises that both members of the unit influence each other, the illness (e.g., ERF) and the treatment (e.g., dialysis) (Revenson et al., 2016b). Considering the impact on the unit rather than just the individuals in the dyad (i.e., ‘patients’ or ‘partners’) may illuminate processes, interactions or effects occurring within the dyad or to the dyadic relationship which have not been acknowledged in individual-focused research (Revenson et al., 2016).

While dyadic research may offer depth to our understanding of the effects on couples, it also introduces challenges. These challenges are most evident in three key areas: recruitment, confidentiality and bias. Firstly, recruiting only dyads may significantly reduce the number of potentially eligible participants, which may affect the researcher's ability to recruit adequate sample sizes. Consideration must also be given to whether or not the research question can be answered by recruiting people who simply happen to be in a dyad or alternatively recruiting both members of the dyad. When both members of the dyad are to be recruited, researchers must provide opportunities for each individual member to voluntarily consent or decline (Ummel & Achille, 2016). The three empirical studies (Chapter 4: Study 2, Chapter 5: Study 3, Chapter 6: Study 4) in this programme of research included dyads in which both members of the dyad participated. During recruitment for these studies, the researcher provided letters of invitation and participant information sheets (PIS) which outlined the aims of the studies and invited each member of the dyad to take part (this included individual PIS in Study 2 and individual consent forms in each study). In the Study 2, seven patients were not interested in participating which meant their partners were then ineligible; however, no patients gave their partner's disinterest in the study as a reason for declining to participate. In Study 3 (development of the SDQ), one couple did not take part because the partner had caring responsibilities which demanded her time; therefore, her husband did not take part in the cognitive interviews. In Study 4 (longitudinal), three partners declined to participate at the screening stage, and two partners and one patient did not return their questionnaires (and the other member of the dyad did) after recruitment. However, these figures only reflect non-recruitment and attrition where it was clear that one member of the dyad's participation affected the others. All participants were reminded that they may withdraw at any time and did not have to give a reason.

The next challenge is confidentiality, which includes considerations about how to conduct the research and how to disseminate it. In qualitative research, researchers must consider whether the research question requires the interviews to be conducted jointly or separately. In Study 2, the researcher endeavoured to interview each participant separately because she was particularly interested in the overlaps and divergences in their experiences (Eisikovits & Koren, 2010). In separate interviews, researchers must not let the information gathered in the first interview bias the second and must not reveal to the other member of the dyad anything said by the other (Ummel & Achille, 2016). Although separate interviews may allow the participant to speak more openly about their experience, it may make disseminating the findings more difficult as the members of the dyad may recognise a quotation from the other (Ummel & Achille, 2016). To protect the internal confidentiality of the dyads (that they would not be able to identify their partner from a quotation), the consent form asked for permission to change minor details about the participant or their experiences to protect their confidentiality. In Study 4, participants were asked not to confer about the questionnaires, and each were given sealable envelopes alongside their questionnaires, where applicable.

Lastly, bias is an issue in dyadic research. As mentioned above, the researcher must constantly reflect on her role in the research process to avoid inadvertently biasing the interviews or analysis (Ummel & Achille, 2016). Another potential source of bias in dyadic research is that those who take part are more likely to have higher relationship satisfaction and less negative affect (Hagedoorn et al., 2015). To minimise this bias, the researcher did not exclude participants from the studies if they had mental health issues and attempted to recruit dyads with various relationship experiences. Despite the challenges of dyadic research, they may be overcome with careful and conscientious planning.

2.6 Study 1: Literature review of quality of life in ERF patients and their partners

The aim of this study was to answer the research questions:

- What do we know from the existing quantitative research about QOL in ERF patients and their partners?
- What do we know from the existing qualitative studies about the experiences of ERF patients and their partners and how their experiences may relate to QOL?
- Are there differences in QOL between ERF patients and their partners?

2.6.1 Background

A systematic review was conducted from November 2014 -February 2015, addressing the original research aim of this thesis (which was to describe and understand the effects of home haemodialysis on QOL in patient-partner dyads). Only four studies were found which met the inclusion criteria (which were that studies measure or explore QOL or related constructs in adult HHD patients and their partners, conducted after 1988 and written in English). The findings of the systematic review indicated that the intended scope of the programme of research (patients starting home haemodialysis and their partners) was too narrow. Therefore, the researcher consulted clinicians and colleagues in the National Institute for Health Research (NIHR) Clinical Research Network to discuss the feasibility of the programme of research, and whether the remit should be broadened to different types of dialysis. A literature review was then conducted as a scoping exercise to summarise the existing ERF research in patients and their partners in order to gain a better understanding of the broader ERF literature.

2.6.2 Rationale for a narrative literature review

Quality of life in ERF patients and their partners is an emerging area of research. Few qualitative studies exist which explore QOL, and existing quantitative studies tend to measure health status and functioning rather than general QOL (Boateng & East, 2011; Gilbertson et al., 2019). Due to the lack of research in HHD patients and their partners identified in the previously mentioned systematic review, the term partner is defined in the literature review as a person who provides informal care in the form of physical, treatment-related or emotional support to an ERF patient. By using a broad definition of a partner and not limiting the review to dyads, a wider range of studies may be included that could inform the research question.

Therefore, the purposes of the narrative literature review were 1) to assess the existing quantitative research describing QOL in ERF patients and their partners, 2) to use the qualitative studies to understand the experiences of ERF patients and their partners and how their experiences may relate to QOL, and 3) to inform the design and objectives of a subsequent qualitative study designed specifically to examine the experience of ERF patients and their partners. The narrative literature review followed guidelines which facilitate replicability and increase transparency by defining the research objectives, search and inclusion strategies (Waterfield, 2018).

The inclusion criteria were that 1) quantitative studies must measure QOL, using a recognised measure of QOL (as opposed to health status or functioning) in adult ERF patients and their partners, 2) qualitative studies which explore the experiences of adult ERF patients and their partners and 3) written in English. A total of 14 studies were identified which met the inclusion criteria (8 qualitative, 4 quantitative and 2 mixed methods).

2.6.3 Rationale for narrative review of quantitative results

In a narrative literature review, the aim is to summarise or tell the story of the results within individual studies. The outcome of the search and review of the quantitative studies yielded five studies (4 quantitative and 1 of the mixed methods studies; the other mixed methods study was not included as it did not contain a measure of QOL but is included in the narrative synthesis of the qualitative findings). Due to the heterogeneity between them, a narrative review which described the findings of each study and compared their findings, where appropriate, was conducted.

2.6.4 Rationale for using narrative synthesis of qualitative findings

Integrating, or synthesising, research provides a way of summarising existing research and may also identify gaps in the literature (Pope & Mays, 2006b). While summarising and integrating comparable results is widely accepted in quantitative research, there is some debate about whether or not the findings of qualitative studies should or can be combined (Pope & Mays, 2006b). This argument stems from the fact that qualitative studies often focus on a specific group with a specific issue in a specific setting, therefore hindering generalizations. Furthermore, the philosophical assumptions underlying individual studies may be at odds with the aims of synthesis. In line with the pragmatic and contextualist position of this thesis, the findings from the studies included in the review do reflect a version of truth and knowledge which may be examined to answer questions that would inform research and may provide insight into the experiences of a population of people, in this case ERF patients and their partners.

The aim of narrative synthesis is “to generate new insights or knowledge by systematically and transparently bringing together existing research findings” (p. 145, Pope & Mays, 2006b). Narrative synthesis matched the aims of this review, which was to distil the impact of ERF on QOL in patients and their partners from a rich body of qualitative literature. Therefore, a pre-defined conceptual construct of QOL was utilised to guide the analysis. The WHOQOL (Harper, Power, & Grp, 1998) six domain structure of QOL (see Table 2.1) was selected as it is multi-dimensional and covers areas that have been described as affected over the ERF illness trajectory (e.g., health & functioning, psychological/spiritual, social & economic, family)(Jablonski, 2004).

During the analysis, the findings of each qualitative study were mapped onto the WHOQOL domains and facets. This was achieved by creating a table in a word processing document with the domains and facets as rows and a column for each qualitative study. As an extract from a study was mapped onto the table, it was labelled ‘patient,’ ‘partner’ or ‘both’ to indicate the source. These steps allowed the findings to be compared between studies and participant characteristic (e.g., patient or partner).

Table 2.1

World Health Organization Quality of Life (WHOQOL) domains and facets

General QOL	Overall QOL Health
Physical domain	Pain and discomfort Energy and fatigue Sleep and rest
Psychological domain	Positive feelings Thinking, learning, memory and concentration Self-esteem Body image and appearance Negative Feelings
Level of independence domain	Mobility Activities of daily living Dependence on medication and treatment Working capacity
Social relationships domain	Personal relationships Practical social support Sex life
Environment domain	Physical safety and security Home environment Financial resources Health and social care availability and quality Opportunities for acquiring new information and skills Participation in and opportunities for recreation/leisure Physical environment Transport
Spirituality/Religion/ Personal Beliefs domain	Spirituality Religion Personal Beliefs

Adapted from “The World Health Organization Quality of Life Assessment (WHOQOL): Development and general psychometric properties” by The WHOQOL Group, 1998, *Social Science & Medicine (46)*12, p.1569-1585. Copyright Elsevier Science Ltd.

2.6.5 Reflexivity

Reflexivity is a vital part of qualitative research (Braun & Clarke, 2013), and as the philosophical assumptions of this chapter have discussed, the researcher plays an integral role in deciding what is knowledge and how it is interpreted. Braun and Clarke (2013) distinguish between two types of reflexivity, functional and personal. Functional refers to how the research was designed and conducted, whereas personal refers to the researcher's preconceptions, thoughts or context which may have influenced the research (Braun & Clarke, 2013). As these highlight important considerations when conducting qualitative research, both will be addressed and discussed in turn in terms of their influence on the narrative literature review and in the following studies.

In regard to functional reflexivity, choosing a pre-defined QOL structure to synthesise the data may have hindered the researcher from identifying other topics which are also related to QOL but not included within the WHOQOL domains or facets. To minimise this, the researcher mapped as much of the qualitative findings onto the WHOQOL table as possible. In instances where they did not clearly tie in, they were mapped to the domain that best matched the concept. An example of this is that patients and their partners frequently discussed death and the terminal nature of ERF. The WHOQOL does not include a facet or domain on death, and therefore the researcher mapped data related to this topic to the health facet. Although attempts were made to minimise the bias of using a predefined structure, there is a possibility that some findings related to QOL were not fully captured by the researcher in the analysis.

In personal terms, the researcher, solely, conducted the analysis. In most circumstances the researcher would feedback to the research team or send them drafts of the emerging analysis. However, in this case, the researcher worked independently due to time restraints. However, the narrative synthesis was reviewed by the research team on its completion and by two lecturers in health psychology (outside of the research team), and then further refined and reviewed again in December 2019. These additional checks suggest that the findings of the narrative review and synthesis are trustworthy.

2.7 Study 2: Qualitative study on the impact of dialysis on the dyadic relationship between male patients and their female partners

This study addressed the following research question:

- What is the impact of early dialysis on the dyadic relationship between patients and their partners?

2.7.1 Design

Qualitative methods, with a cross-sectional design, were selected to address the research question. The findings of the semi-structured interviews, conducted with spousal type dyads, were analysed using an inductive dyadic thematic analysis (DTA). The rationale for each of these elements of the study's design are discussed in turn.

2.7.2 Rationale for qualitative methods

The findings of the narrative literature review indicated that the preliminary stages of going onto dialysis ("early" dialysis), and in particular the impact of the changes occurring during early dialysis on the dyadic relationship, were not well-researched or well-understood in the ERF patient-partner dyadic literature. The use of qualitative methodologies may assist the researcher in identifying important issues and questions to be addressed in this field (Creswell & Plano Clark, 2011). Therefore, we chose qualitative methodologies to explore this topic.

2.7.3 Recruitment of patient-partner dyads to the study

The reason for including dyads, rather than two samples of patients and partners who were not in couples, was to explore not only the impact of ERF and dialysis on each member of the dyad individually but also the effects on the dynamics of their relationship. The literature review indicated that studies tend to recruit dyads with various relationship types (i.e., parent-child, spousal, sibling-sibling). In this programme of research, the dynamic between couples was a particular interest, and therefore spousal-type dyads were the focus of this study. The findings from the literature also showed that only 3 studies (two qualitative and 1 mixed methods studies) had used qualitative methods to explore the effects of ERF and dialysis in patient-partner dyads. Of these, none had included dyads from the early phases of dialysis or across all modes of dialysis (haemodialysis or peritoneal dialysis). Therefore, we aimed to recruit spousal-type dyads from the early phases of dialysis (pre-dialysis, starting dialysis and establishing dialysis) in which patients were on, or preparing, for conventional haemodialysis (HD), home HD or peritoneal dialysis (PD). The following sampling grid was used to ensure we recruited dyads from across the phases and modes of dialysis in order to fully address the research question (Table 2.2).

Table 2.2

Sampling framework guiding recruitment

	Phase of dialysis		
Mode of dialysis	Pre-dialysis	Starting dialysis	Establishing dialysis
Conventional haemodialysis	2 dyads	2 dyads	2 dyads
Home haemodialysis	2 dyads	2 dyads	2 dyads
Peritoneal dialysis	2 dyads	2 dyads	2 dyads

This study received ethical approval from a National Health Service (NHS) Research Ethics Committee (REC; Ref no. 15/LO/2016; Appendix C). The patient-partner dyads in this study were recruited from a single renal unit in North West England. Members of patients' renal care team identified patients who met the inclusion criteria. The inclusion criteria were that patients and partners were over 17 years old, spoke English fluently and were in a spousal-type relationship. Patients were either preparing for, or had recently started, their first form of outpatient dialysis to treat ERF (i.e., incident patients). They comprised three groups: (a) *pre-dialysis*, patients in the hospital's low clearance clinic with an estimated glomerular filtration rate (eGFR, a clinical marker denoting how well the kidneys are removing toxins in the blood) of ≤20, but without a start date for dialysis; (b) *starting dialysis*, patients on a form of outpatient dialysis <6 months; (c) *establishing dialysis*, patients on outpatient dialysis >6 months, but less than 16 months.

The researcher conducted the recruitment of this study. Patients who gave their consent to be contacted were given a letter of invitation (Appendix D) to the study and a participant information sheet (patient version, Appendix E; partner version Appendix F).

A total of 44 patients met the inclusion criteria. Of these, 22 patients (20 male & 2 female) and their partners (20 female & 2 males) were recruited and participated in the semi-structured interviews. The reasons for non-recruitment were lack of response to the letter of invitation (n=10), not interested in taking part (n=7), responded after data collection was completed (n=2), too busy (n=2), and other reasons (n=1).

All dyads were opposite-sex couples, with the final sample including 20 female and two male partners. Twenty out of 22 dyads were married or living as married; among the remaining two dyads, one was engaged and the other separated but identified themselves as a ‘couple.’ Of the total sample, 37 participants classified themselves as White British with seven from other ethnic groups (European, Asian and Afro-Caribbean). The average age of patients was 63 years (range 39-80); and partners 62 years (range 39-87). Of the total sample, 20 were retired, 14 were unable to work due to limitations placed on them by ESRD, dialysis or other health reasons, and 10 were in paid employment. Dyads were classified into three phases of early dialysis (8 pre-dialysis, 7 starting, and 7 establishing) and either planning for, or utilising, a form of out-patient dialysis (16 HD, 6 PD). All participants gave their consent in writing before taking part in the study.

The findings presented in this study (Chapter 4: Study 2) report the impact of dialysis on only 20 of the dyads (the 20 male patients and their female partners). The first write up of this study included the full sample (22 patients and their 22 partners). However, in order to facilitate comparisons between the dyads, and on the advice of the reviewers who read the paper prior to its publication in *Qualitative Health Research*, the two dyads with female patients and male partners were not included in the final analysis.

2.7.4 Rationale for cross-sectional semi-structured interviews

In this strand of the programme of research a cross-sectional design was used to explore the experiences of dyads who were at different points on the ERF illness trajectory. While a longitudinal design would have allowed the exploration of the effects of dialysis on the dyads as they progressed on the trajectory, it was not chosen for two main reasons, namely recruitment and issues related to longitudinal designs. Firstly, the number of patients starting dialysis each month (on average 3-4) at the main renal unit was not sufficient to allow the recruitment of an adequate sample size and conduct follow-ups in the time available. When recruitment factors (e.g., people not interested in taking part in research, attrition) and inclusion criteria (e.g., incident patients, spousal-relationship) were assessed in relation to the population size, it was estimated that it would take over a year to recruit 20 dyads. Secondly, the researcher considered other elements of a longitudinal design, such as logistical (e.g., time required to analyse the data) and relational issues (e.g., the researcher builds a relationship with the participants which may bias the findings) (Calman, Brunton, & Molassiotis, 2013). Taking these factors into account, a cross-sectional design was deemed most suitable.

Within qualitative methodology there are numerous ways to elicit the thoughts and experiences related to the research topic, such as interviews, focus groups or analysing documents or media (Pope & Mays, 2006a). Focus groups rely on interactions between the members of the group and provide insight into how people communicate or relate to issues (Kitzinger, 2006). While focus groups could yield interesting insight into the dyadic relationship in patients and their partners, people may view their relationship as a sensitive topic and be reluctant to discuss it in a group setting. Therefore, interviews were selected as our method of data collection. Semi-structured interviews, preferably conducted separately with individual members of each dyad, allowed the participants to discuss their relationship in their own way but also ensured that topics important to the research were addressed (Britten, 2006). A topic guide was created by the researcher, and agreed upon alongside the research team, to address the gaps identified in the literature (see Table 2.3).

2.7.5 Rationale for dyadic thematic analysis

The results of the narrative literature review highlighted that although ERF patient-partner dyads are increasingly being included in research the analytical techniques employed do not lend themselves to a dyadic perspective. That is the analysis tends to be conducted at the group level (i.e., patient or partner) with comparisons made within or between the groups, rather than between members of the dyad. A dyadic perspective, or analysis, seeks to explore or examine the effects one member of the dyad has on the other, and how these effects may affect broader constructs, such as health, depression or QOL (Revenson et al., 2016). A dyadic analysis may identify patterns or relationship dynamics that cannot be observed in individuals and, thus, may bring a new perspective to the current knowledge (Revenson et al., 2016).

Table 2.3

Topic guide used in semi-structured interviews

Topic	Questions	Probes
Quality of life (QOL)	○ What effect has kidney disease/dialysis had on your QOL? ○ In what ways has your QOL changed since you/your partner was diagnosed with kidney disease/began dialysis?	○ Expand on areas of QOL that may have been impacted: sleep, relationships, mobility ○ Consider how their QOL is different from earlier stage in dialysis care
Factors related to QOL	○ What has helped you maintain your QOL during this period? ○ What has had a negative effect on your QOL during this period? ○ Which of these factors has changed as you have progressed with pre-dialysis care/dialysis? ○ What is most important in helping you maintain your QOL?	○ Expand on factors that have helped them maintained their QOL: help from nursing staff, getting financial aid, having confidence ○ Expand one factors that may have had a negative impact: not enough information or training, feeling lonely, changes in the care plans
Impact of dialysis on the dyadic relationship	○ In what ways might kidney disease/dialysis affected your partner's QOL? ○ Could you tell me about any effects it's had on your relationship with your partner?	○ Are there any ways your partner's daily life has changed since you began pre-dialysis care/starting dialysis? ○ Are there any ways kidney disease/dialysis has brought you closer? ○ Are there any ways it has added strain?

The dyadic analytical technique used in this study followed the guidelines for dyadic thematic analysis (DTA) set out by (Eisikovits & Koren, 2010). The procedures involved in the analysis are described in full in Chapter 4.

2.7.6 Reflexivity

Both functional and personal reflexivity are discussed in Chapter 4 within the Methods section (Trustworthiness of the data and Reflexivity).

2.8 Study 3: Development of a measure for patients preparing to start dialysis and their partners: the Starting Dialysis Questionnaire (SDQ)

This study had multiple steps and drew on data obtained in Study 2 and Study 4. In this study we aimed to address the following research questions:

- *Drawing on their experience, what psychological and interpersonal factors do patients and partners relate to QOL during the early phases of dialysis?*
- *Can we develop a measure to assess these factors (the SDQ)?*
    - *If so, does the SDQ have good acceptability and psychometric properties?*

2.8.1 Design

This study has multiple phases and started with a second analysis of data collected in Study 2 (discussed in sections related to Study 3.1 later in this chapter and also in Chapter 5). The cognitive interviewing part of the study (Study 3.2) was conducted with a subset of the participants from Study 2. The recruitment of this subset of participants is described below. The last part of this study (Study 3.3) utilised cross-sectional data obtained from the pre-dialysis time point in the quantitative longitudinal study (Chapter 6, Study 4) in order to evaluate the preliminary psychometric properties of the SDQ.

2.8.2 Contributing data and participants

Study 3.1 – The data from all 22 dyads recruited in the qualitative study (semi-structured interviews) were used to address and answer the research question as fully as possible. A secondary analysis was conducted and included the experiences of both male and female patients, and their male and female partners.

Study 3.2 – The participants in the cognitive interviews (Study 3.2) took part in the over-arching qualitative study (22 patient-partner dyads who took part in semi-structured interviews). All 22 dyads, who consented to being contacted for follow-up studies, were mailed a letter of invitation to participate in this phase of the study. Five of the eight dyads who responded participated in the cognitive interviews.

Study 3.3 – The questionnaire data used to evaluate the psychometric properties of the SDQ were collected from participants at the pre-dialysis timepoint (baseline) in Study 4 (Chapter 6). These participants were different from the participants in Study 2. Study 4 was a longitudinal quantitative study conducted in 10 renal units across England and with different inclusion criteria than in Study 2.

2.8.3 Rationale for questionnaire development

The findings from the DTA suggested that patients and their partners are significantly affected by the early phases of dialysis, both their dyadic relationship and QOL. Furthermore, the findings indicated that psychological and interpersonal factors, such as acceptance, positivity and how the dyad worked together, were related to QOL. Therefore, these findings suggest that psychological and interpersonal constructs should be assessed as predictors of changes in QOL in the quantitative strand of the research (Chapter 6).

A review of the literature to identify existing questionnaires which measured the constructs which had been identified as important in the qualitative data was conducted in February-March 2017. The researcher identified 16 questionnaires related to the relevant constructs (7 dyadic coping, adjustment or satisfaction questionnaires; 6 illness cognition questionnaires, 1 couples communication questionnaire; 1 optimism questionnaire and 1 questionnaire on expectations for QOL and health after renal transplants). The researcher examined the questionnaires to determine their utility for the research questions of the current body of work (Streiner & Norman, 2008) and presented her review to the research team. In deciding whether a questionnaire could be used in the quantitative study the questionnaire had to fulfil the following criteria: 1) address psychological or interpersonal relationship dynamics, 2) be amenable to changes in wording (e.g., if a general questionnaire about illness, it needed to be possible to change “illness” to “kidney disease” or “treatment” to “dialysis”), 3) be applicable to patients and their partners, 4) not replicate items on the WHOQOL-BREF (the primary outcome measure in the quantitative study) and 5) be concise to reduce question burden during a stressful point in ERF treatment.

An example of a questionnaire that was reviewed is the illness acceptance sub-scale of the Illness Cognition Questionnaire (Evers et al., 2001), which assesses a person’s own acceptance of their illness in general. Although concise (6 items) the items’ phrasing made it difficult to adapt to dialysis and to patients’ partners. After debate and consideration, it was deemed that only the questionnaire on communication was suitable for inclusion. Therefore, the development of a measure that addressed pertinent topics related to QOL in patient-partner dyads commenced at the conclusion of the DTA in Study 2.

In exploratory sequential mixed method designs, it is not uncommon that the findings of the qualitative strand lead to the creation of a study specific instrument, or measure (Creswell & Plano Clark, 2011). Although measure development was not part of the original design, it provided an opportunity to strengthen the quantitative strand with knowledge gained in the qualitative. Furthermore, this programme of research was funded by the Medical Research Council UK, the researcher had access to training from an expert in questionnaire development, and adequate time remained in the programme of research to undertake this strand of the research, all of which are factors to be considered when designing and implementing research.

2.8.4 Rationale for theoretical thematic analysis

The first step in measure development is to determine what constructs need to be studied. This step can be achieved in a variety of ways such as focus group, expert opinion or research (Streiner & Norman, 2008). Data gained through research (data generated in the semi-structured interviews in Study 2) was analysed using a theoretical thematic analysis. Theoretical thematic analysis means that the analysis is guided by the theoretical ideas or the researcher's pre-existing knowledge (Braun & Clarke, 2013). The researcher's previous analysis of the Study 2 data provided evidence that psychological and interpersonal factors related to QOL, and these guided the secondary analysis which focused on elucidating precisely which factors were important (Braun & Clarke, 2013). The full description of how this analysis was conducted is included in Chapter 5: Study 3.1 (Analysis).

2.8.5 Rationale for cognitive interviews

Before a newly developed measure is used in research, the items should be tested for inclusion with the target population to assess whether they are able to understand and answer the questions, or items (Streiner & Norman, 2008). One method of testing both these areas is cognitive interviewing (Streiner & Norman, 2008; Willis, 2005). Willis (2005) recommends testing the items in a sample of participants with an interest in the specific area. To this end, the participants, who gave their consent to be contacted in follow-up studies, from Study 2 were mailed letters of invitation to participate in the cognitive interviews (Appendix J). Eight dyads responded and five dyads took part in the cognitive interviews (see Chapter 5, Study 3.3). Their participation in two phases of the SDQ's development provided them an opportunity to validate the conclusions drawn from the analyses but may have reinforced constructs or themes which were unique to this study. To mitigate this bias, the SDQ was also presented to a patient and public renal research group who reviewed the items and provided feedback. A full review of the methods and refinements to the SDQ as a result of the cognitive interviews and group feedback are provided in Chapter 5: Study 3.2.

2.8.6 Rationale for preliminary psychometric analysis

The second phase in item selection uses statistical analyses to evaluate the properties and performance of the individual items, collectively known as psychometrics (Streiner & Norman, 2008). This phase of testing should be conducted with participants who did not take part in earlier phases of instrument development so that the constructs may be tested for generalizability (Creswell & Plano Clark, 2011). Therefore, the psychometrics were conducted using data from Study 4, which recruited an entirely new sample of patients and their partners at around the time the patient was starting dialysis (Chapter 6). Patients' and their partners' scores on the SDQ, WHOQOL general QOL and demographics at pre-dialysis were evaluated to determine preliminary psychometrics properties

The first steps in evaluating a measure are to assess the distribution of the scores and to test reliability and homogeneity (Streiner & Norman, 2008). Histograms as well as skew and kurtosis values were assessed, and no significant effects were found (the values are presented in full in Appendix O). Reliability measures the proportion of variation between individual responses to the total variation in the scores and was assessed using Cronbach's α for internal consistency, scores of 0.70-0.90 interpreted as good internal consistency (Streiner & Norman, 2008). Internal consistency was initially evaluated by domain summary score and then each item's contribution to the domain summary score was assessed. Tests of homogeneity provide an indication of the similarity of responses to the domain total score if that item was not included in the domain (Streiner & Norman, 2008). Pairwise correlations were used to determine inter-item correlations, with a value of >0.2 reflecting homogeneity with the other items in the domain (Streiner & Norman, 2008). To assess construct validity, pairwise correlations were calculated between the domains of the SDQ and between each domain and QOL (as measured by the WHOQOL general QOL facet).

2.8.7 Reflexivity

In the development of the SDQ, the preliminary steps involved qualitative methods (3.1 – construct identification using theoretical thematic analysis and 3.2 – assessing the comprehensibility of the items through cognitive interviews). Therefore, functional and personal reflexivity is presented here for these steps in the development process.

In using theoretical thematic analysis, the researcher may have limited her exploration and identification of the constructs related to QOL. It is possible that constructs other than psychological or interpersonal factors may be have been related to QOL and that the researcher was biased by the findings of the DTA. However, an outcome of the analysis was the identification of 'dialysis expectations' which was not a finding in the DTA. Another consideration is the impact of the researcher on the cognitive interviews. The participants in the cognitive interviews were familiar with the research topic, and a rapport existed between the participants and the researcher. However, this rapport may have biased their participation, as in they may have given responses they thought socially suitable (Streiner & Norman, 2008). The researcher followed a cognitive interview protocol to minimise inadvertent bias during the cognitive interviews.

2.9 Study 4: Starting dialysis improves quality of life for patients but is impaired, initially, for their partners: a multi-centre, longitudinal study

In this final study of the thesis we aimed to address the following research questions:

- Does QOL change in patients and their partners as they transition from pre-dialysis to 12 weeks after starting dialysis?

- Are there differences between patients' and partners' QOL over this transition period?

2.9.1 Rationale for quantitative study

The quantitative strand of this mixed methods design served two purposes. Firstly, the study was designed to provide a description of the impact of starting dialysis on QOL in patients and their partners, an under-researched area of some importance to both patients, partners and clinicians. Secondly, the results provided an opportunity to conduct preliminary psychometric evaluation of the SDQ, which would give an indication of the reliability of the interpretation made across the research.

2.9.2 Recruitment of patient-partner dyads to the longitudinal, quantitative study

Research sites

The study received ethical approval from the Health Research Authority (Appendix Q) and an NHS REC (Ref no. 17/NW/0501; Appendix R). The study was adopted onto the NIHR Clinical Research Network portfolio (CPMS ID 35781; Appendix P), and 10 renal units across England carried out the study. In each participating renal unit, a site investigator (SI), who was usually a renal research nurse, primarily conducted the study, although instances the local chief investigator also played an active role in the study.

Before the study commenced recruitment, the researcher conducted a site initiation visit which included detailed introduction to the study. The researcher delivered training to the sites (SI, local chief investigator and additional team members assisting with the study) which addressed all the topics included in a set of standard operating procedures, devised by the researcher (Appendix W). The researcher provided each site with participant information sheets (Appendix T), pre-printed questionnaire packets (patient and partner versions for each time point – pre-dialysis, 6 weeks after starting and 12 weeks after starting; see Appendix U & V for pre-dialysis versions) or postage, if requested.

The SI worked with the renal care teams within their nephrology unit to identify potentially eligible patients. If the SI was not part of the renal care team, then a member of the renal care team approached the patients and obtained their consent to be contacted by the SI in writing. The SIs then screened the patients for inclusion and, if meeting the inclusion criteria, provided them with a letter of invitation (Appendix S) and participant information sheet. All participants consented in writing before participating in the study. In order for the participant's data to be included in the study, both members of the dyad had to return the pre-dialysis questionnaires. In 5 of the 88 dyads recruited, only one member of the dyad returned the questionnaire pack; therefore, their data were not included in analysis.

The SIs provided paper versions of the questionnaire packs to the participants either directly at clinic appointments (or dialysis sessions at follow-ups) or posted them to the participants. The questionnaires were returned to the SI at the next clinic appointment or posted back to the SI in pre-paid envelopes. The SIs then scanned the questionnaires, removing any potentially identifiable data (e.g., date of birth, renal centre name), and sent copies to the researcher.

Participants

The inclusion criteria for the patients in the study were that they 1) were in the care of a nephrologist for ERF, 2) have clinical evidence indicating that they would start dialysis in the next 2 months, 3) were planning to receive a form of out-patient dialysis for the management of ERF (including HD – conventional at the renal dialysis or satellite unit and those training for home HD – and PD), 4) had someone that they considered to be their "partner" (e.g., spouse, civil partner, girlfriend or boyfriend) and 5) were 18 years or older.) Both patients who were starting on their first form of renal replacement therapy (RRT) or who had a failing transplant were planning to start dialysis (but had not been on a form of out-patient dialysis in the last 6 months) were eligible for the study.

The inclusion criteria for partners were that they were the "partner" of an eligible patient and 18 years or older.

Patients were excluded if they had acute kidney injuries requiring dialysis, but which were expected to resolve, and if either the patient or the partner were unable to read or comprehend English.

A total of 83 patients and their partners, in a spousal-type relationship, were recruited to the study from November 2017 – September 2019. Recruitment, attrition and participant characteristics are described in detail in Chapter 6.

2.9.3 Rationale for longitudinal design

A prospective, panel longitudinal design was selected for the quantitative study as it permitted the examination of changes in QOL and exploration of the direction of associations with these changes (Bowling, 2005). The term panel means that the same participants are followed-up across the study duration (Bowling, 2005). In designing longitudinal studies, two issues in particular must be taken into account: the timing of the follow-ups and attrition (or the loss of participants at future between follow-ups) (Bowling, 2005). Follow-ups are recommended to occur at points when participants are expected to experience changes in the assessed variables (Bowling, 2005). Consultant nephrologists provided insight as to when they notice changes in their patients’ health and well-being, which they said could be as early as four weeks in some patients but generally by six weeks. The second follow-up (12 weeks after starting) marks the end of the critical 90 day period in dialysis, which has been associated with an increased risk of death and hospitalization (Robinson et al., 2016). The timings of the follow-ups (6 and 12 weeks after starting dialysis) were discussed with the cognitive interview participants and also the patient-public renal research group. Both groups confirmed the follow-ups to be points when patients and their partners would be likely to experience shifts in their QOL.

Attrition is the second consideration, and important in longitudinal studies as the aim is to assess trends in the variables. If significant attrition occurs, it may limit the analysis and also bias the results (e.g., if the attrition occurs for non-random reasons like death) (Bowling, 2005). Attrition was discussed a potential issue in this study given that the first 90 days of dialysis is period marked with high risks as well as being under-researched longitudinally, so limited evidence exists to inform attrition rates in research during this period. We inflated our target sample size by 20% to account for high rates of attrition that may occur between follow-ups.

2.9.4 Rationale for using survey methods

Surveys, or questionnaires, are widely used to examine social and health experiences and test hypotheses related to these in a sample of the target population (Bowling, 2005). Like any method, there are several design issues to be considered, such as how and where the questionnaires are completed and response bias due to conditioning or conferring (Bowling, 2005). While questionnaires that are administered to the participant (e.g., face-to-face, over the telephone) limit order effects and non-response, they also take more time and training to conduct and may bias participants' responses (e.g., the participants may give responses they think are socially desirable).

In this study, we offered participants the option of self-reporting or having the questionnaire administered. It was also acceptable for the participants to complete the questionnaire in the clinical setting or at home. These decisions were made to facilitate participation in the study (our previous research indicated that pre-dialysis participants are often over-whelmed at clinical appointments and prefer to take documents home for consideration). Although the instructions stated that patients and their partners should not confer as they completed the questionnaires, it is possible that some dyads spoke with each other as they completed the questionnaires. Furthermore, the longitudinal nature of the study means that participants may have remembered their previous responses, or their partners, or become conditioned to the questions and, therefore, may not have marked responses that reflected their thoughts (Bowling, 2005).

In order to minimize these effects, the SIs were provided training by the researcher on how to administer the questionnaires and the importance of the questionnaires being completed independently. Another way of maintaining the engagement of participants in studies is it ensure the study is of interest to them. That this quantitative study was informed by the qualitative strand and the questions in the SDQ were assessed during cognitive interviews provide some assurance that the research was relevant to the participants.

2.9.5 Rationale for the questionnaires

The questionnaires selected for inclusion in this study assessed the following constructs: QOL, dialysis expectations, accepting dialysis, dyadic relationship characteristics, anxiety symptoms, depressive symptoms and symptom burden. Both patients and their partners completed each measure at every time point.

The WHOQOL-BREF was selected to measure QOL. The reasons for selecting the WHOQOL-BREF and its characteristics are described in full in Chapter 6 (Methods section).

Dialysis expectations, accepting dialysis and dyadic relationship characteristics were assessed using the SDQ. Its characteristics are discussed in full in Chapter 5.

Symptoms of anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). It consists of 14 questions and may be divided into two sub-scales, one for symptoms of anxiety and one for symptoms of depression (seven questions each). Sub-scale scores range from 0-21 with higher scores indicating more symptoms related to anxiety or depression. It has been validated in both ill and well populations (Spinhoven et al., 1997) and in dialysis patients (Griva, Kang, et al., 2014).

Symptoms in patients and partners were assessed using the Palliative care Outcome Scale – Symptoms (POS-S) (POS, 2017). Patients completed the POS-S Renal and partners used the POS-S Generic. The POS-S Renal consists of a list of 17 common renal-related symptoms, and the POS-S Generic lists 13 symptoms commonly reported in the general population. Participants indicate how affected they have been by each symptom by selecting a score on a five-point 0-4 scale (0=Not at all, 1=Slightly, 2=Moderately, 3=Severely, 4=Overwhelmingly). An overall symptom severity score is calculated by adding up the scores for each symptom with scores ranging from 0-68 (patients) and 0-52 (partners). The number of symptoms is calculated by counting symptoms with a score of ≥2.

Participants also provided demographic information (age, gender, ethnicity, marital status, highest level of education and employment status) at the first time point, pre-dialysis.

2.9.6 Rationale for using multilevel modelling

In longitudinal analysis, repeated measures within individuals must be accounted for. If ignored and all data are treated as independent, standard errors of parameter estimates will be underestimated resulting in increased type I error rates (false positives). Although many types of analysis, such as repeated measures analysis of variance, are suitable for handling repeated measures, multilevel models (MLM) for examining change have shown better flexibility in accommodating missing data, non-normally distributed data and uneven follow-ups (Curran, Obeidat, & Losardo, 2010). Multilevel models estimate the variation between participants on within-participant changes in a variable. In other words, it provides a statistical representation of changes occurring within individuals in comparison to the differences between others in that group. As the focus of the study was in changes in QOL and describing patterns of change over the transition onto dialysis, MLM fit with the research question. Moreover, as missing follow up data were likely, MLM would allow us to use all available data, rather than only complete cases.

Additionally, in the study there were multiple observations which were nested within an individual, nested within a dyad; this creates a three-level structure and requires a three-level model, which was used to estimate changes in QOL (Steele, 2008). It is not possible to model a three-level data structure in an ANOVA framework but is easily accommodated in MLM. A three-level data structure, such as the one described here, is not uncommon in health research. To test the association of explanatory, or moderator, variables with changes in QOL, two-level models were used. In these models, the patients' and partners' data were analysed separately, which removed the highest level (dyad), thus resulting in a two-level structure.

Multilevel models (MLM) or structural equation models may be used to examine change and yield comparable results (Steele, 2008). We chose to frame the analysis of the changes in QOL using MLM as it accommodates the intra- and inter-correlations of repeated measures within individuals in nested a social group, such as the patient-partner dyad.

In the original analysis plan, secondary and tertiary research questions were set out. The secondary research question was to distinguish between changes in QOL on the basis of baseline scores on dialysis expectation, accepting dialysis, dyadic relationship characteristics, anxiety symptoms, depression symptoms and symptom burden. The tertiary research question was to examine whether dyadic effects existed within the couples and overtime in relation to QOL, psychological and relationship factors. However, with the final sample size at 12 weeks (39 dyads), the analysis would not have been able to detect, with any degree of certainty, the small interaction effects that would have been of interest.

Chapter 3: Quality of life in patients with established renal failure and their partners: A literature review

Preface

This paper has been formatted in accordance with the manuscript guidelines of the journal where it will be submitted for consideration, *Health Psychology Review.* The authors are Currie Moore, Suzanne Skevington, Sandip Mitra and Alison Wearden. The PhD candidate designed the literature review, conducted the search and selection process, extracted the data, analysed the data and wrote the first version of the manuscript, under the supervision of Prof. Alison Wearden, Prof. Suzanne Skevington and Dr. Sandip Mitra. All authors reviewed the first version of the manuscript, provided feedback and contributed to and approved the final version of the manuscript.

3.1 Abstract

Although research in established renal failure (ERF) which includes patients and their partners is growing, a review of their quality of life (QOL) or experiences related to QOL has not been conducted. The aim of this literature review was to describe QOL in both patients and their partners and examine how ERF affects each of them. The existing literature (including quantitative, qualitative and mixed methods studies) was searched for inclusion. Of the 69 studies identified, 14 were included in this review. A narrative review summarized the results of the 4 quantitative and 1 of the mixed methods studies. A narrative synthesis, using the WHOQOL structure to frame the qualitative findings, was conducted across the 8 qualitative studies and 2 mixed methods studies. The narrative review indicated that overall patients reported their QOL as poor. However, patients reported their overall and social QOL as good. Partners reported their QOL similarly to patients in terms of overall QOL but better across the WHOQOL-BREF domains. The outcomes of narrative synthesis suggest that all the WHOQOL domains were affected by ERF and dialysis. Psychological QOL was reported the most negatively by both patients and their partners. Furthermore, dialysis mode and phase of dialysis were revealed to be important factors relating to QOL. Limited research exists which examines QOL in ERF patients and their partners, especially during pre-dialysis. ERF significantly affects all areas of QOL, with many patients and their partners reporting and describing impaired QOL on dialysis. Future research should focus on patient-partner dyads and use measures which assess general QOL rather than health functioning.

3.2 Introduction

Established renal failure (ERF) is a chronic and long-term illness that culminates in the irreversible loss of kidney function. Artificial means of replacing kidney function, such as dialysis,[1] sustain ERF patients' lives but are not as efficient as healthy kidneys, and, therefore, there is worsening physical functioning over time (van Loon et al., 2017). Considerable research has been conducted to investigate the effects of ERF, and dialysis, on health status and functioning in ERF patients (Liem et al., 2007). Health status and functioning is often discussed alongside, or even conflated with, quality of life (QOL), although some would argue that these are distinct constructs (Moons et al., 2006). The World Health Organization (WHO) defines QOL as "*an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns*" (p. 43,The WHOQOL Group, 1994).

Using this definition of QOL, Joshi (2014) conducted a review of the ERF literature with the aims of assessing the suitability of current QOL tools and also of identifying factors that affect patients' QOL. The findings from this review suggest that many forms of measurement found in the literature, such as the SF-36 and SF-12 (which forms part of the Kidney Disease QOL scale), do not address key factors that relate to patients' QOL, as defined by the WHO, such as patients' perceptions of their treatment and psychological well-being.

Further to this, little is known about how ERF and dialysis affect QOL in patients' partners, despite dialysis patients highlighting the importance of their partners in their care and well-being (Moore et al., 2018). A systematic review with meta-analysis of informal caregivers, or partners, of haemodialysis (HD) patients found that burden, depression and health status are the most frequently examined constructs with only eight out of 61 studies assessing QOL (Gilbertson et al., 2019). Their findings indicate that partners have poorer health functioning, higher rates of depression and anxiety and more stress when compared to control groups and population norms. Compared to HD patients, partners had better health functioning and fewer depressive symptoms. In a literature review by Low, Smith, Burns, and Jones (2008) on the impact of ERF on partners' family life and psychological health, partners reported fatigue, social isolation, restrictions on their lives and increased responsibilities. Having an increased sense of responsibilities, emotion-focused coping and marital strain were negatively associated with their psychological health.

Although these reviews provide valuable insight into the effects of ERF and dialysis on patients and partners, to our knowledge, a review does not exist which focuses on patients and *their* partners. A partner is defined here as a person who provides informal care in the form of physical, treatment-related, or emotional support to an ERF patient. Patients and their partners are mutually affected by, and influential on, the illness and its treatment (Revenson et al., 2016); however, despite it being a mutual experience, each member of the dyad may be affected differently. Therefore, research which includes the viewpoints of both patients and their partners is integral for gaining broader knowledge of the impact of illness and treatments, such as ERF and dialysis (Revenson et al., 2016b).

Furthermore, a review is lacking which examines the existing patient-partner literature as to the effects of ERF on QOL. The WHO definition and

WHOQOL structure provided Joshi (2014) with an effective way to outline the ERF patient literature and adopting this approach may also add insight to patient-partner research. In another study, Finnegan-John and Thomas (2013) mapped the findings from semi-structured interviews and focus groups onto the WHOQOL structure to discern the impact of ERF on patients' and partners' QOL. They found that ERF affected every WHOQOL domain. As demonstrated by Joshi (2014) and Finnegan-John and Thomas (2013), the WHOQOL structure provides a useful tool by which to systematically tabulate and explore QOL in patients and their partners.

In this literature review, quantitative, qualitative and mixed methods studies, which included both patient and their partners, are analysed with a focus on QOL in ERF patients, preparing for or on dialysis, and their partners. The aim is to provide a consolidated review of the existing research and to answer the following research questions:

1. What do we know from the existing quantitative research about QOL in ERF patients and their partners?
2. What do we know from the existing qualitative studies about the experiences of ERF patients and their partners and how their experiences may relate to QOL?
3. Are there differences in QOL between ERF patients and their partners?

3.3 Methods

This literature review was conducted in April-June 2015 to inform the design of a qualitative study and updated in December 2019.

3.3.1 Inclusion Criteria

Studies were considered for the final sample if they met the following criteria:

- Quantitative studies measuring QOL in adult ERF patients and their partners.
- Qualitative studies on the experiences of adult ERF patients and their partners.
- Written in English.

3.3.2 Exclusion Criteria

Studies were excluded if they met any of the following criteria:

- Did not conduct an empirical study on QOL.
- Did not measure QOL using a recognised QOL measure (i.e., measured health status or functioning).
- The focus of the study was on decision-making with respect to renal replacement therapy, acute kidney failure, renal transplants, palliative or conservative care in ERF.

3.3.3 Search Strategy

The studies included in the literature review were found via searches on Web of Science and Medline using search terms (dialysis OR chronic-kidney-disease OR end-stage-renal AND quality-of-life AND care* OR spous* OR partner OR family OR dyad*). Additionally, the lead author (researcher) hand-searched key papers' reference section.

3.3.4 Selection Process

The researcher conducted the selection process for this review (Figure 3.1). Initially, every articles' title and abstract were read. Sixty-nine articles were identified as potentially eligible, and the full texts scrutinised for inclusion. Articles were excluded if they did not meet the inclusion criteria (21 did not measure QOL, 12 used a health status measure, 7 patients only, 6 partners only, 5 on modality decision-making, 2 included partners who were not explicitly the partners of the included patients and 2 were not empirical research).

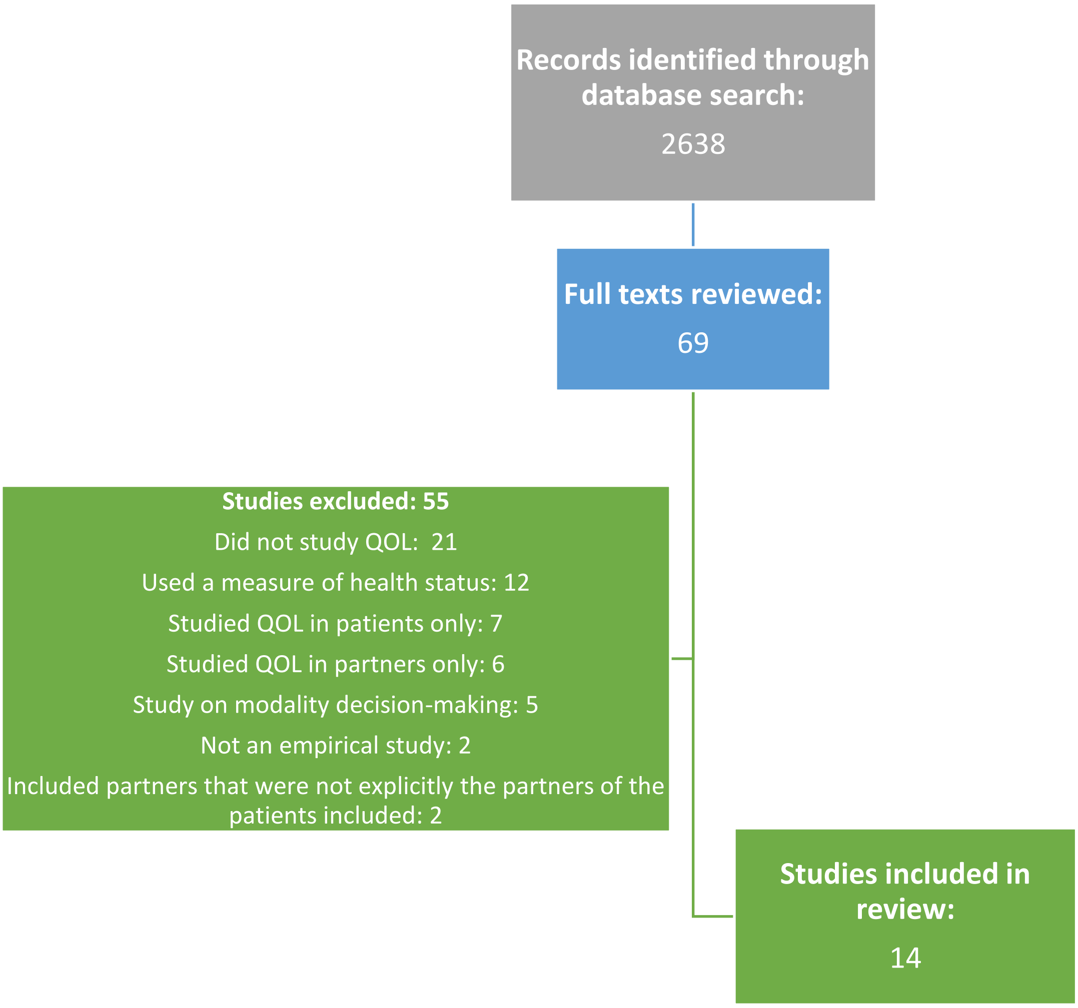


Figure 3.1
Results of the search strategy and process for inclusion in the review

3.3.5 Data analysis and extraction

A total of 14 studies (4 quantitative, 8 qualitative and 2 mixed methods[2]) were identified for inclusion in this review. The data extracted from each study included the title, authors, year of publication, country in which the study was conducted, purpose, design, sample characteristics, analysis, measures (quantitative and mixed methods studies) or data collection methods (qualitative studies), results and conclusions. These were then placed in a table.

3.3.5.a Quantitative studies

Only five studies (4 quantitative and only of the 1 mixed methods studies) met the inclusion criteria. Due to the heterogeneity between these studies, a meta-analysis could not be conducted. A narrative review to describe QOL in patients and their partners within these studies was then conducted.

3.3.5.b Qualitative studies

Narrative synthesis (Pope & Mays, 2006b) was used to summarise the findings of the 10 included studies (8 qualitative and both mixed methods). The original WHOQOL structure (The WHOQOL Group, 1994) provided the deductive framework. The WHOQOL reflects a subjective, general view of QOL in health and was developed cross-culturally to address components of QOL that are relevant to both healthy and ill people (Skevington & McCrate, 2012). It comprises 24 facets across six domains of QOL (physical, psychological, level of independence, social, environment and spirituality, religion and personal beliefs) and a general facet consisting of 2 items, one on overall QOL and one on satisfaction with health (The WHOQOL Group, 1994). The researcher chose this framework as it provides a general, multi-faceted conceptualisation of QOL and facilitates the distillation of the complex effects of ERF and dialysis on patients and their partners.

The researcher read the findings until a closeness with the data had been attained. The findings of each qualitative study were then mapped onto WHOQOL framework. This was achieved by using a table in a word processing document with rows for WHOQOL domains and facets and separate columns for each study. Each mapped entry onto the chart was labelled ‘patient,’ ‘partner’ or ‘both’ to compare similarities and differences in their experiences. Finally, the findings were summarised to provide the overall synthesis of QOL in ERF patients and their partners.

3.4 Results

A total of 14 studies, consisting of eight qualitative, four quantitative and two mixed methods (whose findings were included in the review where relevant, see Footnote 2), were identified which included ERF patients and their partners. Overall, these studies included 800 patients and 670 of their partners. Of these, seven studies (3 quantitative, 2 qualitative and 2 mixed methods) included 586 patient-partner dyads; however, the patients and their partners were not necessarily spousal-type dyads and included patients’ family members (e.g., their children, parents).

Five studies (4 qualitative and 1 quantitative) included ERF patients and their partners; however these were not considered dyadic as not every patients’ partner participated in the study (i.e., in Anees, Hameed, Mumtaz, Ibrahim, and Khan (2011) they recruited 125 HD patients and 50 of their family members). Baillie and Lankshear (2015) reported that half the patients did not want to include their partners in the study. Ekelund and Andersson (2010) presented their findings by group, those in a patient-partner dyad and those without a partner. In the present analysis, only the findings which could be attributed to the patient-partner dyads were extracted and integrated in the narrative synthesis.

Two studies included other patient and partner relationships. Firstly, Monaro, Stewart, and Gullick (2014) included three patients who did not have a partner and one partner participated in the interview but the patient did not. In addition to this, one study conducted by (Wellard & Street, 1999) used an ethnographic approach and included three male home-dialysis patients and five their family members (three wives plus two other family members).

An overview of these studies is provided in Appendix A. The ‘Design’ section of Appendix A includes the labels ‘Dyadic,’ ‘Not matched’ and ‘Other’ to describe the patient-partner relationships within the study (as described above), and the ‘Sample’ section provides the details reported in each study about the characteristics of the patients and partners.

The findings from these studies will be discussed in turn by methodology (quantitative and then qualitative) with a focus on QOL in patients and their partners and highlighting similarities and differences in their QOL.

3.4.1 Quantitative studies

Five studies (Al-Rawashdeh et al., 2020; Anees et al., 2011; Ferrario, Zotti, Baroni, Cavagnino, & Fornara, 2002; Ferri & Pruchno, 2009; Khaira et al., 2012) were found which assessed QOL in both patients and their partners. One mixed methods study (Courts, 2000) is not included in the quantitative narrative review as it did not include a measure of QOL but is included in the narrative synthesis of the qualitative studies. The studies included in the quantitative review were conducted in five countries (Jordan, Pakistan, Italy, USA and India) and included 662 patients who had been on haemodialysis (HD, see Footnote 1) for an average of 46 months and 587 of their partners. Only one study used a longitudinal design

(Ferri & Pruchno, 2009). Two studies (Ferri & Pruchno, 2009; Khaira et al., 2012) used a single item to measure QOL, which was scored on a 1-5 Likert scale (1=Poor, 5= Excellent). Two studies (Al-Rawashdeh et al., 2020; Anees et al., 2011) used the WHOQOL-BREF and presented the domain scores, which are calculated by taking the means of the individual items within the domains and then transforming them to a 0-100 scale, as per the WHOQOL guidelines. On this scale, 50 is the midpoint where scores < 50 indicate poor QOL. One study (Ferrario et al., 2002) utilised the Satisfaction with Life Scale (SWLS). In both the WHOQOL-BREF and SWLS, high scores reflect good QOL and satisfaction with life. Quality of life was the primary outcome measure in three of the studies (Al-Rawashdeh et al., 2020; Anees et al., 2011; Ferri & Pruchno, 2009).

Quality of life in patients

Both male and female patients in Khaira et al. (2012) reported their QOL similarly (2.8 ±1.0 vs. 2.5 ±1.1, p=0.42) with their scores suggesting patients' QOL is poor. In Ferri and Pruchno (2009), patients reported their QOL as good at baseline and the one-year follow-up (3.35 ±1.06 & 3.30 ±0.968). The patients in Al-Rawashdeh et al. (2020) reported their QOL to be poor in the physical, psychological and environment domains of the WHOQOL-BREF but reported good social QOL. In Anees et al. (2011) patients' scores on the WHOQOL-BREF suggest moderate QOL in the psychological, social and environment domains (average transformed score of 51 across domains) and poor QOL in the physical domain.

Further to this, Anees et al. (2011) compared QOL in patients who had been on dialysis for more than eight months to those who had been on dialysis for less than eight months. They found that patients who had been on dialysis less than eight months reported poorer QOL in the physical and social domains when compared to patients who had been on HD for longer (non-transformed physical domain scores: 11.11 ±3.4 vs. 9.69 ±3.44, *p*=0.02; non-transformed social domain: 13.64 ±3.76 vs. 11.54 ±4.44, *p*=0.05). The raw domain scores of the WHOQOL-BREF were transformed to the WHOQOL 0-100 scale by the researcher, which facilitates interpretations of domain scores. In the physical domain, both sets of patients reported their physical QOL to be poor (transformed physical domain scores: patients >8 months 44 vs. 36 in patients < 8 months). In the social domain, patients on HD for more than 8 months had good QOL whereas those on HD for less than 8 months had poor social QOL (transformed social domain scores: 60 vs. 47). There were no differences between patients' QOL in the psychological or environment domains based on length of time on dialysis.

Ferrario et al. (2002) did not report any descriptive statistics related to patients or partners' SWLS scores; therefore, QOL in patients and partners cannot be reported. However, the relationship between QOL in patients and their partners will be reported in the *Differences in quality of life between patients and partners* section.

Quality of life in partners

Both male and female partners in Khaira et al. (2012) reported their QOL as poor (2.8 ±1.1 vs. 2.7 ±1.2, *p*=0.83). Although partners provided their own assessments of their QOL at baseline and follow-up in Ferri and Pruchno (2009), the means and standard deviations were not reported. The partners in both Al-Rawashdeh et al. (2020) and Anees et al. (2011) indicated their QOL to be good across the domains of the WHOQOL-BREF.

Differences in quality of life between patients and partners

In Khaira et al. (2012), differences in QOL scores were only assessed by gender within the patient and partner groups. However, an inspection of the reported means and standard deviations of the QOL scores by group (patients vs. partners) suggests that there were no differences in how patients and partners report their QOL (n=49 dyads, 2.65 ±1.05 vs. 2.75 ±1.15). In Anees et al. (2011), patients reported poorer QOL in the physical, psychological and social domains than their partners (see Appendix A for statistics) whereas in Al-Rawashdeh et al. (2020) partners reported statistically higher QOL scores than the patients across all the domains of the WHOQOL-BREF. In Ferrario et al. (2002), the SWLS scores in patients and partners were not strongly correlated ($\beta=-0.08$, $p>0.05$); however, in Ferri and Pruchno (2009) patients' and partners' overall QOL scores were found to be positively correlated at baseline ($\beta=0.525$, $p<0.01$) and the one-year follow-up ($\beta=0.554$, $p<0.01$). These findings provide mixed evidence as to the differences in QOL between HD patients and their partners.

3.4.2 Qualitative studies

The 10 qualitative studies (Andrew, 2001; Baillie & Lankshear, 2015; Courts, 2000; Ekelund & Andersson, 2010; Ferrario et al., 2002; Monaro et al., 2014; Wellard & Street, 1999; White & Grenyer, 1999; Wise, Schatell, Klicko, Burdan, & Showers, 2010; Wright & Kirby, 1999) were conducted in five countries (3 Australia, 3 UK, 2 USA, 1 Sweden and 1 Italy) and included a total of 138 ERF patients and 83 of their partners. Of these, 61 were HD patients and 55 of their partners; 26 were peritoneal dialysis (PD, see Footnote 1) patients and 17 of their partners; 61 were either HD or PD patients (exact sub-sample size numbers not discernible) and 43 of their partners; 27 were home HD (HHD) patients and 27 of their partners; and 3 were home dialysis patients (HHD or PD not specified) and their 5 partners (consisting of the patients' 3 wives and 2 additional family members). Only one study reported the experiences of 10 ERF patients at the pre-dialysis stage and their partners (number of partners not reported, Andrew, 2001). Due to limited studies with ERF patients and partners in the pre-dialysis phase, the summary of the literature focuses on how dialysis affects QOL. A synthesis of the thematic analysis is summarised in the following section with quotations and the author's interpretation provided in Appendix B.

Quality of life in patients and partners

Below, QOL in patients and their partners is described in relation to the domains of the WHOQOL, starting with the facets of general QOL and then the six domains. Within each section a summary is provided of how patients and their partners described their QOL in relation to these domains, and any differences or similarities in their experiences are highlighted

Overall QOL. Patients described dialysis as having both positive and negative effects on their QOL. Some of the differences in how patients discussed the effects of dialysis on overall QOL were associated with the type of modality (e.g., HD, HHD, PD) or phase of treatment (e.g., pre-dialysis, starting dialysis, long-term dialysis experience). For instance, patients on HHD or PD, home-based treatments, remarked that they had more autonomy, control and freedom (Courts, 2000) and had better overall well-being and had got their life back (Wise et al., 2010; Wright & Kirby, 1999). In contrast, those on other forms of dialysis spoke of how it consumed their lives or forced them to change their lifestyles (e.g., move from the countryside to the city) (White & Grenyer, 1999). Likewise, partners also had mixed views on the impact on their overall QOL, with some saying it improved their life (Ekelund & Andersson, 2010) while others said it brought significant changes their lives, roles and responsibilities (Courts, 2000; White & Grenyer, 1999; Wise et al., 2010). Both patients and partners noted that the period of time around diagnosis and starting dialysis were particularly difficult and psychologically challenging (Andrew, 2001; Baillie & Lankshear, 2015; Monaro et al., 2014).

Health. In general terms, patients spoke about their health in relation to dialysis more than partners. Patients highlighted that dialysis had both positive (Monaro et al., 2014; Wise et al., 2010; Wright & Kirby, 1999) and negative (Monaro et al., 2014) effects on their health. Only one partner spoke of her own health, highlighting the pressure on her to be healthy to look after the patient (White & Grenyer, 1999). Both patients and partners spoke of dialysis keeping the patient alive (Ekelund & Andersson, 2010; White & Grenyer, 1999; Wise et al., 2010) but also discussed the terminal nature of ERF (Baillie & Lankshear, 2015; White & Grenyer, 1999; Wright & Kirby, 1999).

Physical domain. In the physical domain, patients noted the negative physical symptoms associated with dialysis such as itching, sleep issues, low energy (Ekelund & Andersson, 2010; Monaro et al., 2014; Wright & Kirby, 1999) and peritonitis (a potential problem for PD patients, Baillie & Lankshear, 2015). Patients, who had switched to HHD and were well-established on it, reported that it improved their energy and physical health (Wise et al., 2010); however, there was not a consensus in patients who had recently started centre-based HD, with some reporting both positive and negative effects of dialysis on their physical QOL (feeling better vs. fatigue, Monaro et al., 2014). Partners spoke infrequently about their physical QOL, and those that did reported feeling tired (White & Grenyer, 1999). Overall, patients and partners discussed the effects of dialysis similarly and as having a negative impact on their physical QOL; however, some patients experienced improvements in their physical QOL.

Psychological domain. Patients spoke of the negative impact dialysis had on their psychological QOL, such as feeling depressed and anxious, having suicidal thoughts and expressing deep anger towards dialysis and its impact on their lives (Ekelund & Andersson, 2010; White & Grenyer, 1999). They also discussed changes to their appearance (presence of a fistula and side effects of medications), the noticeable decline in their cognitive abilities, particularly before dialysis, and often feeling worthless or not a person (Ekelund & Andersson, 2010; Wright & Kirby, 1999). However, some PD patients in Wright and Kirby (1999) spoke of positive changes in themselves and used humour and reframing to adjust to the limitations on them due to dialysis. Similarly, HHD patients reported feeling less depressed (Courts, 2000) and having more hope than when they were on in-centre, conventional HD (Wise et al., 2010). Further to this, the findings indicate the presence of more negative feelings such as fear and grief (Andrew, 2001; Baillie & Lankshear, 2015; Courts, 2000; Monaro et al., 2014) during early phases of ERF (i.e., diagnosis, pre-dialysis, starting dialysis).

Partners also recalled the early phases being stressful (Baillie & Lankshear, 2015; Courts, 2000). Overall they referred to their psychological QOL negatively and discussed being fearful and worried about the patient (Ekelund & Andersson, 2010; White & Grenyer, 1999) while also feeling angry or sad about their situation (Courts, 2000; Ekelund & Andersson, 2010; Wise et al., 2010). One partner spoke about the future with a sense of hopelessness (White & Grenyer, 1999). Both patients and partners described dialysis as changing their sense of self which led to struggles adapting to their new self and their roles (Monaro et al., 2014).

A difference between QOL in patients and their partners within the psychological domain is that partners did not indicate that dialysis had any positive effects on their QOL. Both patients and partners described their psychological QOL as impaired; however, some patients identified ways in which their QOL improved after starting dialysis (e.g., more hopeful and positive, less depressed).

Level of independence domain. Quality of life in terms of the level of independence domain was again viewed both positively and negatively. Patients and partners on home-based treatments tended to state positive effects such as it allowed them more freedom and control of their lives (Baillie & Lankshear, 2015; Courts, 2000; Wise et al., 2010), allowed the patient to work (Courts, 2000) and self-care gave them more independence (Wright & Kirby, 1999). However, despite these positive effects there were considerable negative effects on level of independence, which were mentioned across all modalities and by both patients and partners. Most notably, they described their loss of freedom which was borne out of being restricted in their daily activities (e.g., due to limitations on food and liquid intake associated with the ERF and dialysis diet), their dependence on the dialysis machine and relying on others for day to day survival (Baillie & Lankshear, 2015; Ekelund & Andersson, 2010; Monaro et al., 2014; White & Grenyer, 1999;

Wise et al., 2010). For many patients and partners, their work capacity was negatively impacted, with many patients unable to work (White & Grenyer, 1999) and with partners experiencing an increased work-load within the household (Wellard & Street, 1999). In Wright and Kirby (1999), PD patients noted that being able to work was important to them in adjusting to dialysis and regaining their sense of self-worth. Patients and partners did not express differences in their QOL in the level of independence domain; in this domain dialysis had a mutual effect.

Social relationships domain. Quality of life in terms of social relationships were described negatively due to the amount of time, energy and planning it took up in their lives (Monaro et al., 2014; Wellard & Street, 1999; White & Grenyer, 1999). In this domain, dialysis had a mutual impact on QOL in patients and their partners. Both noted that strong relationships were vital in order to undertake home-based treatment (Courts, 2000; Wise et al., 2010), and Monaro et al. (2014) perceived that spousal dyads were less negatively impacted than other types of relationships.

Most dyads in these studies spoke lovingly and with kindness of each other (White & Grenyer, 1999; Wise et al., 2010), and some dyads even flourished in spite of the demands of dialysis (Wise et al., 2010; Wright & Kirby, 1999). However, some patients and their partners indicated that dialysis added strain and exacerbated existing tensions (Monaro et al., 2014; Wise et al., 2010). Some partners recalled the lack of discussion about their taking on the caregiver role for the patient – it was simply assumed they would do it (Wellard & Street, 1999) which may lead to resentment within the patient-partner dyad (Monaro et al., 2014; White & Grenyer, 1999). While some patients worried about the burden they placed on their partners (Ekelund & Andersson, 2010; White & Grenyer, 1999; Wise et al., 2010), others seemed unaware of the burden of dialysis on their partner (Wise et al., 2010).

In regards to sex-life, both patients and partners commented that it was an issue and that their sex-life was impaired by ERF and dialysis (Ekelund & Andersson, 2010; White & Grenyer, 1999; Wright & Kirby, 1999).

Environment domain. The environment domain covers a broad range of topics, some of which were discussed by patients and partners and others that were not. Patients spoke about concerns over their financial resources whereas partners did not mention this. The prospect of having a kidney transplant, a highly relevant issue to this population and associated with access to healthcare, gave some patients hope (Baillie & Lankshear, 2015; Ekelund & Andersson, 2010; Wright & Kirby, 1999) yet could also be a source of anger and frustration (Baillie & Lankshear, 2015; White & Grenyer, 1999). For those on HHD or PD, medicalising the home was often spoken of matter-of-factly (Baillie & Lankshear, 2015; Wellard & Street, 1999) with patients pointing out the positives of it (Courts, 2000) and partners more likely to refer to it negatively (Wise et al., 2010). Opportunities for travel and leisure were discussed frequently by both patients and partners (Baillie & Lankshear, 2015; Courts, 2000; Ekelund & Andersson, 2010; Wellard & Street, 1999; White & Grenyer, 1999; Wise et al., 2010; Wright & Kirby, 1999); however, it was notable that partners discussed the negative effects of dialysis on their opportunities for travel and leisure more than patients. Patients and partners expanded on their difficulites accessing health care (Courts, 2000; Wellard & Street, 1999) and called for more individualized and family-centred care (Ekelund

& Andersson, 2010; Wise et al., 2010). Some differences in QOL in the environment domain existed between patients and their partners, with patients reporting the negative effects on their finances whereas partners highlighted the negative effects on their opportunities for travel and leisure.

Spiritual, religious and personal beliefs domain. In regards to Spiritual, religious and personal beliefs, patients and partners both demonstrated the role of these beliefs, which ranged from just getting on with it to trusting in God to help them manage the demands of the treatment (Wise et al., 2010; Wright & Kirby, 1999).

In summary, taken together this synthesis highlights the various effects dialysis has on all areas of QOL in patients and their partners and that in many instances it affects the members of the dyad differently. Furthermore, these findings provide some evidence that phase of dialysis (starting vs. long-term) and mode of dialysis may be factors related to QOL.

3.5 Discussion

In conducting this literature review, 14 studies were identified which examined QOL or explored the experiences of ERF patients and their partners. It is the first review, to our knowledge, to focus on patients and their partners and assess similarities and differences in their QOL. A key finding was that research in the early phases of dialysis, namely pre-dialysis and just after starting dialysis, is lacking. This review also highlighted the dearth of dyadic research in ERF, with only 7 of the 14 studies matched the patients with their partners.

The narrative review of the four quantitative and one mixed methods studies indicated that QOL was generally reported to be poor in HD patients; however, one study found good overall QOL, which remained stable over a one-year period (Ferri & Pruchno, 2009), and in another patients reported good social QOL (Al-Rawashdeh et al., 2020). Quality of life in partners was described variously between the studies, with two studies reporting partners QOL to be good across the WHOQOL-BREF domains (Al-Rawashdeh et al., 2020; Anees et al., 2011) and one reporting poor overall QOL (Khaira et al., 2012). In regards to the differences between QOL in patients and their partners, the partners in two studies had better QOL than the patients (Al-Rawashdeh et al., 2020; Anees et al., 2011) whereas both patients and partners reported their QOL similarly in two other studies (Ferri & Pruchno, 2009; Khaira et al., 2012). The findings of this narrative review indicate that further research needs to be conducted to better understand QOL in ERF patients and their partners.

The narrative synthesis of the qualitative studies highlighted that mode of dialysis and phase of dialysis were important factors in QOL. The psychological domain of the WHOQOL was most affected and was generally described as poor by both patients and their partners. Patients discussed their physical QOL more than partners. QOL in the social, level of independence and spirituality, religion and personal beliefs domains was mutually affected by dialysis. In the environment domain, patients and partners expressed differences in how dialysis affected their finances and opportunities for travel and leisure. Taken together, the findings from this review suggest that ERF, and in particular dialysis, significantly affects QOL in patients and their partners.

3.5.1 Quantitative studies and results

Only five studies were found in the existing ERF patient-partner literature which measures QOL in its broader conceptualisation, rather than health functioning. Dyadic research is an emerging area of research in ERF and currently there is a paucity of studies that evaluate QOL using a measure that addresses topics important to both members of the dyad (Manns et al., 2014). Furthermore, all these studies were conducted with HD patients and only one utilised a longitudinal design.

Despite all the patients being on HD, differences existed in the QOL scores which could be due to patients' length of time on dialysis. The patients in Khaira et al. (2012) had been on dialysis for approximately 14 months rated their QOL as poor whereas in Ferri and Pruchno (2009) patients rated their QOL as good but had been on dialysis for an average of six years. This evidence suggests that QOL is impaired over the first year of dialysis and may improve as patients establish themselves on dialysis. Studies (Ginieri-Coccossis et al., 2008; Griva, Yu, et al., 2014; Tsai et al., 2010) which have used the WHOQOL-BREF to assess QOL in patients established on dialysis also found patients to have good QOL which corresponds with the results in Ferri and Pruchno (2009).

3.5.2 Qualitative studies and findings

That eight qualitative and two mixed methods studies were found that included patient-partner dyads indicates a growing recognition in the field of the importance of the dyadic unit in research and in achieving health care objectives. Despite the inclusion of dyads, only two studies (Monaro et al., 2014; White & Grenyer, 1999) noted the effects of dialysis on the dyadic relationship, and only in one study did the authors provide a dyadic level interpretation of the findings (Wise et al., 2010). Evidence from the narrative synthesis on QOL in the social relationship domain indicates that ERF, and dialysis, may negatively affect the dyadic relationship between some patients and their partners (e.g., the assumption partners will take on the caregiving role; worry and concern about the strain dialysis adds to relationship). The dyadic relationship has yet to be explored across dialysis modalities or in the early phases of dialysis. Future research which adopts a dyadic perspective may add valuable insight to dyadic characteristics that are associated with relationships that are strengthened by dialysis and those which are strained by it.

3.5.3 Narrative analysis

A narrative analysis was conducted for both the quantitative and qualitative findings. Due to heterogeneity between the measures used in the quantitative studies, it was not possible to conduct a meta-analysis. The inclusion of general measures of QOL, such as the WHOQOL-BREF, in future studies would greatly benefit research in this field because it would allow future reviews to statistically analyse QOL scores across the studies. In the narrative synthesis, using the WHOQOL structure to map the experiences of the patients and their partners revealed the complex and nuanced effects of dialysis on their QOL and helped the researcher to interpret the studies' findings.

3.5.4 Strengths & Limitations

A strength of this study was its focus on QOL patients and their partners and the inclusion of both quantitative and qualitative studies to address this. The narrative synthesis, drawn from variable and rich accounts of ERF patients and their partners, indicated how their QOL may be affected by dialysis, which has not been reported before in the ERF patient-partner literature.

The main limitation of this review is that only seven studies include patient-partner dyads, and the dyadic relationships varied within these studies (i.e., some studies included a spousal and parent-child dyadic relationships). Therefore, it was not possible to ascertain the impact of ERF or dialysis on distinct dyadic relationships, such as between spousal-type dyads. An exception to this is Wise et al. (2010) who investigated the effects of short daily home HD on patients and their spouses at the dyadic level which yielded rich insight as to how dialysis impacts members of the couple mutually and separately. Because dialysis often occurs in the rich context of a patient-partner dyad, it would be beneficial to know how other modes of dialysis impact their relationship and each member of the dyad's QOL.

Future research is needed which assesses QOL in its broader conceptualisation and utilises dyadic analytical techniques. This area of research could also benefit from longitudinal studies, especially those which include all modes of dialysis and include dyads where the patient is in the early phases of dialysis.

Footnotes

[1] Dialysis refers to two common types, or modes, of treatment in established renal failure patients: haemodialysis (HD) and peritoneal dialysis (PD). In HD, the patient’s blood is removed from their body via arteriovenous fistula in the arm or neck/thigh catheter (also called a tesio line). The blood is then filtered through a dialysis machine to remove toxins. The UK’s NICE guidelines recommend a minimum of 12 hours per week of dialysis. This type of dialysis may be referred to as maintenance, conventional, or in-centre dialysis as it is usually conducted in renal centres and meets the minimum requirements. Patients on this prescription of dialysis usually have three dialysis sessions per week which are 3-5 hours per session. Home HD refers to dialysis that is conducted in the patient’s home. In home HD patients have more freedom to choose the day and length of their dialysis sessions. Due to this, home HD may be referred by other names such as nocturnal (meaning patients dialyze overnight), interval (meaning patients dialyze every other day), short daily/high frequency (meaning patients dialyze for a few hours every day). Research indicates that more frequent and longer sessions are linked with better health outcomes such as better removal of smaller molecules and reduced reliance on medications (Mitra & Jayanti, 2014).

In PD, the toxins are removed through a different process. In PD, a catheter is inserted in the patient’s abdomen. Through this catheter, a special cleaning fluid, called dialysate, is inserted into the patient’s peritoneum (lining of the abdominal cavity). Over a period of 2-3 hours the dialysate absorbs the body’s toxins. The toxin-rich fluid is then drained out via the catheter. Once the fluid is drained, more fluid is then inserted and the process restarts. These changes of fluids are referred to as exchanges. There are two types of PD: continuous ambulatory PD and automated PD. In continuous ambulatory PD (CAPD) the patient conducts the exchanges several times during the day (usually 4 times), and it does not require special machines so can be done at home or other settings (such as an office or hotel). In automated PD, the exchanges are conducted every night by a machine and usually takes up to 8 hours to complete the full cycle of exchanges.

[2] One of the mixed methods studies (Courts, 2000) did not use a recognised measure of QOL but in the qualitative arm of the study they conducted interviews with HHD patients and their partners and reported the findings of the interviews. The quantitative results they reported were extracted and are provided in Table 1. However, the results were not summarised in the quantitative narrative review. The findings from the qualitative portion of the study are also included in Table 1 and were integrated into the overall narrative synthesis of the qualitative studies.

The other mixed methods study (Ferrario et al., 2002) used a recognised measure of QOL but only reported correlations between the patients and partners' scores whereas other studies included descriptive statistics for the QOL measure. Therefore, the results are only summarized in relation to the second research question (*Results: Quantitative studies: Differences in quality of life between patients and partners*). Interviews were conducted with only the patients' partners, and the findings reported were limited. The findings are presented in Table 1 and are discussed in regard to the narrative synthesis were applicable.

Chapter 4: Impact of dialysis on the dyadic relationship between male patients and their female partners

Preface

This paper was published in *Qualitative Health Research* (Moore, Skevington, Wearden & Mitra, 2019) and has been formatted in accordance with the manuscript requirements of the journal. The authors are Currie Moore, Suzanne Skevington, Alison Wearden and Sandip Mitra. The PhD candidate designed the study, wrote the topic guide, obtained ethical approval, recruited the participants, conducted the interviews, analysed the data and wrote the first draft of the manuscript under the supervision of Prof. Alison Wearden, Prof. Suzanne Skevington and Dr. Sandip Mitra. A professional transcription service transcribed the interviews. All authors commented on the first draft of the manuscript written by the PhD candidate, made suggestions for improvement and approved the final version of the manuscript.

4.1 Abstract

The objective of this study was to explore the impact of three early phases of renal dialysis, namely pre-dialysis, starting dialysis, and establishing dialysis, on dyadic relationships. Twenty UK-based dyads (20 male patients and their female partners) participated in semi-structured interviews and discussed the effects of dialysis on themselves and their relationship. Dyadic thematic analysis, facilitated by dyadic-level charting, integrated participants' experiences and enabled identification of patterns across dyads. We found that dialysis had positive and negative influences on identity, social relationships, and mental health, forming the themes: Prioritizing the Patient, Carrying the Burden, and Changing Identities. The final theme, Managing the Relationship, described how dyads prevented dialysis from negatively impacting their relationship. Dyadic-level charting provided a systematic examination of individual and dyadic experiences. These findings indicate that access to informational and support services for dyads as they prepare to start dialysis may minimize negative effects on their relationship.

4.2 Introduction

End stage renal disease (ESRD) is a progressive disease culminating in the irreversible loss of kidney function. Artificial methods, namely dialysis, may be introduced to remove wastes and toxins from the body. While dialysis sustains patients' lives, it also places demands on the patient and those closest to them (Low et al., 2008). Patients and their care partners form a unique unit, or dyad, who may influence each other when adjusting to chronic illness treatments, such as dialysis (Revenson et al., 2016).

In the UK, approximately 7,000 people start a form of renal treatment each year (Hole, Gilg, Casula, Methven, & Castledine, 2018). The primary reason for renal failure is diabetes (28%), with 64 years the average age of onset. Over 60% of patients starting dialysis are male (Hole et al., 2018) with research indicating females are the predominant care partners (Low et al., 2008). For over 80% of ESRD patients, dialysis will be their first form of treatment (Gilg, Methven, Casula, & Castledine, 2017). Dialysis is provided free of charge via the NHS and may be conducted at renal units in hospitals, independent centres, or in patients' homes. The two main forms of dialysis are haemodialysis (HD) and peritoneal dialysis (PD). In HD, treatments provided in renal units are termed 'conventional' HD (CHD) and those conducted in the patient's home referred to as home HD (HHD). In PD, patients generally conduct their treatment at home. Renal care teams primarily consist of renal nurses and physicians. Despite the prevalence rates increasing each year, there remain too few psychologists and social workers, leaving patients and their partners without vital support as they manage and cope with the complexities of renal disease (Seekles et al., 2017). Furthermore, current pre-dialysis education may not adequately prepare patients and their partners for starting dialysis (Combes et al., 2017).

Dialysis impacts all areas of patients' and their partners' quality of life (QoL, Finnegan-John & Thomas, 2013) and affects their relationship variously, sometimes strengthening their relationship sometimes introducing guilt and frustration (Walker et al., 2015). However, the majority of research with patient-partner dyads was conducted with patients who had been on dialysis for an average of two years. Jablonski (2004) distinguished between the early phases of dialysis and longer-term adjustment in the ESRD illness trajectory. The early phases include pre-dialysis, starting dialysis, and first few months of dialysis, collectively referred to as the "crisis phase" (Jablonski, 2004, p.54), and the longer-term adjustment called the "chronic phase" (Jablonski, 2004, p. 54). One study conducted in the crisis phase (Monaro et al., 2014) included 11 CHD patients who had started dialysis in the last three months, plus five of their family members. Family members described caregiving as all-encompassing, with those in spousal relationships voicing doubts about whether their relationship would survive the demands of dialysis. These findings suggest that patients and partners may face significant relationship challenges during the early phases of dialysis, yet it has not been explicitly explored.

Research with dyads in the chronic phase includes Ekelund and Andersson (2010) and White and Grenyer (1999) who recognized the broader social context in which dialysis occurred and explored its impact on patients and their partners. Ekelund and Andersson (2010) used a discursive analytic approach to understand the meaning of ESRD within dyads and referenced changes to physical and psychosocial aspects of the dyadic relationship. White and Grenyer (1999), using a phenomenological approach, reported the impact of dialysis on the dyadic relationship from the separate perspectives of patients and their partners. Patients spoke positively of their partner and the impact on their relationship whereas the partners acknowledged strain, burden, and changes to their emotional and physical relationship. Though neither of the above studies analyzed their data so as to provide an integrative dyadic perspective, the findings provide insight as to how the dyadic relationship may be affected.

Research with dyads in other chronic conditions, such as multiple sclerosis (Kleiboer, Kuijer, Hox, Schreurs, & Bensing, 2006), suggests that maintaining the balance or equity within the relationship is important. Dyads in which patients and their partners reciprocated in showing some form of care for each other, whether instrumental or emotional, restored the balance within the relationship (Kleiboer et al., 2006). In a study of heart failure patients and their partners, Retrum, Nowels, and Bekelman (2013) found that dyads with congruent notions of planning for, and managing, the illness also had less distress or tension within their relationship. These findings provide insight into dyadic relationship characteristics which facilitated adjustment in other chronic illnesses.

In dyadic thematic analysis (DTA), the researcher analyses the views of both individuals in the unit, then makes interpretations across the dyad to yield a third perspective (Eisikovits & Koren, 2010). It is particularly useful when examining situations that have a mutual impact on the dyad, yet the members of the dyad may report different views, such as in long-term illnesses (Eisikovits & Koren, 2010). For example, Koren, Simhi, Lipman-Schiby, and Fogel (2016) used

DTA to explore expectations of caregiving in multi-generational step-families which brought out the complexity of commitment and decision-making in these families.

Wise et al. (2010) adopted a dyadic perspective to examine the impact of short daily HHD on dyads where the patients had been on dialysis for an average of 17 months. Using grounded theory, they drew out the similarities and inconsistencies between the dyadic narratives and identified four relationship styles. Dyads characterized by high levels of convergence responded most positively to the challenges of short daily HHD. These insights suggest that DTA may be a useful approach to understand the dynamics of adjustment in dyads across all types of dialysis and during the early phases of treatment.

We aimed to explore the impact of early dialysis on spousal-type dyads, with a focus on the impact of dialysis on the dyadic relationship. We therefore set out to recruit dyads within the crisis phase of dialysis, which include pre-dialysis, starting dialysis, and the initial adjustment period. We then used DTA to integrate the patients' and partners' narratives. With the aim of recruiting a relatively homogenous sample to compare experiences, we focused on male patients and their female partners, who also represent a significant proportion of patient-partner dyads in the ESRD population.

4.3 Methods

4.3.1 Participants and Recruitment

Participants were drawn from the renal register of a UK hospital trust between January and July 2016. Patients and partners were over 17 years old, spoke English fluently, and were in a spousal-type relationship. Patients were either preparing for, or had recently started, their first form of out-patient dialysis to treat ESRD (i.e., ‘incident’ patients). They comprised three groups: (a) pre-dialysis, patients in the hospital’s low clearance clinic with an estimated glomerular filtration rate (a clinical marker denoting how well the kidneys are removing toxins in the blood) of $\leq$ 20, but without a start date for dialysis; (b) starting dialysis, patients on a form of outpatient dialysis < 6 months; (c) establishing dialysis, patients on outpatient dialysis > 6 months, but less than 16 months.

Thirty-four patients met the eligibility criteria. Of these, 20 took part in the study, together with their partners. A partner was defined as a person in a spousal-type relationship who provided informal care in the form of physical, treatment-related, or emotional support to the patient. The reasons for non-recruitment were (a) lack of response to the letter of invitation (5 patients), (b) not interested in taking part (5 patients), (c) responded after data collection was completed (2 patients), and (d) other reasons (2 patients). Purposive sampling ensured that a range of dyadic experiences could inform the research question. The sampling framework focused on two patient characteristics, namely dialysis phase and type of dialysis.

The final sample comprised 20 male patients and 20 female partners. Eighteen of the 20 dyads were married or living as married; one was engaged, and the other separated but identified as a “couple.” The average relationship length for was 30 years (range 5-55 years). 35 participants classified themselves as white British; five were from other ethnic groups (European or Asian). The average age of patients was 63 years (range 39-80); and partners 62 years (range 39-87).

Seventeen participants were retired, 10 were in paid employment, 11 were unable to work due to limitations placed on them by ESRD or dialysis, and two were unable to work for other health reasons. Dyads were in three phases: pre-dialysis (6), starting dialysis (7), and establishing dialysis (7). Patients were currently utilizing, or planning to utilize, three types of dialysis: CHD (8), HHD (7), and PD (5).

4.3.2 Procedure

All participants gave verbal and written consent prior to data collection. The study received UK ethical approval from an NHS Research Ethics Committee (Ref no. 15/LO/16).

Qualitative methods were selected as the most appropriate to explore factors that influence dyadic relationships in the early phases of dialysis. Choosing semi-structured interviews ensured all participants were asked similar open-ended questions while giving them the freedom to discuss the topic and reveal experiences in their own way (Britten, 2006). The lead author, Currie Moore (CM), conducted interviews with each member of the dyad individually, wherever possible. Three dyads requested to be interviewed together, and one patient was present during his partner's interview. The research team created the topic guide based on previous literature and clinical experience. Questions asked about the impact of dialysis on the dyadic relationship, QOL, and factors influencing their QOL. Probes aided the exploration of topics more fully, as necessary. The exact wording and order of the questions varied to suit the natural flow of the interview.

Interviews took place in participants' homes or in a private space at the hospital, whichever was more convenient to them. All interviews were audio-recorded and then transcribed verbatim by a professional transcription service. CM reviewed each transcript while listening to the audio-recording to ensure accuracy and removed personal identifiers at this time. The interviews lasted on average 50 minutes (range 11-102 minutes).

4.3.3 Data Analysis

Thematic analysis was used to analyze the data inductively and followed recommended guidelines (Braun & Clarke, 2006, 2013). We adopted a critical realist epistemology which recognizes the broader context in which participants report their experiences and shape their reality (Braun & Clarke, 2006). As recommended by Eisikovits & Koren (2010), a thematic analysis was conducted on each dyad's data, with the patient's data analyzed first, the partner's second, and then DTA was undertaken.

The patient's transcript was first read for familiarity and re-read until CM gained a sense of the interview. CM noted any initial reactions, thoughts, or key details at this stage. The transcripts were then coded by CM line-by-line. Inductively-driven codes allowed the nuanced experiences within the narrative to emerge and were grouped to create initial themes within the data. NVivo (Version 10, QSR International) was used to manage the data. Then, an initial summary of the patient's experience was written.

To maintain the focus on the dyad, CM constructed a chart containing a table with two columns, patient and partner. The rows of the table consisted of thematic headings relating to the dyadic relationship, QOL, and inductive emerging themes. CM populated the chart with short summaries or quotations to capture the patient's experiences and then repeated the process in the second column for the partner. After this, the DTA began. Notes made during the individual thematic analyses of instances where the patient or partner had overlaps or contrasts were added to each chart. Overlaps or contrasts occurred at both the descriptive (e.g., length of time on dialysis) and perceptual levels (e.g., attitudes towards dialysis; Eisikovits & Koren, 2010). Finally, CM wrote a summary of each dyad before proceeding to the next dyad. After all dyads had been analyzed in accordance with the above steps, CM read and re-read all the charts to get a sense of similarities, differences, and key themes emerging from the dataset. Visual aids (e.g., mind-maps, dyadic notecards) facilitated comparisons between dyads. The developing analysis was discussed among the entire research team several times during the analysis process. The analysis was refined until it clearly represented core themes in all the dyads' narratives.

4.3.4 Trustworthiness of the analysis

CM conducted all the interviews in a conversational style to promote rapport and openness in the interview using non-directional phrases and prompts to minimize her impact on the data. In DTA the researcher plays an active role in making sense of the participants' experiences, which adds a layer of interpretation to the analysis. This third perspective, gained from multiple perspectives and data sources (e.g., individual interviews with both dyad members), reduces risks of misinterpretation (Eisikovits & Koren, 2010).

To ensure the authors' analysis accurately portrayed the experiences of the dyads, an overview of the findings was mailed to all dyads, and they were invited to provide feedback. Four dyads responded and confirmed the analysis captured their experiences. One participant recognized that dyads who are hoping for a transplant might be less accepting of dialysis as it was not their preferred form of treatment. To prevent the loss of internal confidentiality (where a member of the dyad recognizes his or her partner), limited individual and dyadic identifiers are provided in the Results.

4.3.5 Reflexivity

In conducting this research, CM developed extensive knowledge of the dyads, their shared meanings, and experiences, which she relied upon to integrate their perspectives and construct the emerging thematic model. As recommended by Ummel and Achille (2016), CM kept a reflexivity journal to note her own attitudes and limit inadvertent biases from influencing the findings. Her female gender may have affected what male patients were comfortable discussing whereas female partners openly shared their concerns, and even distress. Many partners expressed their isolation and distress during the interviews. The research team supported CM and assisted her in maintaining a non-biased view.

Most interviews were conducted with patients and their partners consecutively. Although beneficial in some respects, this required CM to “bracket” information gleaned in the first interview while conducting the second. Of the three dyads who requested joint interviews, one partner whispered her thoughts to CM when the patient left the room; the implications of these were considered during analysis. In the other jointly-interviewed dyads, participants expressed strong opinions and did not speak confidentially to CM. Joint interviews may add depth and remove issues relating to internal confidentiality that exist in dyadic research (Polak & Green, 2016).

4.4 Findings

In the early phases of dialysis, patients became the priority which led to a shift in dynamics within the dyads. This resulted in partners carrying the burden, and both parties experiencing changes in their identities. Dyads who managed their relationship together buffered their relationship from the negative effects of early dialysis through positivity, normalizing dialysis, or accepting it. Although dyads were at different phases of early dialysis, they discussed similar social, psychological and relationship issues, regardless of the phase or type of dialysis. Variations in their experiences are noted within the themes.

4.4.1 Prioritizing the Patient

Patients and partners acknowledged that patients were the main priority. Partners stated that their lives were centred around the patient's health or dialysis:

> *It has all become centred around him, the focus on him because he's the person that's ill.* Partner, Pre-dialysis
>
> *I don't get put first very often. If he's got something happening, he'll make sure he gets to do it. . . Our life revolves around that [dialysis], and if he's well, if he's this . . . It's all about him.* Partner, Establishing

Partners accepted this shift in their focus as it allowed the patient to look after his own health and treatment, which was keeping him alive: "He's got to do his own thing to keep himself alive" (Partner, Establishing). Patients recognized they were putting themselves first and that this affected their partners: "I appear now to be a lot more focused on my needs, rather than her needs. I'm aware that I need to do certain things [for myself and dialysis], and I put those above everything else" (Patient, Establishing).

Partners prioritized patients in a physical sense and by acting as their advocates. Physically, partners stated that they needed to be healthy and well to provide support to the patients, "I've got to be fit too, haven't I? [To] look after him" (Partner, Establishing). Partners needed to be in close physical proximity to the patient and had to plan their day accordingly, "I do get out on my own for at least an hour a day. But before that, I have to make sure that his blood sugar isn't too low, or he doesn't feel sick, or everything's sort of okay" (Partner, Pre-dialysis).

As advocates, partners ensured the patients received the care or information that they needed. In the early phases of dialysis, and in particular pre-dialysis, patients may experience cognitive impairments which inhibit their ability to plan, rationalize, or communicate. Partners knew what the patient wanted and often said they had to be persistent with health care professionals to get this for them. When acting as the patient's advocate, they prioritized the patient's wishes and preferences, even when these differed from their own. In contrast, in one dyad, the patient changed the type of dialysis he wanted to utilize as his preferred type would have been burdensome to his partner. Although being advocates added to their responsibilities, partners spoke matter-of-factly about it and described it as part of being in their relationship. For one partner it meant attending all the patient's appointments with him as his health worsened to ensure he kept "ownership and control" of his treatment. A partner in the establishing phase reflected on the journey from pre-dialysis to the present and stated, “I’ve fought for him - to get him what he’s got and get him where he is.” To the partners, advocacy was another way in which they prioritized the patient and his needs.

4.4.2 Carrying the Burden

Both patients and partners discussed how partners carried physical and emotional burdens within the dyadic relationship. Physically, partners took over managing the household, working extra jobs to compensate for lost income, or preparing the house for home-based dialysis. A partner in the starting phase stated, “He can’t cope with anything like that [dealing with utility providers to set up dialysis]. Really, he leaves it all to me.”

Dyads in the starting and establishing phases reflected on the pre-dialysis stage as being a difficult time in their relationship because the patient’s health was deteriorating and often the symptoms of ESRD were insidious or invisible. One dyad in which the patient suffered from extreme fatigue, breathlessness, and poor mobility (common features of ESRD) provided rich insight to the impact that carrying the physical burden had on their relationship. Even though his partner was aware of his symptoms and their effects on him, there was no relief from the day-to-day pressure on her:

> *We were really arguing [before he started dialysis]. Because I thought, part of the time, he was putting it on. . . So I was getting niggly because I’m trying to hold my job down. . . But you do, don’t you? You’re going to get niggly, because you get tired, and then when you get tired, you start an argument.* Partner

> *She has had to start doing almost everything. Literally everything. . . All it seems to do is put pressure on her. . . which in turn puts pressure on me, so I just want things done.* Patient

Although these quotations suggest that partners harboured resentment for carrying these burdens, they downplayed it and stated that carrying the burden was part of their commitment to the patient and their job to do what the other could not do. One partner in the starting phase captured this sentiment by saying, “We look after one another, and that’s what we’ve always done. . . that is the bottom line.”

Emotionally, partners’ experiences and attitudes varied at the different phases. Partners in the pre-dialysis phase discussed more anxiety and concern about the impact of dialysis on their life than patients or those in other phases, “You’re a bit in limbo. . . We’re hoping that he’s got a more positive future; that hopefully he’s not going to be in pain and having all the problems that he has. . . it’s [dialysis] an unknown for us.” The dyads described the complex and idiosyncratic nature of ESRD, which often meant that patients did not follow a set path as renal function declined. Not knowing when dialysis would start or how the patient would respond to it added to their anxieties. Partners of patients who had started CHD or HHD expressed relief that the patient had begun treatment; now they could begin fitting it into their lives, “It [dialysis] just turned my life to not knowing what is going to happen next, to having some sort of plan in place. . . I know he’s going there [dialysis unit]. He’s safe. . . so that’s the calming part of having dialysis” (Starting). In contrast, those starting PD did not express relief at starting dialysis. Instead they spoke of the intensity of the training and how it limited their free time. Those establishing dialysis were settling into a routine with dialysis but were now facing the chronicity of it, “Sometimes you stress yourself, [you] say, ‘Ugh, stuck with that one [dialysis]’. . . But now you’re stuck, you can’t go anywhere. That’s sad” (Partner, Establishing).

In all phases, partners openly discussed the emotional burdens they carried, such as loneliness, worry, and distress. Although partners were often relieved when patients started dialysis, it also brought loneliness and did not alleviate their worry. Two partners in the starting phase stated, “I have been feeling quite lonely, as if I didn’t have a partner” and “Basically, I think you're worried all the time, you know?” Some partners elaborated on the basis of their worry which was attributed to the vulnerability of the patient’s life brought on by ESRD:

> *I’m getting upset now, thinking about it [ESRD; begins to cry], just thinking about him. The dialysis doesn’t bother me at all. It’s just him. . . We’re a bit close. [Crying].* Partner, Starting
>
> *It’s the fear factor. I’m so petrified that he’s going to die.* Partner, Establishing

Often, the emotions that partners expressed during interviews had not been shared with the patient, nor with others in their support network:

> *You try not to let it upset you really [starts crying] because you’ve got to be strong for him.* Partner, Pre-dialysis
>
> *[Whispered] I don’t let him know that I worry. Don’t let him see me worried.* Partner, Establishing

Many partners hid their distress to prevent it negatively affecting the patient and refrained from discussing their own emotional and physical burdens with renal care teams because they did not want to divert attention from the patient. Furthermore, partners described the lack of ESRD-specific groups where they could share their experiences and seek emotional support from others facing similar circumstances.

4.4.3 Changing Identities

Both parties discussed changes in their identity, which occurred at individual and dyadic levels. At an individual level, participants stated that they now saw themselves differently or that their partner perceived them differently, compared to before having ESRD. Many participants gave up careers that they loved in the pre-dialysis phase due to the demands of ESRD. It was difficult for participants to reconcile with their new identity because changes, such as giving up work, had been forced on them by circumstances. One partner in the establishing phase elucidated this sentiment when she said, “Sometimes I feel like a spare part, if that makes sense? So it's been a huge change [stopping work]. . . but at the same time, something had to give.”

One dyad who had a difficult journey to dialysis spoke frankly with each other about the divergent changes in themselves and their relationship, brought on by ESRD and dialysis. The patient, who had seen himself as a “dominant” person, stated, “The illness changed me to a weaker person.” Getting over this change in his self-perception was a big issue in coming to terms with ESRD and accepting changes in the relationship. His partner recognized that she too had changed and was now more “independent” and “stronger.” However, she reflected that the new strength may have made her “too hard.” They also discussed the variable impact of the changes on their relationship, from creating tension which they had to learn to work through to giving opportunities for personal growth. Other dyads echoed similar shifts in self-perceptions and the effects on their relationship. For example, some patients now described themselves using terms with negative connotations:

> *She just thinks I’m more disabled than before . . . Before [she would say], ‘Have you had your food?’ Now [she says], ‘Eat your food’.* Establishing
>
> *It's like having another baby for her, having me.* Pre-dialysis

At the dyadic level, both discussed how they viewed each other differently within the relationship. A significant change to occur in the dyads was the partner’s social status in the relationship. There was high convergence within the dyads that the partner had shifted to a carer or best friend with participants saying, “She’s moved over to being my carer really” and “Lately I suppose it’s more that we’re like best friends than anything.”

The change in social status within the relationship was often associated with changes in their sexual and intimate relationship, which some participants discussed spontaneously. While patients acknowledged the effect of dialysis and ESRD on their sex life and intimate relationship, they questioned whether it was solely due to dialysis or a part of natural aging:

> *It does affect your sex life. . . because when you start taking hypertensives you get erectile dysfunction, which is rather upsetting. So that kind of thing is dire, and very irritating, compared to what I used to be. Again, people*

> *say you deteriorate with age anyway, but I don't think I would have deteriorated to the extent that I have done.* Patient, Establishing

One patient stated that his complex history with ESRD and dialysis made it a difficult topic to discuss, "It's not easy to talk about [with my partner] because you can't discuss that [sex life] in isolation because you tend to think about, well, how have we got [here]?" Partners spoke less frequently than patients about the impact on their sex life, but those who did reaffirmed the patients' views saying, "There's not much of a sex life anymore" (Partner, Establishing).

ESRD and dialysis affected the intimate relationship variously. Many dyads began sleeping separately as early as pre-dialysis, to ensure better rest for both, and often due to the patient's symptoms (e.g., restless leg syndrome, itching). They noted that the change in where they slept impacted how they interacted as couple, with one partner reflecting that they no longer shared their thoughts and plans in a natural way like they once had, in bed with a cup of tea. However, for some dyads dialysis promoted intimacy in their relationship. One partner credited dialysis with improving his well-being, "Before that [dialysis] he had a bit of a [sexual] problem, but he wouldn't admit it . . . He smiles more and laughs more, you know, it's great" (Starting). Patients also noted how it changed how they interacted with their partner, with one patient saying, "I'm a bit more tender towards her as well" (Starting). For one dyad, dialysis facilitated intimacy as the patient distracted himself during an uncomfortable step in his PD procedures by giving his partner a massage, "After the initial drain, I don't get into bed until that's over because it's too uncomfortable. Normally what I do is massage [partner's name]."

The changes in identity also affected how dyads experienced their daily life. Both expressed a sense of lost independence, which they previously enjoyed in the relationship, and stated that they now they "live in each other's pockets" (Patient, Pre-dialysis). Although dyads were now physically together more, they spent time attending appointments related to dialysis, rather than enjoying leisure activities. Both lamented how the illness and dialysis impacted on their time together:

> *At one time we did everything together, now we don't.* Patient, Pre-dialysis
>
> *Sometimes you'll see couples out doing stuff, and it's always me on my own. Just doing everything by myself. . . I just think, 'Oh, wouldn't it be nice if we could share these things?'* Partner, Pre-dialysis

ESRD can affect patients' mental and cognitive functioning which they described as being like a "zombie" or having your head in "a muzzy [mosquito] cloud." One dyad agreed on the positive effects of dialysis; he said, "I came out as a different person. . . Everywhere was bright. . . my head was clear." Dialysis also had a positive impact on his relationship with his partner who said, "I've got my husband back."

4.4.4 Managing the Relationship

The themes *Prioritizing the Patient*, *Carrying the Burden*, and *Changing Identities* demonstrated significant ways that the early phases of dialysis impact dyads. However, the final theme, *Managing the Relationship*, shows how some dyads buffered the relationship by being positive, normalizing dialysis, or accepting dialysis.

Across all dyads, patients and partners repeatedly adopted a stoical attitude towards dialysis; they stated, “You just have to get on with it, don’t you?” (Patient, Starting). Fourteen dyads, who appeared to be the most successful at getting on with it, described their relationship as a “partnership” and spoke of them being “together” or “close:”

> *We've just always faced things and done things together, you know. . . And we tend just to cling to one another and just keep putting one step forward because there's only one way to go. And, as I said, he is very strong and I'm able to leech his strength and together we get through it.* Partner, Starting

Six dyads spoke of the overwhelming nature of ESRD and dialysis and its impact on their relationship. They spoke of being “together, but not as close” and seemed to be managing separately, rather than together.

There were no differences between the two styles of management (together and separate) in terms of relationship length or age (see Table 4.1); however, three out of six of those managing separately were in the pre-dialysis phase, and four of the six were on, or preparing for, CHD. Both groups discussed dealing with issues such as patient’s poor health, strong views on dialysis-related issues (e.g., hoping for a transplant), or dealing with significant life events (e.g., family members’ death, other chronic illnesses). In the separate group, these issues exacerbated relationship strain where in together dyads they did not impact their joint, team-like approach. These patients and partners prevented dialysis from taking over their lives by engaging in collaborative coping, meaning that they worked together and took account of each other’s way of handling stress (Berg & Upchurch, 2007). Two dyads sought counselling within renal services during the pre-dialysis phase to assist them with the stress and anxiety of this time period.

Table 4.1
Background characteristics of dyads by management style

Management style (n= dyads)	Together (14)	Separate (6)
Mean relationship length	29.6 years	27.6 years
Age range	39-87	49-73
Phase of dialysis		
Pre-dialysis	3	3
Starting	6	1
Establishing	5	2
Mode of dialysis		
Conventional haemodialysis	4	4
Home haemodialysis	7	0
Peritoneal dialysis	4	2

Dyads managing the relationship together minimized the impact of early dialysis on the relationship by being positive, normalizing dialysis, or accepting it. Within the dyads, it was not important who managed the relationship (i.e., patient or partner) only that someone actively promoted at least one of these attributes. Often partners managed the relationship, but in six dyads the patient took the lead.

Participants stated that positivity was critical to managing the relationship, “I’m positive and he’s better. . . I keep telling him, you’ve got to look forward” (Partner, Starting). Participants often looked to the other member of the dyad for their positivity. As long as one of them was positive, the other remained positive. Quotations from two dyads reflect this and show that in some dyads the patient was the one managing the relationship and in others it was the partner:

> *She insists that we always have something to look forward to, and a positive attitude. And I think that's working, to a large extent.* Patient, Establishing
>
> *He and I have got a close relationship so, you know, sometimes I know that he thinks about it [dying], but I would just jolly him along a bit . . . You can't dwell on it, you just have to make the best of life really is what I think.* Partner, Establishing
>
> *I look on the bright side, she would say to the point where I'm not realistic, but I am optimistic. I try to see the optimistic side of everything.* Patient, Pre-dialysis
>
> *I probably got strength from his positive attitude.* Partner, Pre-dialysis

Normalizing dialysis was another way of managing the relationship, and dyads normalized it by minimizing its impact on their daily routines and how they talked about it, with one partner in the starting phase saying, "I mean, really, you've just got to be normal, as such . . . Because I don't want to make a big thing of it. . . Just get on with it, you know, and do it." Humour also normalized dialysis by downplaying the negatives. Patients used humour more than partners, although it was often shared between them:

> *But we like getting a wheelchair and hurtling down the corridor from one end of the hospital to the renal clinic down the far end. So that's fun.* Patient, Pre-dialysis
>
> *We're laughing from small things like we named his line [catheter] a really strange name. . . So yeah, we're just trying to laugh at the small things.* Partner, Starting

Accepting dialysis as part of their lives was another way of limiting its impact on the dyadic relationship. By accepting dialysis, participants were able to focus on adapting their lives around it, rather than focusing on what they could not do anymore:

> *We accepted it, you know. We knew that we wouldn’t be going to walk up inclines of any length. We just found things to do. Name a garden centre round here - we visited it; and we just found things to do that he could manage.* Partner, Pre-dialysis

Rather than being despondent about their limited leisure choices, they found positives which facilitated accepting dialysis. Dyads, who managed their relationship together and who exhibited some of these attributes, buffered the dyadic relationship from the stressors of early dialysis.

4.5 Discussion

In this study, we explored how the early phases of dialysis affect the dyadic relationship between male patients and their female partners. Across the phases, participants described similar experiences and responses to the stressors of early dialysis. In these dyads, patients became the priority, which led to partners carrying significant burdens, and both parties facing changes in their identities. Despite shifts in their responsibilities and identities, dyads who exhibited a ‘together’ approach and had one member of the dyad actively managing the relationship buffered the relationship from potentially negative effects of dialysis. Participants stated that promoting positivity, normalizing dialysis, or accepting dialysis were important in managing their relationship.

These findings contribute to current knowledge as it is one of the first to explicitly report the impact of dialysis, particularly in the early phases of dialysis, on the dyadic relationship. Unlike other studies (e.g., White & Grenyer, 1999), it directly addressed and analyzed the mutual impact of dialysis on spousal-type dyads. It also expanded on the findings of Wise et al. (2009) who investigated dyadic characteristics in couples established on a specific form of HHD, by focusing on the early phases of dialysis and across dialysis modalities. There is a dearth of research on the experiences of pre-dialysis patients and their partners, and ours is one of the first to provide insights into this area.

In this study, we explored several aspects of partners' experiences, which had not been examined before in-depth. For example, the partners revealed the extent to which they took on tasks that were not necessarily related to dialysis but allowed dialysis to occur (see Carrying the Burden). Partners provided more detail about their emotional state when elucidating the nature of their worries (i.e., the vulnerability of the patient's life), which has not been reported previously (Monaro et al., 2014; Walker et al., 2015; Wise et al., 2010). The theme *Prioritizing the Patient* highlighted the significant change in focus that occurred within the dyadic relationship. Despite partners playing an integral role in the successful delivery of patient care, there remains a need for more partner-focused research and services to ensure they are well-supported in their role (Gayomali, Sutherland, & Finkelstein, 2008).

Three previous studies (Finnegan-John & Thomas, 2013; Wise et al., 2010; White & Grenyer, 1999) have reported that partners experienced role changes and shifts in their identities but did not then elaborate on the nature of change.

Our analysis, at both the individual and dyadic level, may help health care professionals to anticipate when patients and partners would be likely to experience shifts in identity and then be ready to provide support to reduce emotional distress (Lively & Smith, 2011). For example, in the present study, patients described changing from a “healthy, active person” to “disabled.” Identifying as someone who is disabled may impact on how patients engage with their disease and treatment, which could have long-term treatment effects.

Patients and partners in our study discussed the impact of dialysis on their sex-life (see Changing Identities), which has previously only been mentioned by partners (Monaro et al., 2016; White & Grenyer, 1999). In our study, patients questioned whether ESRD or ageing caused the changes in their sex-life. Both patients and partners suggested that sex-life and intimacy could be difficult subjects to discuss within the dyad. These are areas where health care professionals and counselling services could readily assist dyads by providing information about the impact of ESRD on sexual function or by assisting dyads to have conversations about their sexual relationship. The impact of ESRD and dialysis on dyads’ sexual relationship is an area that warrants further research.

Many of the dyads were adjusting to life with ESRD and minimizing the effects of early dialysis on the relationship, which echoes the thriving and surviving dyadic styles reported by Wise et al. (2009). In the present study, the dyads who worked together offered concrete examples of how they sustained their relationship, namely being positive, normalizing dialysis, and accepting it, which are aspects of collaborative coping processes. Collaborative coping is associated with positive outcomes in patient-caregiver dyads in other chronic illnesses (Revenson et al., 2016b).

The dyads describing themselves as together echo the findings of Kayser, Watson, and Andrade (2007) who explored dyadic coping in breast-cancer patients and their partners and found that those who were mutually responsive described it as a “we-disease” (p. 410). However, despite the team-like approach, partners in the present study carried significant physical and emotional responsibilities on their own. Even within the dyads managing together, some partners engaged in protective buffering, meaning they did not disclose their emotional distress to the patients (see Carrying the Burden). Partners of people with long-term conditions may feel that it is their responsibility to care for patients and may refrain from disclosing the burden with those outside the family (Parveen, Morrison, & Robinson, 2011); such non-disclosure has been associated with greater distress in dyadic research in other long-term illnesses (Revenson et al., 2016b). We found that partners of ESRD patients do not have an outlet whereby they can express their feelings of worry, fear, and distress. This is in line with the findings of Welch et al. (2014), who reported the partners of HHD patients expressed significant worries for the patients but lacked access to support.

The qualitative technique, DTA is a novel approach to dialysis research and provided valuable in-depth views of how dyads experienced and made sense of the early phases of dialysis. Across the themes, the dyads’ narratives corroborated the effects of dialysis and offered further insight into each theme. For example, in *Carrying the Burden,* patients were aware of their partners’ distress but not the extent of it. If DTA had not been used in this study, it is unlikely that the theme *Managing the Relationship* would have been developed. This theme required scrutinizing emerging themes within each dyad, and then identifying how and who within the dyad minimized the impact of dialysis. Although DTA offered new insights, it posed issues when seeking participant validation and presenting the data in a way that maintained the confidentiality of the dyad. Furthermore, pseudonyms were not used nor were dyadic-level details provided which may prevent readers from seeing the complex and nuanced experiences occurring within individuals and dyads. Ummel and Achille (2016) provide an overview of issues which should be considered when designing and implementing qualitative dyadic research, as it is important to understand the costs and benefits of these issues and recognize how they impact the data, analysis, and dissemination.

This is the first time that DTA has been used with dyads in the early phases of dialysis. DTA offers a more holistic perspective than analyzing the two interviews separately, such as with phenomenology or group-based thematic analyses, by highlighting dynamic interconnections between the members of the dyadic unit. The use of dyadic-level charts in our analysis facilitated the management of large quantities of rich data and provided a useful way to examine emerging patterns within and across dyads.

Ours is the first study to our knowledge to investigate the experiences of dyads at three crucial phases early in dialysis and across three dialysis modalities. While on the surface a patient or partner in the pre-dialysis phase may have different daily experiences from those establishing dialysis, participants' narratives revealed common underlying themes (e.g., patient the main priority).

Examining dyads at these different phases allowed nuances in experience to arise, such as the prevalence of anxiety in pre-dialysis.

While a homogenous sample in terms of gender, geographic location, ethnicity, and spousal-type relationships facilitated comparisons between dyads, further qualitative studies are needed to explore the impact of early dialysis on minority ethnic groups and other dyadic relationships (e.g., female patient-male partner; non-spousal dyads). We focussed on dyads of male patients-female partners as they represent the majority of spousal-type dyads starting dialysis. While we only had the views of female partners, in a recent study (Williams et al., 2017) male caregivers of ESRD patients also discussed changes to their role in the relationship, emotional and physical burdens, and described similar coping strategies. Dyads in the present study had been in their current relationship for an average of 30 years; studying those in newer relationships might have produced different findings. Because of the dyadic focus of the research, patients with partners who did not consent to take part were not included; their views may differ from those presented here. The cultural context of our study could limit the interpretation of the findings. While the sample displayed some British male cultural norms (e.g., stoicism), the patients also discussed their frustrations and emotions (see Changing Identities) as well as adopting a ‘just get on with it’ attitude (see Managing the Relationship). The sample in this study included five people from different cultural and ethnic groups, and their data supported the themes and overall analysis.

4.5.1 Implications for clinicians and services

Patients and their partners began experiencing a number of stressors early in the pre-dialysis phase which remained as they adjusted to dialysis. Partners reported few support services available to them despite high levels of distress, burden, and social changes. They also expressed a keen interest in informational and support services, offered via online or in-person community groups, where they could ask questions or voice their concerns. There is a need for assessment and support for both members in the dyad starting at pre-dialysis and on-going throughout the ESRD trajectory. When working with spousal-type dyads or families, it may be beneficial to assess the dynamics of the relationship and then provide information or counselling that can foster positivity, normalize dialysis, and acceptance of dialysis.

Chapter 5: Development of a measure for patients preparing to start dialysis and their partners: the Starting Dialysis Questionnaire (SDQ)

Preface

This paper has been formatted in accordance with the manuscript guidelines of the journal where it will be submitted for consideration, *Health and Quality of Life Outcomes.* The authors are Currie Moore, Alison Wearden, Lesley-Anne Carter, Sandip Mitra and Suzanne Skevington. The PhD candidate designed the research, developed the studies' protocols and design, obtained the necessary ethical approvals, recruited the participants in the cognitive interviews, conducted the cognitive interviews, collected and managed the questionnaire data, conducted all analyses and wrote the first version of the manuscript, under the supervision of Prof. Alison Wearden, Prof. Suzanne Skevington, Dr. Lesley-Anne Carter and Dr. Sandip Mitra. All authors reviewed the first version of the manuscript, provided feedback and contributed to and approved the final version of the manuscript.

5.1 Abstract

Background: The transition onto dialysis is a stressful time that affects both patients and their partners. Research suggests that psychological and interpersonal characteristics within the couple are related to how well they adapt to dialysis. The aim of this multi-phase, mixed methods study was to develop a measure, the Starting Dialysis Questionnaire (SDQ), that is applicable to both patients and their partners and assesses these constructs.

Methods: Data from semi-structured interviews with patients and their partners (n=22 couples) were analysed using theoretical thematic analysis to identify and define psychological and interpersonal constructs related to QOL in the early phases of dialysis. Next, items addressing these constructs were derived from the interviews. Then, cognitive interviews (CIs) with renal patients and their partners (n=5 couples) assessed the face validity and comprehensibility of the developing SDQ. Lastly, preliminary psychometric properties of the items and domains of the measure were evaluated in a sample of pre-dialysis patients and their partners (n=83 couples).

Results: Three themes related to QOL were identified, namely dialysis expectations, accepting dialysis and dyadic relationship characteristics. The CIs refined the SDQ and established its face validity. Psychometric assessments indicated that overall the items performed well and did not show significant floor or ceiling effects. Good internal consistency was found within the three domains, and good correlations existed between the items within each domain.

Conclusions: The SDQ is a short measure (34 items) that assesses key psychological and interpersonal factors in patients and their partners as they start dialysis. It could offer a clinically useful tool to assist clinicians in preparing patients and partners for dialysis.

5.2 Introduction

Dialysis is a treatment for people who are in established renal failure (ERF) and whose kidneys can no longer eliminate toxins from the body. Starting dialysis has been identified as a stressful time in the treatment pathway for patients and also their family members, or partners (Jablonski, 2004). Patients and their partners form a unique social unit, or dyad. Members of the dyad are mutually affected by treatments, and dyadic characteristics may also affect treatment- and health-related outcomes (Revenson et al., 2016b).

Previous qualitative research found that psychological and interpersonal factors within the dyad played an important role in adjusting to dialysis and minimising the impact of it on the dyadic relationship and quality of life (QOL) (Moore, Skevington, Wearden, & Mitra, 2019). Moore et al. (2019) interviewed both members of 20 dyads at various times around the start of dialysis. They described significant changes in their identities, roles within the relationship and responsibilities. However, dyads who acted as a team buffered their relationship from these stressors by being positive, accepting dialysis or normalizing dialysis. Assessing these psychological and interpersonal characteristics in both patients and their partners in the pre-dialysis phase and after starting dialysis may identify dyads who would benefit from additional support over this transition.

A scoping review of the literature was conducted to find existing questionnaires that measure dialysis expectations, accepting dialysis and relevant dyadic relationship characteristics, for use in a longitudinal study of QOL and its correlates in ERF patients and their partners during the period of transition onto dialysis. The search yielded 16 questionnaires which measured constructs related to psychological and interpersonal factors (7 dyadic coping, adjustment or satisfaction questionnaires, 6 illness cognition questionnaires, 1 couples communication questionnaire, 1 optimism questionnaire and 1 questionnaire on expectations for QOL and health after renal transplants). Each questionnaire was reviewed and assessed for use in the longitudinal study on the basis of the following criteria: 1) address psychological or interpersonal relationship dynamics, 2) be amenable to changes in wording (e.g., if a general questionnaire about illness, it needed to be possible to change “illness” to “kidney disease” or “treatment” to “dialysis”), 3) be applicable to patients and their partners, 4) not replicate items on the WHOQOL-BREF (the primary outcome measure in the quantitative study) and 5) be concise to reduce question burden during a stressful point in ERF treatment. The only questionnaire suitable for inclusion was the couples’ communication questionnaire.

In order to assess the psychological and interpersonal factors described by Moore et al. (2019) as related to maintaining the dyadic relationship and QOL, the present study aimed to develop a Starting Dialysis Questionnaire (SDQ). The sub-studies presented here are the three phases of the SDQ’s development. First, using existing interview data, the psychological and interpersonal factors relating to QOL were identified and defined through qualitative analysis (Study 3.1). Then the questions, or items, which were generated from the findings of qualitative analysis, were assessed for comprehensibility and relevance in cognitive interviews (Study 3.2). Lastly, preliminary psychometric properties of the items and domains of the SDQ were evaluated (Study 3.3).

5.3 Study 3.1: Identification of psychological and interpersonal factors related to QOL and generation of items

5.3.1 Aims

- To identify and define key psychological and interpersonal factors that relate to QOL in patients and their partners during the early phases of dialysis.
- To develop items related to these factors using an inductive, data-driven approach.

5.3.2 Methods

Design

We conducted a secondary analysis of data collected in a cross-sectional, qualitative study which explored the impact of the early phases of dialysis on patients and their partners (Moore et al., 2019). The early phases of dialysis were defined as the period when patients are preparing to start dialysis (e.g., pre-dialysis) and the initial months after starting dialysis (Jablonski, 2004).

Participants

Participants were recruited from a single renal unit in England. The inclusion criteria were that patients and partners were over 17 years old, spoke English fluently and in a spousal-type relationship. Pre-dialysis patients were drawn from the hospital's renal registers and had an estimated glomerular filtration rate (eGFR, a clinical marker denoting how well the kidneys are removing toxins in the blood) of ≤20 but did not have a planned start date for dialysis. Those in the initial months after starting dialysis were defined as patients utilising any form of outpatient haemodialysis (HD) or peritoneal dialysis (PD) for less than 16 months.

Of the 34 patients meeting the eligibility criteria, 22 patients (20 males and 2 females) and their partners (20 females and 2 males) agreed to take part in the study. The average age of the participants was 63 years (range 39-87).

Procedure

This work was part of a larger study that received ethical approval from a UK National Health Service (NHS) Research Ethics Committee (REC, Ref. no. 15/LO/16). All participants gave their consent in writing before participating in the study.

Face-to-face semi-structured interviews were conducted with participants by the lead author (the researcher), lasting an average of 50 minutes. Four dyads requested to be interviewed together, and two patients were present during their partners' interview. The interviews followed a topic guide developed by the research team which included questions on QOL, factors related to QOL, their partners' QOL and the impact on their relationship. Participants who were on dialysis were asked about their current experiences in relation to these topics and also asked to how these were affected by starting dialysis. The interviews were audio-recorded and transcribed verbatim.

Analysis

In this analysis of the interviews, the researcher focused on psychological and interpersonal factors that participants described as affecting their QOL in the early phases of dialysis. The findings from the initial analysis of the over-arching study indicated that factors such as acceptance, positivity, working as a team and changes to daily life affect the dyadic relationship, and ultimately QOL. With this knowledge guiding the analysis, a theoretical thematic analysis was conducted to consolidate and define these factors (Braun & Clarke, 2006, 2013)

The analysis began with researcher re-analysing the dyadic charts created during the previous study; the details of the initial analysis and findings are reported in the corresponding publication (Moore et al., 2019). Briefly, a dyadic thematic analysis, following recommended guidelines (Eisikovits & Koren, 2010), was conducted with each dyad analysed in turn, beginning with the patient and followed by the partner. The first step was familiarisation with the data (repeated readings of the interview transcripts) followed by line by line coding using inductively driven codes. The codes were then assimilated into working themes and transferred onto a dyadic chart. The researcher created a chart for each dyad which consisted of a column for the patient and another for the partner. The rows of the chart were QOL, factors related to QOL, partner's QOL and impact on relationship. The chart was populated with concise summaries and quotations to capture each member of the dyad's experiences or thoughts about each topic. The dyadic charts were then analysed for similarities and differences within and between the dyads.

Then the working themes developed in the initial analysis were analysed by group rather than dyad to allow differences in patients' and partners' experiences to emerge. The key themes for each group were then compiled into mind-maps to draw out their relation to QOL. These documents were then compared for similarities and differences between the themes. Next, the themes were integrated and refined to capture the experiences of both patients and partners. The research team continually reviewed the developing themes and examined how they related to patients' and partners' QOL. The themes were refined until everyone agreed they reflected the participants' experiences.

5.3.3 Results

Three themes, *dialysis expectations*, *accepting dialysis* and *dyadic relationship factors (DRC)*, were identified as relating to QOL in patients and partners in the early phases of dialysis. Table 5.1 provides an overview of the themes and codes.

Table 5.1
Themes and codes identified as relating to quality of life in patients and partners in the early phases of dialysis

Dialysis expectations	
Quality of life Health	Patients and partners spoke repeatedly about how their expectations had or had not been met by dialysis. Their primary concerns were on the impact dialysis would have on their quality of life and the patient's health.
Accepting dialysis	
Treatment and illness Lifestyle Actively accepting and control of dialysis Future	Some patients and partners expressed the importance of accepting dialysis and the changes it brought to both of their lives. Some actively accepted dialysis whereas others seemed resigned to it. The amount of control they thought they had over dialysis and plans for a transplant also factored into how accepting they were of dialysis.
Dyadic relationship characteristics	
Team-like Communication Positivity Awareness of self and other	The analysis highlighted the importance of cohesive patient-partner relationships on their QOL. Those who worked as a team, communicated effectively, were positive and showed an awareness for the other person seemed to be the least affected by dialysis.

Dialysis expectations

Participants discussed a range of expectations of dialysis, with some having very high expectations and some having very low. Participants having high expectations which were not met by dialysis often reported their QOL as poorer than those who started dialysis with low expectations. Expectations centred around two key areas: the impact of dialysis on their QOL and the patient's health. In regard to QOL, participants discussed their expectations of dialysis on their overall QOL and several areas of QOL. The areas most commonly discussed were being able to do their day-to-day activities, ability to travel, having holidays, being tied down/restricted freedom, every day seeming the same and the impact on their social life. The other key area which they formed expectations was the patient's health. Patients in particular talked about the expectations they had of dialysis on their energy, mobility, other illnesses, and hoped that dialysis would allow them some 'better' days.

Accepting dialysis

Across the phases of early dialysis and in both patients and partners, being accepting of dialysis was spoken of by participants who discussed their QOL positively. Accepting dialysis occurred across different levels and included 1) being accepting of the illness and treatment itself, 2) being accepting of lifestyle changes as a consequence of it, 3) being actively accepting and feeling like they would have some control and 4) the role of dialysis in their future. Those who accepted the routines and restrictions of dialysis, and ERF, often used social comparisons or reframing to downplay the impact of dialysis and facilitate acceptance. In regard to lifestyle, participants stating they had a good QOL accepted the limitations imposed by dialysis and adjusted their lives to limit the negative effects of dialysis (e.g., finding hobbies that did not strain their energy). Those who actively accepted dialysis, as opposed to those stating they had no choice about it, and those who talked about having control of dialysis spoke positively about their QOL. The final aspect of accepting dialysis was that participants who presented the best QOL had accepted dialysis as part of their future and were not pinning all their hopes on a transplant. Those with high hopes for a transplant were less accepting of dialysis and were less able to minimise the impact of dialysis on their QOL.

Dyadic Relationship Characteristics

Dyads that had good QOL had developed effective ways of communicating, working together, were mutually understanding and at least one of them was positive about dialysis. Dyads who adopted a team-like approach spoke about the importance of 'being on the same page,' balancing their dialysis-related duties, each person's involvement complementing the needs of the other, spending time together as a couple and being steadfast in their love and care to each other. The communication style within the dyad was important to how effectively and cohesively they worked together. It was important to be able to discuss fears, worries and issues about dialysis, but not let these overwhelm their lives and negatively impact their QOL. Being listened to was noted as important. Both members of the dyads remarked that being positive and optimistic were critical to facing dialysis and maintaining their QOL. Cohesive dyads often stated they got strength from each other. Humour and normalising dialysis were used to help promote positivity and these attributes were evident among those who stated their QOL as good. Finally, being empathetic with each other and limiting the burdens on each other were key characteristics of dyads who spoke of their QOL positively. Alongside being aware of each other, participants stated the need to be an individual with the dyad (i.e., getting time for one's self or having a hobby outside of the dyad). In dyads where an awareness of each other was lacking participants were more likely to cast blame on the other or talk about dialysis increasing their worry, loneliness or isolation.

Preliminary items were drafted to address the concepts within each theme and drawn from the data in order to capture patients' and partners' language (see Appendix G). An iterative process then commenced whereby the research team reviewed the questions and suggested changes. Examples at this stage were to improve comprehensibility (e.g., making question structure clearer and reducing ambiguity), add context (e.g., frame of reference such as 'in 6 weeks'), and remove redundancy (e.g., items that asked about similar constructs). Two versions of the measure were required (one for patients and one for partner), and the items were adapted to be applicable to patients or their partners and over phases of dialysis (pre-dialysis and dialysis). The items across each version addressed the same core concepts to facilitate comparisons between the patient and partner versions, and over time. Response scales were then applied to the items, and further modifications were made as necessary to ensure consistency between question wording and response options.

Existing questionnaires related to these themes were re-assessed during item generation. Reviewing these questionnaires honed the conceptualisation of the theme "accepting dialysis," which was originally labelled "acceptance." A substantial body of research exists on acceptance which does not reflect the views expressed by the participants in our study, who discussed being accepting of dialysis, a treatment, rather than ERF, the illness. In the dyadic relationship characteristics (DRC) theme, four questions about communication were adapted from the Couples' Illness Communication Scale (Arden-Close, Moss-Morris, Dennison, Bayne, & Gidron, 2010) and used in the measure.

Both versions of the SDQ were reviewed by a patient and public renal research advisory group, consisting of five ERF patients, a renal nurse, a lecturer and a professor in health services, who assessed its feasibility, acceptability and length of time to complete (approximately 20 minutes). They recommended using the term 'partners' rather than 'caregivers' and adding a question on relationship satisfaction. The SDQ was updated to reflect their feedback.

The results of this phase of the study were the developing versions of the SDQ which were adapted to apply to patients and partners and at two phases of dialysis (pre-dialysis and after starting dialysis, or dialysis). Thus, a total of four versions of the SDQ were created (see Appendix K, L, M & N). The pre-dialysis SDQ consisted of 33 questions on both patient and partner measures. The dialysis SDQ consisted of 34 questions on both versions. The items utilised 1-5 response scales adapted from the UK version of the WHOQOL (Skevington & Tucker, 1999). The dialysis SDQ also contained two open-ended items with free text response boxes.

5.4 Study 3.2: Refinement of the SDQ using cognitive interviews

5.4.1 Aims

- To use cognitive interviewing (CI) to assess the comprehensibility and validity of the SDQ in a sample of ERF patients and their partners.

5.4.2 Methods

Design

CIs were conducted from June to August 2017 with a subset of the participants who took part in the qualitative semi-structured interview study (previously described in Chapter 4 and Chapter 3.1), each participant being interviewed once.

Cognitive interviewing was selected as the method to examine the comprehensibility and applicability of questionnaires. It is a qualitative method in which participants, usually from the target population, provide feedback on all aspects of the measure (Willis, 2005; Willis & Artino, 2013). Both think-aloud interviewing and concurrent verbal probes were used within the CIs. In think-aloud interviewing, participants verbalise their thoughts about the question and how they form their responses (Willis, 2005). Concurrent verbal probes are prompts about a question's meaning or phrasing asked immediately after a question is answered (Willis, 2005). While think-aloud interviewing limits researcher bias, some participants may not be comfortable with this task or may speak about aspects of the measure not immediately relevant to the research objectives (Willis & Artino, 2013). To limit inadvertent bias, the researcher, who conducted the CIs, received training from an expert in instrument design prior to data collection.

Participants

Patients and their partners who took part in the over-arching study, and who gave their consent to be contacted in follow-up studies, were sent a letter of invitation and participant information sheet. Of the 20 dyads invited, eight responded. Of these, three couples were not interviewed due to: the patient dying before the interview could be arranged and his partner no longer wishing to take part (1); the unexpected poor health of a family member (1), and data collection having already ceased by the time the couple responded (1).

All the recruited couples classified themselves as White British and were married (relationship length 9-50 years). All of the patients were male with an average age of 62 (range of 40-78); partners were female with an average age of 58 (range 40-77). Of the total 10 participants, 8 were retired, 1 worked full-time, and 1 was unable to work. Of the four patients on dialysis, all were on a form of home dialysis (PD or home HD) and had been using dialysis for an average of 21 months (range 16-30 months); 1 patient was in the pre-dialysis phase.

Procedure

This study was a substantial amendment to the previous study which received favourable ethical opinion from a UK NHS REC (Ref. No. 16/LO/2016 – Amendment 2 dated 17 May 2017; approved 9 June 2017; Appendix I). All participants gave their consent in writing before taking part. The CIs were conducted at a time and location which was most convenient to the participants; four dyads chose to be interviewed in their home and one dyad chose to be interviewed in a private room at the renal unit. All the CIs were conducted on an individual basis, except for one dyad who requested to take part in the CI in the same room at the same time.

Before starting the interview, the researcher introduced the SDQ, provided background on its development and intended future use in research, demonstrated how CI was conducted and answered any questions about the study. The participant was given the relevant version of the SDQ and then asked to think out loud as they worked through each item. The participants were informed that the researcher may ask additional questions between items. The procedures and verbal probes for the CIs are provided in Table 5.2.

Table 5.2
Cognitive interview procedure and verbal probes

Introduction	The SDQ is going to be answered by people about to start dialysis. The questions come from what we learned from the interview study you previously took part in. Today you are helping us make sure it makes sense and is understandable. This is a follow-up study called a cognitive interview, or think aloud. It is different from the previous interview you took part in.
Demonstration of the task	*The researcher shows the participant the SDQ*. *Then, the researcher provides a demonstration of thinking aloud using the following question (not on the SDQ):* *How would you rate your quality of life? 1=Very poor, 2=Poor, 3=Neither good nor poor, 4=Good, 5=Very good.* *Researcher questions the time frame, what is meant by 'quality of life,' and how the answer she marks reflects her assessment.*
Instructions	Please complete the questionnaire but as you work through each question please read it aloud and say what you are thinking. After you have answered a question, I may ask you questions about how you came to your answer. I will answer any question about the questionnaire once we are finished. Please know that you are not being tested – the questionnaire is being tested. There are no wrong or right answers.
Verbal probes	• What does the term X mean to you? • Can you repeat that question in your own words? • How sure are you of your answer? • How did you come to your answer? (What did you think about?) • Was that easy or hard to answer? • How do you feel about answering that question?

Note. Cognitive interview procedures and verbal probes adapted from "Think-aloud, verbal probing, and other techniques" in *Cognitive Interviewing: A tool for improving questionnaire design* by G. Willis, 2005, SAGE Publications, Inc. p. 42-65.

All CIs were audio-recorded, and field notes documented after each interview. Interviews lasted an average of 67 minutes (range 33-101 minutes). Issues raised by a participant were then reviewed with the research team and discussed in subsequent CIs with other participants. The CIs concluded when participants raised no new issues. Quotations are provided to elucidate key points made by the participants. To protect their confidentiality, the quotations are presented with limited identifiers (i.e., only participant type and phase of dialysis).

Analysis

The researcher created charts to collate the CI data, with separate charts for patients and partners. In the chart, the items of the SDQ formed the rows with each participant having a separate column. While listening to the audio-recordings, the researcher transcribed participants' responses and added them to the appropriate chart. The field notes offered additional context and were included on the chart. Then, the responses were coded using an adapted version of the coding framework presented in (Mason, Skevington, & Osborn, 2008) (see Table 4). These were then compiled onto an overall chart (Appendix H) to reflect the full development process. The research team, with expertise in chronic illness, nephrology and questionnaire design, reviewed the outcomes of the CIs and approved of the changes made to the items.

5.4.3 Results

Overall, the concepts within the SDQ were found to be meaningful to the participants. Comments on the measure included:

> *These are good questions to be asking people who may be experiencing these life issues for first time* (Patient, Dialysis)

The CIs revealed issues in comprehension, retrieval, judgement, responding and formatting (details provided in Table 5.3). Although all questions required some form of modification, only five questions raised significant issues in their interpretation and comprehension and, thus, were deleted (Q7, 8, 18, 27, 31). One question was found as only applicable to partners (Q29) as it repeatedly needed clarification in meaning for patients (see Appendix H for the full overview of the development of the questions as a result of the CIs).

The CIs also underlined the extent to which partners are not prioritised during early dialysis. Partners repeatedly asked if the items were asking about their own thoughts, QOL and health. The enmeshment of the partner’s lives in the patients was made evident by one partner questioning if an item was about her own QOL and then forming her response by considering the patient’s health. Two partners stated that their thoughts and views were not important in early dialysis and that they held them back at that stage, “My views weren’t relevant at this point” (Partner, Dialysis) and “I was afraid at first but still always holding something back” (Partner, Dialysis). In light of these comments, the instruction section in the final version of partners’ measures explicitly stated that we were interested in their views and added emphasis to the word “your” in items, where appropriate.

Table 5.3
Coding framework for cognitive interviews and frequency of issues

Aspects of information processing	*Definition*	*Examples*	*Questions*
Comprehension			
Difficult item	Delay in comprehending question meaning and difficulty answering	Q18: Dialysis affects patients' lives in various ways and in early dialysis it is unlikely they could manage many tasks (2/10)	**Q7, 8**, 11, 12, **18**
Wording	Issue with wording or phrasing of the question	Q9: 'Normal life' discussed and 'daily life' suggested (3/10)	Q3, **7**, 9, 12, 15, 20, 32
Need for clarification	Participant needed more information to answer question	Q29: Patients asked if it included time on dialysis or just when they were off it (4/10)	Q1, 2, 29
Misinterpretation	Question not interpreted the way it was intended	Q21: Both patients and partners thought question asked about their own positivity (3/10)	Q21, 22, 29
Multiple interpretations	There are two or more possible interpretations	Q27: Talked about communication in regard to wider context rather than within couple and did not like phrasing (5/10)	Q10, 13, 16, **27, 31**
Semantic difficulties	The meaning of a word or phrase is not understood	Q1: Definition of QOL questioned and noted that everyone may define it differently (1/10)	Q1
Hesitation	Excessive pausing or re-reading while comprehending the question	Q26: Re-read question two times but confidently marked answer (1/10)	Q26

Incomprehension	The meaning of the question is not understood	NA	
*Retrieval**			
Lack of information	Participants did not have knowledge that could inform question	Q3: Partners also stated they had no or low expectations (3/10)	Q1, 3, 5, 16
Judgement			
Relevance	The extent to which the question is relevant to their experience	Q23: Partners commented that during early dialysis they did not express their feelings because they were focusing on being positive or still learning about dialysis (2/10)	Q1, 13, 14, 15, 21, 22, 23, 28
Repetition	A question has the same meaning as a previous one	Q7: Question similar to other Q9, Q16, Q17 (3/10)	**Q7, 8**, 11, 24, 25, 26
Time frame	Refers to the reference point for answering the question	Q1: Patient considered question in reference to QOL before CKD rather than last 2 weeks (1/10)	Q1, 2, 9, 34
Responding			
Hesitation	Excessive pausing or hesitation	Q10: Partner thought about the patient's engagement in overall treatment (1/10)	Q3, 8, 10, 12, 25
Response scale confusion	Difficulty when marking response on the scale	Q22: Selected 1 when verbal reasoning indicated a score of 5 (1/10)	**Q7**, 22, 31, 33
Missed question	Question not answered, either intentionally or accidentally	Q13: Spoke about the question but could not select a response (1/10)	Q3, 12, 13
Response scale wording	Issues with wording of the response scale	Q32: Difficult to differentiate	Q1, **7**, 32

		between 4=A great deal and 5=Completely (1/10)	
Response scale scoring	Issues with the scoring of the response scale	Q12: Noticed the scoring was different from previous questions (reverse scored) and recommended changing it to prevent mistakes (1/10)	Q2, 12, 25
Other			
Formatting	Changes to format recommended	Q9: Recommended moving it after Q6 (1/10)	Q4, 5, 9
Positive feedback			
Important question**	Question highlighted as important	Q6: Patient said it was key to adapting to dialysis (1/10)	Q6, 33, 34
Good question	Participant states that a question is good	Q12: Patient stated they liked it because it asked about an often-overlooked topic (1/10)	Q12, 20, 21, 22
Straight-forward question**	Participant states a question is straight-forward	Q11: Patients stated it was a clear question (2/10)	Q11

Note. Adapted from "The quality of life of people in chronic pain: Developing a pain and discomfort module for use with the WHOQOL," by V. Mason, S. Skevington, and M. Osborn, 2008, Psychology & Health, 23, p. 139.
*Retrieval was added to the framework and adapted from *Cognitive Interviewing: A tool for improving questionnaire design*, by G. Willis, 2005, Sage Publications, pg.38.
***Codes added by the research team.*
Bold question numbers indicate deleted questions.

Participants recommended that items be added on their expectations of dialysis at pre-dialysis, how bothersome dialysis is to partners, the impact on emotional health (2 questions), and feeling isolated due to dialysis. Modifications were made to the stem of the items (e.g., non-leading openings such as ‘to what extent’ and ‘how much’) to facilitate their comprehensibility.

The end result of this phase of the study was the creation of patient and partners versions of the SDQ, including items adapted for use at pre-dialysis and after starting dialysis (see Appendix U & V). The patient versions consisted of 33 items at pre-dialysis and 30 items after starting dialysis. The partner versions comprise 34 items at pre-dialysis and 31 items after patients started dialysis. The items address three domains, dialysis expectations (pre-dialysis: 9 items, dialysis: 6 items), accepting dialysis (7 items at both pre-dialysis and dialysis), and DRC (patient version: 17 items at pre-dialysis and dialysis, partner version: 18 items at pre-dialysis and dialysis). The readability of the questionnaire is at the basic level (Flesch-Kincaid grade level 5.5).

5.5 Study 3.3: Preliminary assessment of the psychometric properties of the SDQ

5.5.1 Aims

- To assess basic psychometric properties of the SDQ in a sample of patients preparing to start dialysis and their partners.

5.5.2 Methods

Study design and setting

Data obtained at baseline (pre-dialysis) in a longitudinal study (Chapter 6, Study 4) were used to evaluate the performance of the individual items, internal consistency of the domains and construct validity. This study was conducted in 10 renal research units across England. All participants gave verbal and written consent prior to data collection. The study received ethical approval in the UK from an NHS Research Ethics Committee (Ref no. 17/NW/0501). Participants completed paper versions of the self-report questionnaires in their homes (95%) or in the renal clinic (5%); of these 97% completed the questionnaires without assistance; two participants completed online versions of the questionnaire.

Study participants

Participants were recruited from the renal registries of the participating nephrology units from November 2017 – September 2018. Patients meeting the following criteria were eligible to participate: 1) they were in the care of nephrologists for ERF, 2) their clinical factors indicated that they were likely to start dialysis in the next two months (e.g., estimated glomerular filtration rate [eGFR, an indicator of how well the kidneys are eliminating toxins] of <10) , 3) they were planning to start on a form of haemodialysis (HD) or peritoneal dialysis (PD), 4) they were in a spousal-type relationship with someone they considered their “partner,” and 5) they were 18 years or older. Included in the study were incident patients (i.e., who had not been on a form of renal replacement therapy before) and patients with a failing transplant who were planning to start dialysis but had not been on any form of out-patient dialysis in the last six months. Patients were not eligible for the study if they had acute kidney injuries.

A partner was defined as a person in a spousal-type relationship who provided informal care in the form of emotional, physical and/or treatment-related support to an eligible ERF patient. Both patients and partners needed to read and comprehend English.

Measures

The SDQ comprises three domains that relate to expectations of dialysis, accepting dialysis and DRC. There are two versions of the SDQ, one for patients and one for partners, and has been adapted for use at pre-dialysis and after starting dialysis. The preliminary psychometrics analysis was conducted using data drawn from pre-dialysis only. In the pre-dialysis SDQ, the patient version consists of 33 items and the partner version has 34 items. The questions use a 1-5 response scale and a response box for the two open-ended questions. High scores indicate high expectations that dialysis will improve health or QOL, being more accepting of dialysis, and cohesive dyadic relationship characteristics. Fives items are reversed scored (accepting dialysis: 12, 13; DRC: 19, 30, 31). The domains contain the following number of items: expectations of dialysis (7), accepting dialysis (7) and DRC (patients: 17, partners: 18). Although the items within the measure address similar core concepts in both patient and partner versions, the phrasing differs slightly between them; therefore, the scores were examined separately by group.

Quality of life was assessed using the WHOQOL-BREF (Skevington et al., 2004). This instrument reflects a multi-dimensional model of subjective QOL in health and is assessed by 26 items. Two items form the WHOQOL general QOL facet and 24 specific items are scored in one of four domains: physical, psychological, social relationship and environment. The primary outcome variable in this phase of the study was WHOQOL general QOL, which is the mean of the overall QOL item (How would you rate your quality of life? 1=Very poor, 2=Poor, 3=Neither good nor poor, 4=Good, 5=Very good) and the health-related QOL item (How satisfied are you with your health? 1=Very dissatisfied, 2=Dissatisfied, 3=Neither satisfied or dissatisfied, 4=Satisfied, 5=Very satisfied) with a scoring range of 1-5. A score less than 3 is commonly regarded as indicating poor or very poor QOL whereas scores more than 3 suggest good to very good QOL.

Socio-demographic information (gender, age, relationship status, ethnicity, employment status, education) was collected via a self-report section in the questionnaires. Clinical data (eGFR, haemoglobin, serum albumin, comorbidities and mode of dialysis) were collected from patients' medical records.

Analysis

Descriptive statistics (means, standard deviations, skew and kurtosis) were calculated for the individual items and the three domain scores by group. The skew and kurtosis values, as well as histograms for the individual items and domains scores, were inspected for non-normal distributions.

Cronbach's α was used to examine the internal consistency the domain scores and the contribution of each item to the domain. The internal consistency was deemed to be good if it was >0.70 but <0.90 (Streiner & Norman, 2008). Pairwise correlations were used to determine inter-item correlations within the domains, correlations between the domains and correlations between the domains and WHOQOL general QOL, with scores > 0.20 considered acceptable (Streiner & Norman, 2008).

5.5.3 Results

Participant characteristics

Between November 2017 and September 2018, 153 patients were invited to take part in the study. Of these, 83 patients and their partners completed the baseline questionnaires. Participants' characteristics are provided in Table 5.4.

Data examination

Questionnaire data were cleaned and overall missing data by domain were as follows: dialysis expectations 3%, accepting dialysis 3% and DRC 2%.

Scale properties

Appendix O provides the results of the preliminary evaluation of the psychometric properties of the patient and partner version of the pre-dialysis SDQ by domain and item. Participants used the full response scale. While there was no significant skew or kurtosis in the distribution of responses to any items (defined as values above 1.0 for each), minor deviations from normality are described below.

In the patient version, the domain scores of both dialysis expectations and accepting dialysis were normally distributed. The DRC domain score were not skewed but had a slight leptokurtic distribution (i.e., the distribution has a sharp peak at the mean). A review of the individual items indicated moderate skew in 8 items (dialysis expectations: 3, 4, 5; accepting dialysis: 10, 13, 14; DRC: 16, 22). Leptokurtic distribution was evident in 10 items (dialysis expectations: 2, 3; accepting dialysis: 13, 14; DRC: 24, 25, 27, 28, 31). However, neither the skew nor the kurtosis levels in these items were deemed sufficient to discard or modify the items.

In the partner version, accepting dialysis and DRC scores were moderately skewed and had slight leptokurtic distribution (see Appendix O). Only 3 items had moderate skew values (dialysis expectations: 1; DRC: 16, 28). Leptokurtic distribution was present in 12 individual items (accepting dialysis: 12, 15; DRC: 18, 21, 22, 24, 26, 27, 29, 31, 32, 34).

Table 5.4

Socio-demographic information of patients and partners at pre-dialysis

	Patients N= 83	*Partners* n= 83
Male n (%)	52 (63%)	31 (37%)
Age *M* (*SD*)	64 (14)	63 (15)
Married n (%)	70 (84%)	70 (84%)
Highest level of education n (%)		
None	4 (5%)	4 (5%)
Primary school	3 (4%)	2 (2%)
Secondary school	40 (49%)	33 (40%)
College or training certification	25 (30%)	36 (43%)
University – undergraduate	4 (5%)	5 (6%)
University – postgraduate	6 (7%)	3 (4%)
Ethnicity n (%)*		
White British	75 (93%)	77 (93%)
Employment status n (%)		
Retired	44 (54%)	45 (55%)
Working full-time	20 (25%)	15 (18%)
Working part-time	5 (6%)	10 (12%)
Unable to work	12 (15%)	6 (7%)
Do not work	-	6 (7%)
Mode of dialysis n (%)		
HD	50 (66%)	-
PD	24 (33%)	-
Clinical variables *M* (*SD*)		
eGFR	9.9 (4.0)	-
Haemoglobin g/L	107.9 (15.9)	-
Serum albumin g/L	37.9 (6.0)	-
Comorbidity risk n (%)		
Low	23 (31%)	-
Medium	42 (56%)	-
High	10 (13%)	-
Primary renal diagnosis n (%)^		
Glomerulonephritis	10 (20%)	-
Polycystic	9 (18%)	-
Diabetes	7 (14%)	-
Renal vascular disease	5 (10%)	-
Hypertension	4 (8%)	-
Other	4 (8%)	-
Uncertain	7 (14%)	-

Note. HD= haemodialysis, PD=peritoneal dialysis, eGFR= estimated glomerular filtration rate.

^ >20% missing data

On initial assessment all the domains showed good internal consistency in both patients and partner versions (patients: dialysis expectations α=0.90, accepting dialysis α=0.750, and DRC α=0.918; partners: dialysis expectations α=0.858, accepting dialysis α=0.810, DRC α=0.901). Each item's contribution to the domain score was also calculated and indicated the internal consistency of the domain improved if some items were removed (patients: 4 items - 7, 13, 14, 19; partners: 3 items - 7, 19, 29).

Homogeneity

Each item was also examined for its relation to the other items in the domain. Low correlations were found between 4 items in patients (dialysis expectations: 7; accepting dialysis 13, 14; DRC: 19) and 4 items in partners (dialysis expectations: 7, DRC: 19, 22, 29). Appendix O contains the item-total correlations for each item.

Construct validity

The domain scores within patient and partner versions were examined for relatedness of the constructs. In the patients, dialysis expectations and accepting dialysis were positively correlated (r=0.3201, p<0.05) and accepting dialysis and DRC were also positively correlated (r= 0.439, p<0.05). Expectations and DRC did not have a statistically significant correlation (r=0.105, p>0.05). In the partners, there was a significant positive correlation between accepting dialysis and DRC (r=0.477, p<0.05). The other domains were not significantly correlated (dialysis expectations and accepting dialysis, r=0.093, p>0.05; dialysis expectations and DRC, r=0.103, p>0.05). These results suggest that the domains are separate constructs which may be related to each other.

The domain scores in patients and partners were assessed for correlations with the WHOQOL general QOL scores at pre-dialysis. In patients, the dialysis expectations domain was negatively correlated with general QOL (*r*= -0.27, *p*<0.05) but neither accepting dialysis nor DRC, as measured here, were strongly correlated with general QOL (*r*=0.02, *p*>0.05; *r*=0.12, *p*>0.05). In partners, DRC had a significant positive correlation with QOL (*r*=0.23, *p*<0.05) but dialysis expectations and accepting dialysis were not correlated with QOL (*r*= 0.4, *p*>0.05; *r*=0.17, *p*>0.05).

Recommendations

These preliminary psychometrics reveal that some items in each version of the SDQ did not perform as well as the others in this sample (4 items in patients - dialysis expectations: 7, accepting dialysis: 13, 14, DRC: 19; 3 items in partners - dialysis expectations: 7, DRC: 19, 29). The removal of these items improved the internal consistency as follows: dialysis expectations – patients: α=0.927, partners: α=0.903; accepting dialysis - patients: α=0.780, partners: no changes recommended; DRC – patients: α=0.928, partners: α=0.902. The removal of these items from the measure should be considered in future research.

5.5.4 Discussion

In this study we aimed to create a measure which addressed key psychological and interpersonal factors in patients and partners during the early phases of dialysis. Using qualitative methods, we identified three factors, namely dialysis expectations, accepting dialysis and DRC, as important during this time period. Then we created questions, derived from rich interview data, which address these constructs. Next, we employed CI techniques to evaluate the comprehensibility and suitability of the questions in sample of ERF patients and their partners. Finally, preliminary psychometric analyses were conducted on both patient and partner versions of the pre-dialysis SDQ and indicated that overall it has good individual item performance and internal consistency. The emerging evidence in regard to construct validity suggests the domains are distinct yet may be related to each other and QOL. The end result is the SDQ which is a patient and partner-centred measure which may be used to assess psychological and dyadic factors when patients and partners are preparing to start dialysis.

The development of the SDQ arose after a review of existing questionnaires in chronic illness and ERF indicated that none applied to the early phases of dialysis and were applicable to patients' partners. While repositories provide access to validated measures and items across a range of illnesses and populations (e.g., Patient-Reported Outcomes Measurement Information System), the usage of these would not have met the nuanced experiences of the dyads preparing to start dialysis. Furthermore, our access to in-depth qualitative data on the experiences of patients and partners during the early phase of dialysis provided an opportunity to fill this gap. Research may be used to create instruments in areas where other questionnaires are not appropriate or little is known about the topic (Streiner & Norman, 2008).

The identification of DRC as important during the early phases of dialysis and related to accepting dialysis and partners' QOL complements findings reported in ERF qualitative research with dyads. Wise, Schatell, Klicko, Burdan, and Showers (Wise et al., 2010), who conducted interviews with patients who had started on short daily home HD (SDHHD) and their partners, noted the importance of relationship characteristics in relation to dyads' adjustment to SDHHD. Dyads who were well-adjusted were optimistic, in a solid relationship, shared duties, had clear roles, communicated effectively and were mutually respectful. Similarly, patients, who had recently started HD, and their family members, described the significant impact dialysis had on their roles and personal relationships (Monaro et al., 2014). Taken together, these findings highlight the vital role the dyadic relationship play in accepting dialysis and QOL, especially in partners, when adapting to dialysis.

There is limited research which has explored the role expectations plays in QOL over the transition onto dialysis. Our qualitative findings indicated that high expectations of dialysis, which if not met, are associated with poor QOL when the patient starts dialysis. This relationship between dialysis expectations and QOL was supported by the preliminary psychometric evaluation where patients' high dialysis expectations were negatively associated with their QOL. This echoes the findings of Stringer and Baharani (2012) who found patients with expectations diminished markedly after starting dialysis. Further research is needed to determine the role of dialysis expectations on QOL in both patients and their partners.

Accepting dialysis is a different perspective on acceptance as it focuses on the treatment rather than the illness. In our analysis of the qualitative interviews, we identified that accepting dialysis had sub-levels comprising both cognitive and behavioural elements. These findings complement a review by Chan (2012) who differentiated between stoic and active acceptance. Active acceptance involved mental processes, such as reconciling negative impact of the illness, and engaging in lifestyle changes. The accepting dialysis domain in the SDQ may provide clinicians a quick and useful way to profile patients and partners and assess their style of acceptance. Although we did not find the relationship between being accepting of dialysis and QOL to be strongly correlated, other research with dialysis patients provides evidence that accommodative coping styles, in which acceptance is a key feature, are positively associated with QOL (Poppe, Crombez, Hanoulle, Vogelaers, & Petrovic, 2013).

The domains of the SDQ complement the biopsychosocial model of QOL which found cognitive appraisals (e.g., illness perceptions, control of illness) and social support to have a medium effect on dialysis patients' QOL (Chan et al., 2012). This model of QOL and its psychosocial correlates has not yet been explored in the partners of dialysis patients, and the evidence in this present study suggests DRC, a specific element of social support (i.e., the patient-partner dyad), is related to QOL in partners. Although research with partners of ERF patients is burgeoning, there remains little consensus as what to measure and how to measure it (Gilbertson et al., 2019). A majority of research examines burden and affect with limited consideration of partners' cognitive appraisals or interpersonal relationship with the patient. Furthermore, these studies tend to be conducted once patients are established on dialysis rather than during the early phases of dialysis.

As little is known about the experiences of patient-partner dyads in the early phases of dialysis, our usage of existing semi-structured interview data permitted an inductively driven approach when identifying factors and generating the questions. In study 3.2, the CIs, further enhanced the measure by ensuring the items used language that was accessible and comprehensible. Through the CIs, valuable insight was gained into complex issues such as item interpretation and response judgement (i.e., partners revealed the extent to which their views are not sought; patients often recalled healthy periods in their life rather than their recent health; hence the need to set clear time frames within the questionnaire). While the researcher aimed to conduct all the CIs individually, one dyad requested their CIs be conducted together. Although shorter duration than the other CIs, the findings within this dyad proved insightful as they debated question meanings and terms between themselves yielding rich natural data that occurs in focus groups.

A limitation of this study was that the CI participants also took part in the over-arching study and were predominantly White British male patients and their female spouses. It is possible that their experiences and the psychosocial factors that impacted them may not be reflective of the wider ERF population. However, the renal research advisory group who reviewed the initial draft of the SDQ confirmed the relevancy of the questions. Another consideration is that four of the dyads had been on dialysis for more than one year when they took part in the CIs. Being established on dialysis may have affected their ability to recall their own attitudes about starting dialysis or identify additional factors important during the early weeks.

A strength of this questionnaire is that it reflects topics that were stated by patients and their partners as important to them to during a stressful time in ERF treatment, and in their relationship. Furthermore, participants had the opportunity to comment on items which were derived from a data set to which they contributed. Their participation in the semi-structured interviews may have facilitated their ability to engage in the CIs (which can be a difficult research task for some people) because they were familiar with the topic and the researcher.

Conclusion

The SDQ is short measure which addresses key psychological and interpersonal factors, which were identified using qualitative methods. The items on the SDQ were created using a data-driven approach and then assessed for comprehensibility through cognitive interviews. The preliminary psychometric evaluation indicates that the items and domains perform well and there is emerging evidence that they are related to QOL. Further research with a much larger sample is needed to assess the structure of the SDQ and validate it for use in renal clinics.

Chapter 6: Starting dialysis improves quality of life for patients but is impaired, initially, for their partners: a multi-centre, longitudinal study

Preface

The paper presented in this chapter was submitted to *BMC Nephrology* in January 2020 and has been formatted in accordance with the guidelines of the journal. The authors are Currie Moore, Lesley-Anne Carter, Sandip Mitra, Suzanne Skevington and Alison Wearden. The PhD candidate designed the research, developed the study protocol, applied for ethical approval and adoption onto the National Institute of Health Research (NIHR) Clinical Research Network, recruited participants and collected data at the central research site, provided training to the nine other research sites and oversaw their data collection, and conducted all the analyses, under the guidance of Dr. Lesley-Anne Carter, Prof. Suzanne Skevington, Dr. Sandip Mitra and Prof. Alison Wearden. The PhD candidate conducted the data entry from November 2017-April 2018, and Ms. Olga Balompa, research assistant, entered the questionnaire data from April 2018 – August 2019, under the guidance of the PhD candidate who provided training and examined the input data for accuracy. The PhD candidate coded the clinical variables, cleaned the data and inspected missing data, under the guidance of the supervisory team. The PhD candidate drafted the first version of manuscript which was commented on by Dr. Rachael Powell as well as the supervisory team. All authors agreed on the interpretation of the results, provided meaningful intellectual content, revised the manuscript and approved the final version.

6.1 Abstract

Background: Quality of life (QOL) is important to renal patients and their partners. Despite the first 12 weeks being a critical time in the treatment pathway, limited research exists which examines how the transition onto dialysis impacts both of their QOL. The aims of this study were to describe changes in QOL in patients and their partners from pre-dialysis to 12 weeks after starting dialysis and to examine if it impacted their QOL differently.

Methods: Patients and their partners, recruited from 10 renal units in England, completed questionnaires at pre-dialysis (n=166 participants, 83 couples), 6 weeks (n=85 participants, 42 couples) and 12 weeks (n=78, 39 couples) after starting dialysis. On each occasion participants completed a QOL questionnaire (WHOQOL-BREF). Multilevel modelling accommodated the nested structure of couples with repeated measures within participants. Three-level random intercept models were used to estimate changes in WHOQOL general QOL and its four domains (Physical, Psychological, Social and Environment). The association of clinical and socio-demographic variables with changes in general QOL were assessed using two-level random intercept models.

Results: Patients reported positive changes in general QOL from pre-dialysis to 6 weeks ($\beta=0.42$, $p<0.001$, 95% CI 0.19, 0.65) and from pre-dialysis to 12 weeks ($\beta=0.47$, $p< 0.001$, 95% CI 0.24, 0.71). Partners' general QOL decreased significantly from pre-dialysis to 6 weeks ($\beta=-0.24$, $p=0.04$, 95% CI -0.47, -0.01) but returned to its original level at 12 weeks. Patients reported improvements in the physical domain between pre-dialysis and 12 weeks ($\beta=6.56$, $p<0.004$, 95% CI 2.10, 11.03). No other domains changed significantly in patients or partners. High comorbidity risk level and female gender were significant moderators of general QOL in patients. No other clinical or socio-demographic variables were significantly associated with changes in general QOL in patients or partners.

Conclusions: Patients reported significant improvements in their general and physical QOL after starting dialysis. Partners' general QOL worsened after patients started dialysis but improved by 12 weeks. Both patients and partners may benefit from additional educational and counselling services in the lead up to, and immediately after starting dialysis, which could facilitate the transition onto dialysis and improve QOL in both.

6.2 Background

When preparing to start dialysis, renal patients and their primary caregivers (partners) consistently state that quality of life (QOL) is an important concern (Moore et al., 2018; Morton, Devitt, et al., 2010; Morton et al., 2011). Quality of life (QOL) is defined by the World Health Organization (The WHOQOL Group, 1994) as "*an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns*" (p. 43). This definition complements the established renal failure (ERF) illness trajectory of dialysis patients, as described by Jablonski (Jablonski, 2004), which indicates that changes occur in all areas of patients' lives as they start and initially adjust to dialysis, referred to as the "crisis" phase (p. 54). Psychosocial interventions delivered in the critical first 12 weeks have been linked with better adjustment and decreased levels of depression in patients (Beder, 2000). Despite general well-being linked to better compliance, attendance of dialysis sessions and adjustment (Kimmel et al., 1998), research primarily focuses on patient survival or hospitalization rates rather than examining QOL (Bradbury et al., 2007; Robinson et al., 2016). Despite playing a key role in patients' dialysis care (Cicolini, Palma, Simonetta, & Di Nicola, 2012; Gayomali et al., 2008), little is known about how partners' QOL is affected during the crisis phase.

Quality of life is a broad field with a multitude of scales to measure QOL and factors relating to it. Although patients and partners state QOL is a primary concern, it is not included as a core outcome measure in ERF randomized control trials due to conceptual difficulties with its meaning and measurement

(Evangelidis et al., 2017). ERF research may benefit from using a generic QOL measure which directly addresses QOL, rather than ERF-specific or health status measures, and includes areas related to QOL (e.g., physical and emotional health, social support). One such measure is the World Health Organization's WHOQOL-BREF short questionnaire (Skevington et al., 2004) which was created by an international collaboration, using an inductively-driven process, with the specific aim of designing a scale to measure QOL across all types of chronic illnesses and healthy people (Skevington & McCrate, 2012). It includes a general QOL facet covering overall QOL and health and four QOL domains, physical, psychological, social and environment. Furthermore, haemodialysis (HD) and peritoneal dialysis (PD) patients and their partners have outlined energy, fatigue, ability to travel, work and sleep (Manera et al., 2019; Urquhart-Secord et al., 2016) as outcomes important to them, all of which are assessed in the WHOQOL-BREF.

Qualitative research including ERF patients and their partners suggests that they experience significant lifestyle changes as they adjust to dialysis (Ekelund & Andersson, 2010; Monaro et al., 2014; Moore et al., 2019) which impacts all areas of their QOL (Finnegan-John & Thomas, 2013). Our recent research with patients in the early phases of dialysis (i.e., pre-dialysis or on dialysis <15 months) and their partners found that couples who adopted a team-like approach minimized the impact of dialysis on their relationship, and ultimately their QOL (Moore et al., 2019). The findings of this study also suggest that starting dialysis affects patients and partners differently. For example, patients spoke of dialysis alleviating their worries and improving their health whereas partners reported an increase in burdens and significant changes in their personal lives.

To date, only one longitudinal study has examined how health status in both patients and partners changes after the start of dialysis. Fan et al. (2008) conducted a single-centre study with PD patients and their partners. Both completed the Medical Outcomes Study 36-Item Short Form Survey (SF-36), which measures various components of physical (PCS) and mental functioning (MCS), before the patient started PD and then again one year later. Before starting PD, PCS and MCS scores for both were lower than those of the general population. At one year, PCS and MCS scores improved modestly, and the social functioning subscale of the MCS showed a statistically significant improvement in both patients and partners. It remains unclear how starting dialysis impacts patients on other types of dialysis (e.g., HD) or their partners. Further research is needed to examine the critical first 12 weeks and investigate QOL in its broader conceptualisation, rather than focusing on functioning as measured by the SF-36.

Therefore, the aim of this study was to assess changes in QOL in patients and their partners, measured by the WHOQOL-BREF, during the crucial transition onto dialysis, from pre-dialysis to 12 weeks after starting dialysis. The primary goal was to describe QOL changes in both WHOQOL general QOL and its domains over this transition period in patients and partners. We also sought to examine whether starting dialysis affects patients’ and partners’ QOL differently. We predicted that patients would report improvements in general QOL at 12 weeks and that partners’ QOL would steadily worsen. Additionally, we examined whether clinical and socio-demographic factors were associated with changes in QOL.

6.3 Methods

6.3.1 Study design and setting

We used a multi-centre, longitudinal design to study changes in QOL in response to starting dialysis in patients and their partners. To closely examine the transition onto dialysis, patients and partners completed the study measures at pre-dialysis, 6 weeks and 12 weeks after starting dialysis. The study was adopted onto the National Institute for Health Research (NIHR) Clinical Research Portfolio (CPMS ID 35781) and conducted by 10 renal units across England. All participants gave verbal and written consent prior to data collection. The study received ethical approval in the United Kingdom from a National Health Service Research Ethics Committee (Ref no. 17/NW/0501).

6.3.2 Study participants

Participants were recruited from November 2017-September 2018. Renal research nurses or members of the clinical care teams identified potential participants from their renal registries. Patients meeting the following criteria were eligible to participate: 1) they were in the care of a nephrologist for ERF, including patients who were starting dialysis in an unplanned manner (i.e., people who have been under the care of nephrologists for less than 3 months before commencing dialysis), 2) their clinical factors indicated that they were likely to start dialysis in the next two months (e.g., estimated glomerular filtration rate [eGFR, an indicator of how well the kidneys are eliminating toxins] of <10) , 3) they were planning to receive a form of out-patient dialysis for the management of ERF, including all forms of HD and PD, 4) they were in a spousal-type relationship with someone they considered their “partner,” and 5) they were 18 years or older.

Incident patients (i.e., those who had not been on a form of renal replacement therapy before) and patients who had a failing transplant and were planning to start dialysis, but had not been on any form of out-patient dialysis in the last six months, were included. Patients were not eligible for the study if they had acute kidney injuries.

A partner was defined as a person in a spousal-type relationship who provided informal care in the form of emotional, physical and/or treatment-related support to an eligible ERF patient. Partners either self-identified as the patient's partner or were identified as such by the patient. Inclusion criteria for partners were that they were in a spousal-type relationship (e.g., spouse, partner, boyfriend or girlfriend) with the patient and were 18 years or older. Both patients and partners needed to read and comprehend English.

6.3.3 Procedure

Those meeting the inclusion criteria were invited to participate by the site investigator (SI). If the SI was not part of the patient's clinical care team, a member of the clinical care team obtained the patient's consent to contact before the SI approached the patient. The SI gave potential participants a letter of invitation and information sheet and provided further information about the study. Participation in the study was voluntary, and all recruited participants gave their written consent prior to taking part. This study only included couples in which both patients and their partners consented to participate and who both returned their pre-dialysis questionnaires. At 6 and 12 weeks, all data from patients and partners were included, even if the other member of the couple did not complete the questionnaire.

Before giving out the questionnaires, the SI reminded participants that the questions ask about their QOL, health and their thoughts about dialysis. Then, the SI either gave paper-versions of the questionnaires to the participants at a clinical appointment or mailed the questionnaires to them directly. Patients and partners completed similar versions of the questionnaires at each assessment and were requested not to confer. Patients and partners completed the questionnaires at home (95%) or in the renal unit (5%). Only three participants (2%) requested the SI read the questionnaire aloud; SIs were trained to administer the questionnaires in a standard manner.

6.3.4 Measures

Quality of life was assessed using the WHOQOL-BREF (Skevington et al., 2004). This instrument reflects a multi-dimensional model of subjective QOL in health and is assessed by 26 questions. Two questions (items) form the WHOQOL general QOL facet and 24 specific items are scored in one of four domains: physical, psychological, social relationship and environment. Participants assess their QOL over the last two weeks and rate responses to each item on a five-point Likert scale, where higher scores indicate better QOL. The primary outcome variable in the present study was WHOQOL general QOL, which is the mean of the overall QOL item (How would you rate your quality of life? 1=Very poor, 2=Poor, 3=Neither good nor poor, 4=Good, 5=Very good) and the health-related QOL item (How satisfied are you with your health? 1=Very dissatisfied, 2=Dissatisfied, 3=Neither satisfied or dissatisfied, 4=Satisfied, 5=Very satisfied) with a scoring range of 1-5. A score less than 3 is commonly regarded as indicating poor or very poor QOL whereas scores more than 3 suggest good to very good QOL. The WHOQOL-BREF domain scores were transformed onto a scale from 0-100 to facilitate comparisons between different domains with unequal item numbers. Domain scores less than 50 indicate poor or very poor QOL. It has been validated in both well (Skevington & McCrate, 2012) and dialysis populations (Griva et al., 2016) and has good internal consistency and construct validity (Skevington et al., 2004). Furthermore, it has been found to be sensitive to change across health conditions (Diehr et al., 2006; Skevington & Epton, 2018)

Additionally, participants completed questionnaires on key factors related to QOL, namely dialysis expectations, accepting dialysis, patient-partner relationship characteristics, anxiety, depression and symptoms. These measures are mentioned here for completeness but will not be discussed further.

Socio-demographic information on gender, age, relationship status, ethnicity, employment status and highest educational level attained was self-reported at pre-dialysis. At 6 and 12 weeks, patients self-reported any changes in their dialysis treatment including mode of dialysis, access site (i.e., how they connected to their dialysis machine; e.g., catheter, fistula), renal unit, and if they had been hospitalized. Clinical data were collected from patients' medical records by the SI in each renal unit at each time point. Clinical data included eGFR (pre-dialysis only), haemoglobin, serum albumin, dialysis adequacy (6 and 12 weeks only), comorbidities and dialysis information (mode of dialysis, unplanned or planned start, patient type – incident or prevalent, and dialysis status 3 months and 6 months after participating). Patients' comorbidity data were scored following the guidelines of Davies, Phillips, Naish, and Russell (2002). In this scoring method, active comorbidities are classified into one of seven domains (malignancy, ischaemic heart disease, peripheral vascular disease, left ventricular dysfunction, diabetes mellitus, systemic collagen vascular disease, and other significant pathology), and the patient's comorbidity risk level is attained by adding the number of domains affected, scoring range 0-7 (0=low risk, 1-2=medium risk, ≥3=high risk).

6.3.5 Statistical analysis

Missing data were reviewed and descriptive statistics (means, standard deviations and percentages) were calculated for the QOL, socio-demographic and clinical variables. To determine if differences in participants who did and did not complete the study, t-tests were used for normally distributed continuous variables and chi-squared for categorical variables.

Multilevel modelling (MLM) provides a robust yet flexible framework to estimate changes over time in nested structures such as couples and can accommodate missing data unlike ANOVA based methods (Curran et al., 2010). For the present data structure, of repeated observations within individuals, nested within a social group (e.g., couple), a three-level mixed effects linear regression with random intercepts was used to estimate changes in WHOQOL general QOL. The MLM equation used for calculating the changes between groups (patients and partners) and over the follow-ups (F1=pre-dialysis to 6 weeks, F2=pre-dialysis to 12 weeks):

$$\mathrm{QOL} = \beta_0 + \beta_1 \mathit{Group} + \beta_2 \mathit{F1} + \beta_3 \mathit{F2} + \beta_4 \mathit{Group} * \mathit{F1} + \beta_5 \mathit{Group} * \mathit{F2} + u + v + e$$

Then, a linear combination of parameters was used to examine whether partners' QOL changed significantly from pre-dialysis to 6 weeks and pre-dialysis to 12 weeks.

To analyse changes in the WHOQOL domains, the above equation and sequence was replicated for each domain by replacing the outcome variable (QOL) with the transformed domain scores in each model.

To examine the association of clinical and socio-demographic variables with changes in WHOQOL general QOL, separate two-level models for patients and partners with interaction for time were conducted for each variable (Patients: haemoglobin, eGFR, serum albumin, mode of dialysis, comorbidity risk, gender and age; Partners: gender and age):

$$QOL_{ij} = \beta_0 + \beta_1 X_j + \beta_2 F1_{ij} + \beta_3 F2_{ij} + \beta_4 X_j * F1_{ij} + \beta_5 X_j * F2_{ij} + v_j + e_{ij}$$

Type of patient (incident or prevalent), start of dialysis (planned or unplanned), dialysis adequacy and primary renal diagnosis were not examined due to >20% missing data in these variables.

Paired sample t-tests were used to examine the differences in patients' scores within the facets of the WHOQOL physical domain at pre-dialysis and 12 weeks. A *p*-value of <0.05 was considered significant. All statistical analyses were conducted using Stata (Version 15.1, Stat Corp, College Station, Texas, USA).

6.4 Results

6.4.1 Questionnaire characteristics

Missing data on the WHOQOL-BREF were minimal at each time point in the WHOQOL general QOL (pre-dialysis (T1): 2% , 6 weeks (T2): 2%, 12 weeks (T3): 0%) and across items of the four WHOQOL domains (T1: 11%, T2: 4%, T3: 4%) with the exception of the item ‘How satisfied are you with your sex life?’ which had a higher percentage of missing data (T1: 11%, T2: 11%, T3: 15%). Questionnaires with >20% missing data across the 26 items were not included in the analysis (T1: 6%, T2: 0%, T3: 0%). WHOQOL general QOL and its domain scores were only calculated if 80% of the items comprising it were completed.

6.4.2 Participant characteristics

Of the 153 patients invited to join the study, 91 (59%) consented. Reasons given for not participating were: the patient or partner did not feel well enough (12), too busy to take part (8), patient started dialysis before informed consent and the first questionnaire completed (4), partner not interested in participating (3), patient waiting to receive a transplant (1), found the questions too intrusive (1), and did not offer a reason (25). Of the 88 couples who both consented, 83 couples returned their pre-dialysis questionnaires. Significant drop out (n=41 patients, 49%; n=40 partners, 48%) occurred from pre-dialysis to 6 weeks. At 12 weeks, two couples and 1 patient who did not take part at 6 weeks completed the 12-week questionnaire. Between the 6 and 12 weeks, 6 couples (14%) dropped out (see Figure 6.1).

Comparisons between participants who took part only at pre-dialysis versus those who completed questionnaires at 12 weeks indicated there were no statistically significant differences between the groups on the basis of QOL, socio-demographic, dialysis or clinical variables. Baseline socio-demographic, clinical and dialysis information are provided for the total sample in Table 6.1.

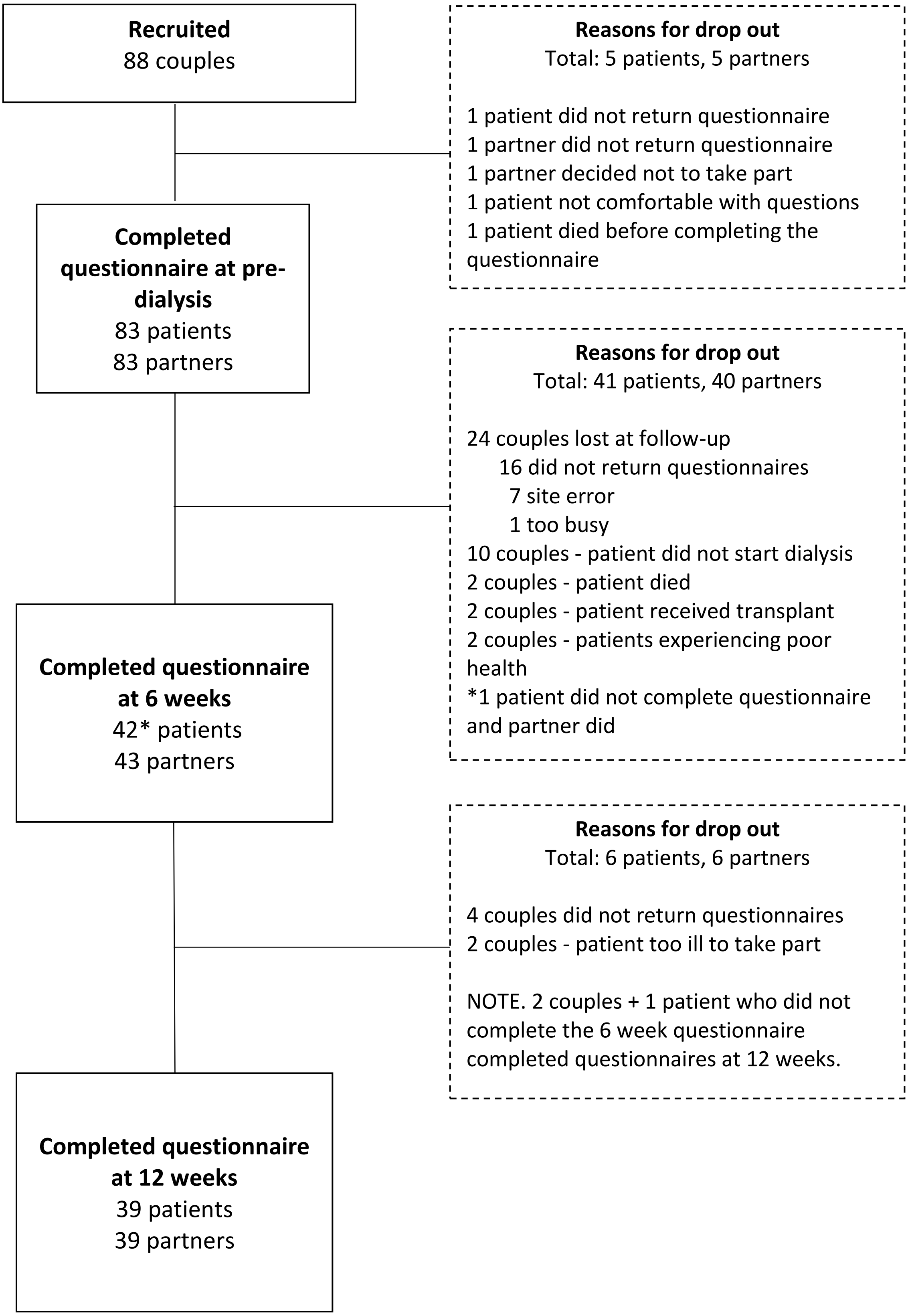


Figure 6.1. Flow chart showing recruitment and retention.

Table 6.1

Socio-demographic information of patients and partners at pre-dialysis

	Patients n= 83	*Partners* n= 83
Male n (%)	52 (63%)	31 (37%)
Age *M* (*SD*)	64 (14)	63 (15)
Married n (%)	70 (84%)	70 (84%)
Highest level of education n (%)		
None	4 (5%)	4 (5%)
Primary school	3 (4%)	2 (2%)
Secondary school	40 (49%)	33 (40%)
College or training certification	25 (30%)	36 (43%)
University - undergraduate	4 (5%)	5 (6%)
University - postgraduate	6 (7%)	3 (4%)
Ethnicity n (%)*		
White British	75 (93%)	77 (93%)
White Other	1 (1%)	1 (1%)
Asian Pakistani	2 (2%)	2 (2%)
Asian Other	3 (4%)	2 (2%)
Mixed/Multiple ethnic groups	-	1 (1%)
Employment status n (%)		
Retired	44 (54%)	45 (55%)
Working full-time	20 (25%)	15 (18%)
Working part-time	5 (6%)	10 (12%)
Unable to work	12 (15%)	6 (7%)
Do not work	-	6 (7%)
Dialysis characteristics n (%)		
Planned start to dialysis^	52 (93%)	-
Incident patient^	54 (90%)	-
Mode of dialysis n (%)		
HD	50 (66%)	-
PD	24 (33%)	-
Clinical variables *M* (*SD*)		
eGFR	9.9 (4.0)	-
Haemoglobin g/L	107.9 (15.9)	-
Serum albumin g/L	37.9 (6.0)	-
Comorbidity risk n (%)		
Low	23 (31%)	-
Medium	42 (56%)	-
High	10 (13%)	-
Primary renal diagnosis n (%)^		
Glomerulonephritis	10 (20%)	-
Polycystic	9 (18%)	-
Diabetes	7 (14%)	-
Renal vascular disease	5 (10%)	-
Hypertension	4 (8%)	-

Other	4 (8%)	-
Uncertain	7 (14%)	-

Note. HD= haemodialysis, PD=peritoneal dialysis, eGFR= estimated glomerular filtration rate.
* Ethnicity codes taken from those used in UK renal units
^ >20% missing data

Descriptive statistics of patients’ and partners’ scores in WHOQOL general QOL and its four domains over the study are provided in Table 6.2. Of the 42 patients participating at 6 weeks, 15 patients had moved to a new renal unit, 3 had experienced a change in their access method, 2 had changed their mode of dialysis, and 13 had been hospitalized since starting dialysis. Between the 6 week and 12 weeks questionnaires, a further 4 patients moved to a different renal unit, 2 had changes in their access site, 4 changed their mode of dialysis, and 4 had been hospitalized. Dialysis adequacy (mean and standard deviation) for these patients were 1.45 (0.47) at 6 weeks and 1.38 (0.36) at 12 weeks; however, there was considerable missing data (>20%) for this variable. The final sample at 12 weeks (78 participants) enabled us 80% power to detect a medium effect (F=0.32) of changes in WHOQOL general and its domains from pre-dialysis to each follow-up. Residuals were assessed and normally distributed in each of the random effects models.

Table 6.2

WHOQOL-BREF scores for patients and partners, raw mean (SD)

	Patients			*Partners*		
	Pre-dialysis n=83	6 weeks n=42	12 weeks n=39	Pre-dialysis n=83	6 weeks n=43	12 weeks n=39
WHOQOL General QOL	2.8 (.9)	3.2 (.9)	3.3 (.9)	3.5 (.9)	3.3 (.8)	3.5 (.8)
WHOQOL Physical	46.4 (21.8)	49.8 (22.3)	54.9 (21.0)	67.3 (21.3)	66.8 (19.2)	67.9 (20.5)
WHOQOL Psychological	61.7 (18.6)	61.4 (21.0)	61.5 (18.8)	66.0 (18.6)	64.9 (15.8)	62.9 (20.1)
WHOQOL Social	63.3 (21.1)	63.8 (21.1)	66.6 (21.0)	64.8 (16.6)	65.0 (16.6)	65.5 (16.1)
WHOQOL Environmental	67.4 (15.1)	68.0 (19.9)	68.0 (16.4)	67.8 (15.8)	70.1 (16.6)	67.4 (17.2)

Note. QOL=Quality of Life, WHOQOL=World Health Organization Quality of Life BREF version. WHOQOL general is the mean of the Overall QOL and Satisfaction with health questions on the WHOQOL-BREF. Higher scores suggest better QOL.

6.4.3 Changes in WHOQOL General QOL

Patients. Patients' general QOL improved from pre-dialysis to 6 weeks (β=0.42, *p* <0.001, 95% CI 0.19, 0.65) and from pre-dialysis to 12 weeks (β=0.47, *p* < 0.001, 95% CI 0.24, 0.71), see Figure 6.2. These changes indicate patients' general QOL improved from poor to good. Appendix X provides the output of the three-level random intercept model for changes in general QOL for patients and partners.

Partners. Results from the linear combination indicated a statistically significant decline in partners' general QOL scores from baseline to follow-up 1 (β=-0.24, p=0.04, 95% CI -0.47, -0.01). General QOL returned to baseline levels at follow-up 2 (β=-0.09, p=0.47, 95% CI 0.33, 0.15).

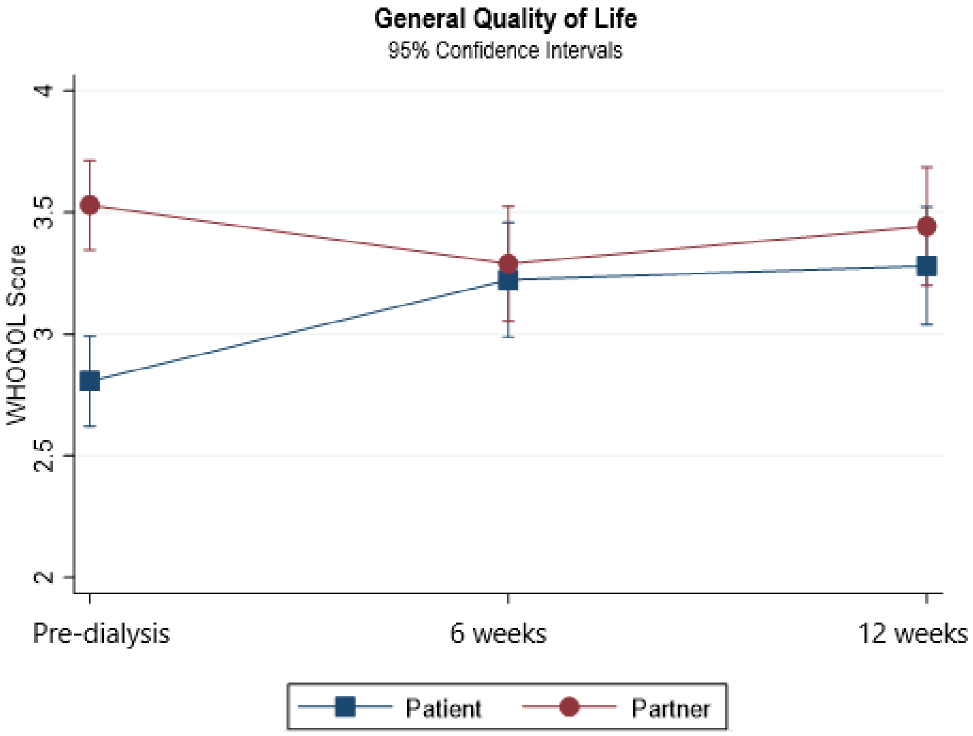


Figure 6.2. Estimated marginal means of WHOQOL general QOL scores of patients and their partners.

6.4.4 Differences between WHOQOL general QOL in patients and partners

Patients reported significantly lower general QOL at pre-dialysis compared to their partners (2.8 vs 3.5; n=83 couples; β=0.72, p<0.001, 95% CI 0.51, 0.93). At 6 and 12 weeks, general QOL was not statistically different between patients or partners (Figure 6.2).

6.4.5 Changes in WHOQOL Domains

Patients. The patients' physical domain scores (Figure 6.3) significantly improved between baseline and follow-up 2 (β=6.56, p<0.004, 95% CI 2.10, 11.03). Within the physical domain, there was a significant difference in sleep scores between pre-dialysis and 12 weeks (n=39, T1: 2.78 ±1.08; T3: 3.33 ±1.11, p=0.0028). This improvement indicates a change from poor sleep at pre-dialysis to good sleep at 12 weeks. No other domain scores had statistically significant changes (see Figures 6.4, 6.5, 6.6). In the psychological domain, the scores decreased but still suggest good QOL. The scores in social and environmental domains indicate good QOL which was stable over the study period. Additional file 3 provides the output of the three-level random intercept models for changes in the domains for patients and partners.

Partners. No statistically significant changes occurred in any QOL domain (Figures 6.3, 6.4, 6.5, 6.6). The physical, social and environment domain scores were stable and indicate good QOL. Similar to the patients, the partners' psychological domain scores decreased from pre-dialysis to 12 weeks but reflect good QOL.

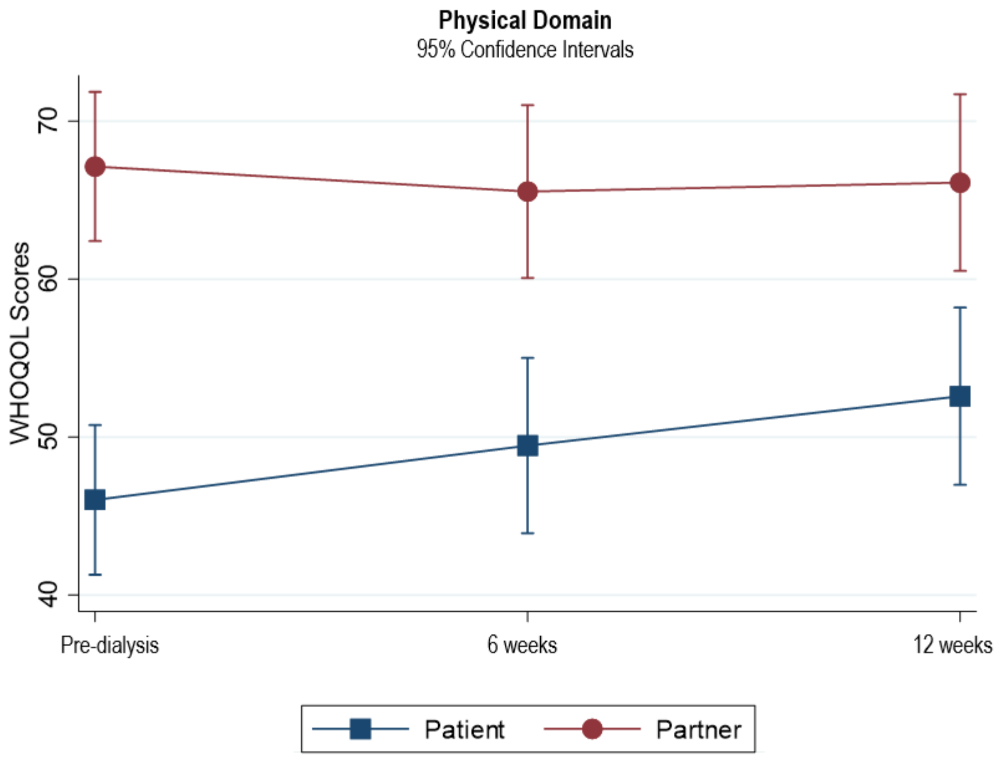


Figure 6.3. Estimated marginal means of WHOQOL physical domain scores of patients and their partners.

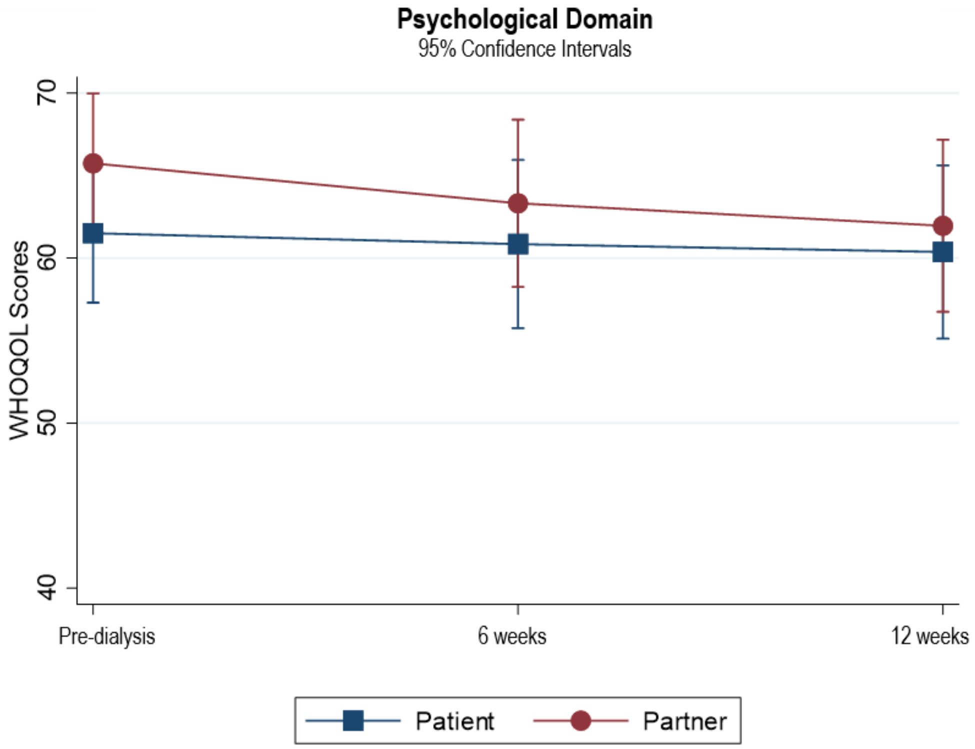


Figure 6.4. Estimated marginal means of WHOQOL psychological domain scores of patients and their partners.

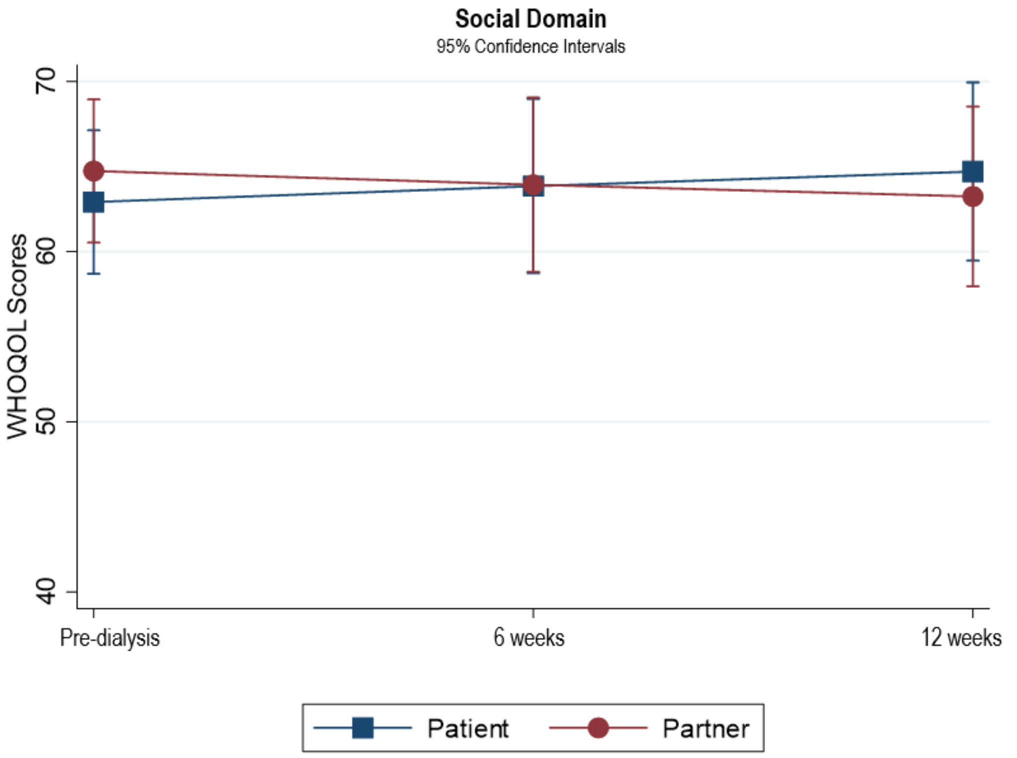


Figure 6.5. Estimated marginal means of WHOQOL social domain scores of patients and their partners.

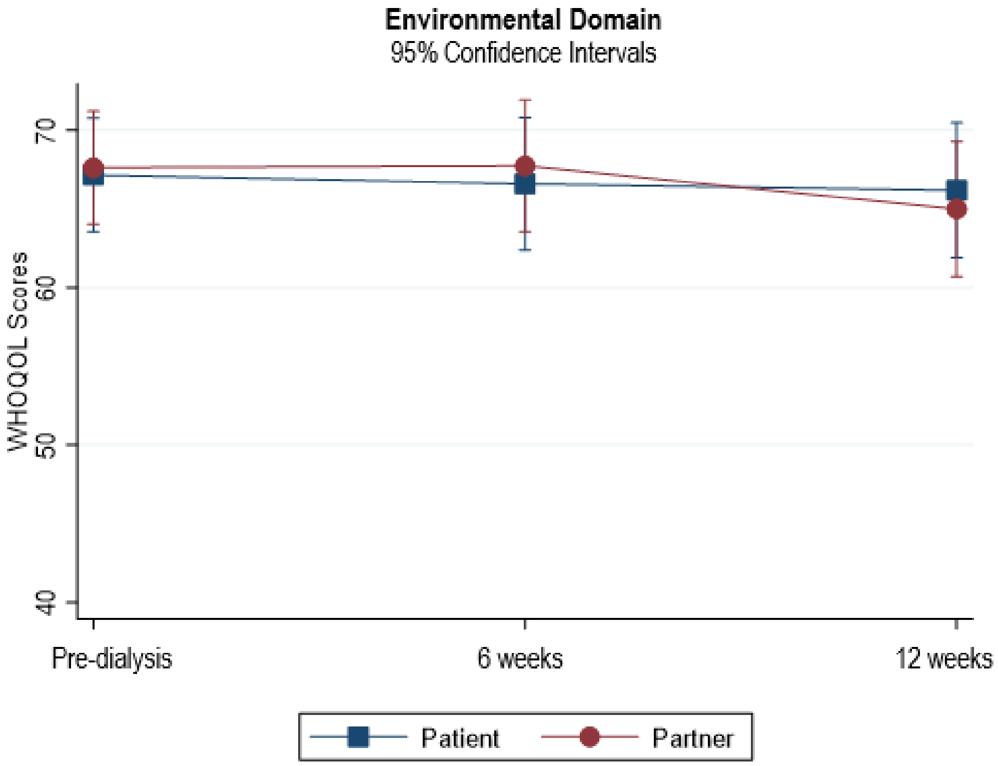


Figure 6.6. Estimated marginal means of WHOQOL environmental domain scores of patients and their partners.

6.5.6 Clinical and socio-demographic variables related to changes in WHOQOL General QOL

Patients. There were no significant associations between general QOL and haemoglobin, eGFR, serum albumin, mode of dialysis (HD or PD) or age. In regard to comorbidity risk level, there were no significant differences in changes in general QOL between patients with low and medium comorbidity risk. Patients with a high comorbidity risk had significantly worse general QOL at pre-dialysis compared to the low and medium risk groups (β= -1.0, p=0.001, CI -1.61, -0.39), but their general QOL was not significantly different from the low or medium risk groups at 6 and 12 weeks (Figure 6.7). There were no significant differences in general QOL between males and females at pre-dialysis and 6 weeks (see Figure 6.8); however, from pre-dialysis to 12 weeks female patients reported significantly better improvements in general QOL compared to male patients (β=0.59, p=0.33, CI 0.48, 1.13).

Partners. There were no significant associations with changes in general QOL on the basis of age or gender.

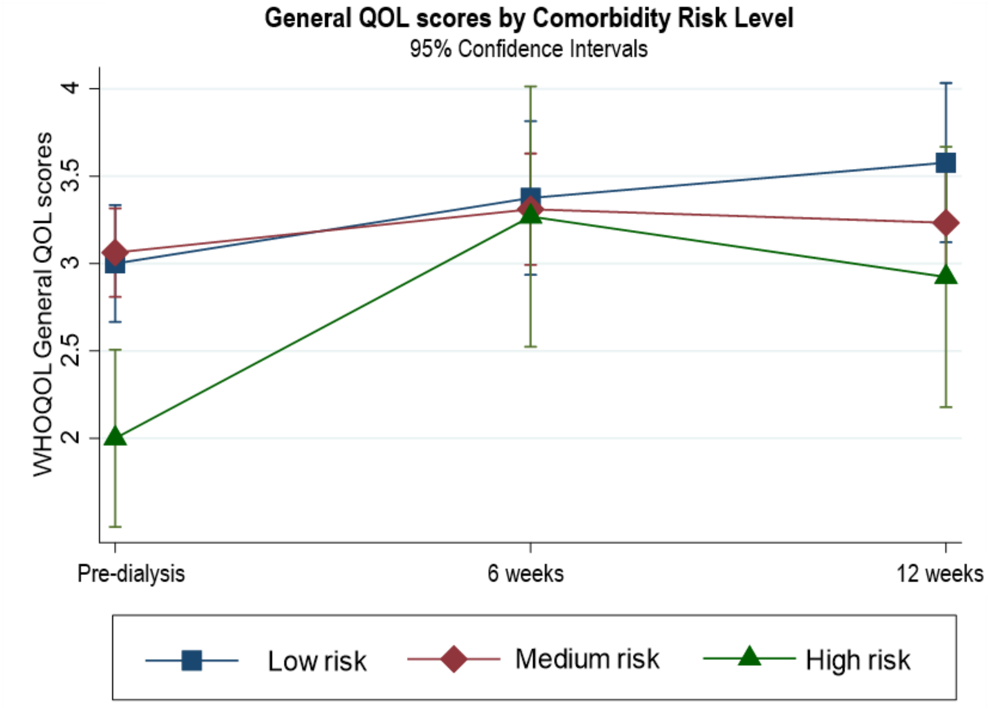


Figure 6.7. Estimated marginal means of WHOQOL general QOL scores of patients by comorbidity risk level.

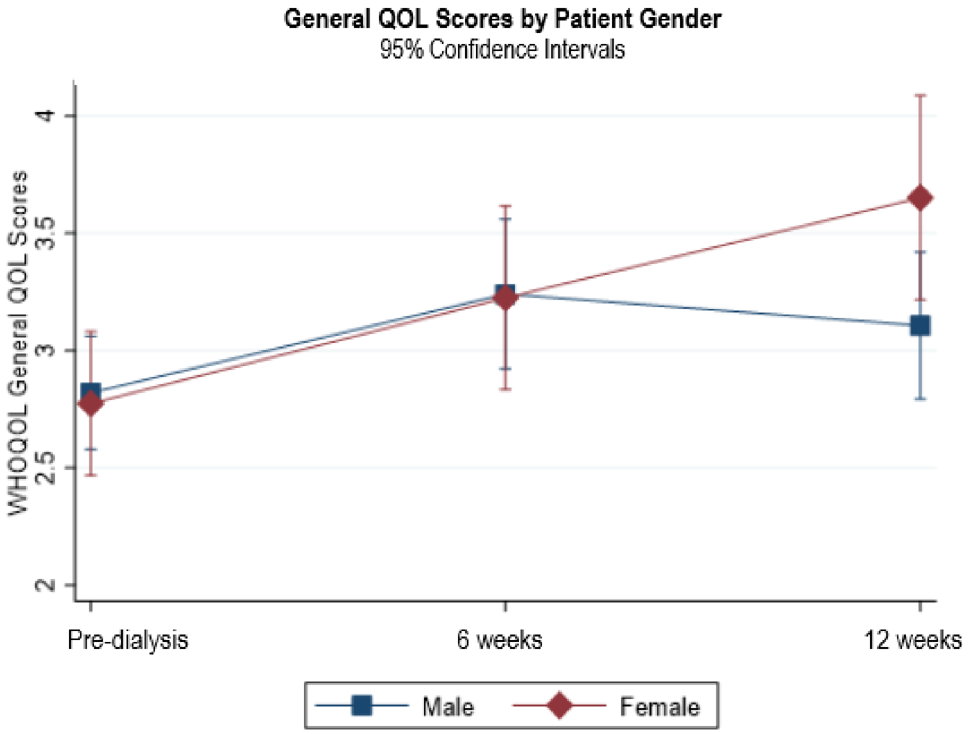


Figure 6.8. Estimated marginal means of WHOQOL general QOL scores of patients by gender.

6.5 Discussion

This study is the first to describe and examine QOL in patients and their partners as patients transition onto dialysis. Patients' general QOL improved from pre-dialysis to six weeks after being on dialysis, with a further modest improvement at 12 weeks. This change marks a shift from poor to good QOL. Even patients with a high comorbidity risk experienced significant improvements in general QOL. Furthermore, female patients reported significant improvements in their general QOL whereas male patients did not. Patients' physical QOL also improved from pre-dialysis to 12 weeks, indicating a change in scores from poor to moderate physical QOL. Within the physical domain, sleep was the key item to improve for patients. In contrast, partners reported their general QOL as impaired after patients had just started dialysis; however, it improved and returned to a similar level as reported at pre-dialysis at 12 weeks. Partners' general QOL remained at good QOL levels throughout the transition period, despite worsening at six weeks. In the psychological, social and environment QOL domains, patients and partners reported good QOL which remained stable over the transition period.

These findings extend our understanding of changes in QOL in both members of a couple when patients start dialysis and provides new information about what happens to QOL in the critical early weeks after starting dialysis. Comparisons between our findings and existing research are difficult to interpret as the only other longitudinal study (Fan et al., 2008) involving patients and partners over the transition onto dialysis used the SF-36 - a measure of health status and functioning rather than a QOL measure. Therefore, a direct comparison between the SF-36 and the WHOQOL-BREF cannot be made, and generalizations between them should be interpreted with this in mind. At pre-dialysis, the patients in the present study only had poor QOL in the general facet and the physical domain, whereas in Fan et al. (2008) PD patients reported both their physical and mental functioning as poor at this stage. Furthermore, partners in the present study reported their general QOL and all domains as good at pre-dialysis whereas the partners in Fan et al. (2008) had impaired physical and mental functioning.

As to the impact of starting dialysis on patients and their partners, our findings also contrast those reported by Fan et al. (2008). In the present study patients and partners reported changes in their general QOL and patients' physical QOL; however, in Fan et al. (2008) only social functioning, a component of mental health functioning, improved at the one-year follow-up in patients and partners. It is possible that our study may have detected a change in the social domain if follow-ups had been conducted one year after starting dialysis, as in Fan et al. (2008). While interpretations across the studies is limited, this present study's findings fill an important gap in our knowledge about the impact of starting dialysis on the QOL of patients and their partners during the critical first 12 weeks.

Comparisons between existing research which used the WHOQOL-BREF in ERF patients and their partners are limited but offer some context for these findings. To our knowledge, only one other study (Anees et al., 2011) included both patients and their partners. Anees et al. (2011) conducted a cross-sectional study in Pakistan with 125 HD patients and 50 of their family members. In the present study patients and partners only differed in physical QOL (with partners reporting better physical QOL than patients) whereas in Anees et al. (2011) partners reported better QOL in the physical, psychological and social domains compared to the patients. Comparing the scores of the patients in the current study with those in Anees et al. (2011), our patients had better QOL across the domains. The partners in both studies had similar QOL in the physical, psychological and social domain; however, the partners in the present study rated their QOL in the environment domain better than the partners in Anees et al. (2011). These comparisons should be made with caution as ours is a UK sample and may differ due to the cultural context or on the basis of renal and dialysis practices.

A growing number of studies have used the WHOQOL-BREF in patient-only samples. These too were conducted in cultural and renal contexts that may differ significantly from the UK. One study, conducted in Korea, used the WHOQOL-BREF with ERF patients in pre-dialysis care (Lee et al., 2013). Comparing the pre-dialysis scores of patients in the present study to their results, our patients reported their QOL better in the psychological, social and environment domains, poorer in the physical domain, and similar general QOL. Our findings, in comparison to studies which included patients established on dialysis (Ginieri-Coccossis et al., 2008; Griva, Kang, et al., 2014; Griva, Yu, et al., 2014; Tsai et al., 2010), indicate that QOL compares similarly across all the domains and general QOL, with the patients in the present study reporting slightly better QOL. The similarity between physical domain scores of this study and the studies which included patients established on dialysis may indicate that physical QOL does not continue to improve as time on dialysis increases. Dialysis only partly removes the toxins from the patient's body (Robinson et al., 2016); therefore, improvements in physical QOL due to dialysis may only be noticeable to patients initially.

Only one study by Kang et al. (2019), conducted in Singapore, utilized the WHOQOL-BREF to assess QOL at baseline and one year in 44 partners of patients established on PD. Compared to partners in Kang et al. (2019), partners in the current study had similar general QOL, psychological and social QOL scores but had much lower physical QOL scores. The partners in the current study had an average age of 63 years (±15 years) whereas in Kang *et al.* the average age was 38 years (±6 years), which may explain the difference in physical QOL scores. Interestingly, the partners in Kang et al. (2019) reported significant impairments in their psychological QOL over the study period. In the current study, partners' psychological scores had a downward trend which may indicate that dialysis and its related stressors have a delayed negative impact on their QOL. In comparison to research conducted in the UK and in the wider caregiving literature, the physical domain scores of the partners in this study are comparable to those reported by healthy participants, whereas the psychological, social and environmental domains are similar to carers of elderly patients (Skevington & McCrate, 2012).

In contrast to the wider ERF and dialysis literature, the findings of the present study indicate good QOL overall in both patients and their partners and improvements in patients' general and physical QOL after starting dialysis. As highlighted above, an issue in comparing our study's finding with other studies in the literature is that a significant proportion of studies utilize the SF-36 and SF-12 (which also form part of the KDQOL) that assess factors related to QOL such as physical and mental functioning (Acaray & Pinar, 2005; Alvarez-Ude, Valdes, Estebanez, & Rebollo, 2004; Belasco, Barbosa, Bettencourt, Diccini, & Sesso, 2006; Celik, Annagur, Yilmaz, Demir, & Kara, 2012; Fan et al., 2008; Gray et al., 2019; Nagasawa et al., 2018; Rioux, Narayanan, & Chan, 2012; Shimoyama et al., 2003; Wu et al., 2004). On average, these studies report dialysis patients and their partners' physical and mental functioning as <50 (scores <50 indicates functioning which is poorer than the general population). Our findings may differ from the literature as it is one of the few studies to be conducted in the UK where patients have access to structured pre-dialysis education. Furthermore, a majority of the patients in the present study started dialysis in a planned manner (i.e., >3 months in the care of a nephrologist). Both pre-dialysis education and starting dialysis in a planned manner have been linked with positive patient outcomes (Rivara & Mehrotra, 2017). Our findings highlight the need for on-going support to partners over the transition onto dialysis to prevent it impairing their QOL.

In the present study, changes in patients' WHOQOL general QOL were moderated by comorbidity risk level and gender. Patients with a high comorbidity risk reported significant improvements in their general QOL that matched the low and medium risk groups. Additionally, female patients reported their QOL to be better than male patients. Our findings differ from that in the ERF literature where high comorbidity and female gender are commonly related to poor QOL (Joshi, 2014; Merkus et al., 1999). However, our findings should be interpreted with caution given the small sample size at 12 weeks (39 patients).

Improvements in the patients' physical QOL scores was due to greater satisfaction with sleep. Other studies have found improvements in patients' sleep quality after being on dialysis for one year, which were also positively associated with QOL and survival rates; however, only a minority of patients (<20%) in these other studies reported better sleep (Unruh et al., 2006; Wu et al., 2004). That the patients in the current study reported improvements in their sleep at 12 weeks provides evidence as to when patients may experience benefits from dialysis.

In this study we used the WHOQOL-BREF because it includes a facet on general QOL and items within the four domains that address topics ERF patients and their partners' state as important to them. Given there is currently little consensus on the best way to measure QOL in ERF (Evangelidis et al., 2017), we used the 2 items comprising the WHOQOL general QOL facet as our primary outcome variable because, unlike the SF-12 and SF-36, it asks participants to rate their overall QOL *and* satisfaction with their health. Global items like the WHOQOL general QOL facet may be a useful way to study QOL at specific time intervals and between groups (Sloan et al., 2002). Furthermore, the four domains of QOL in the WHOQOL-BREF complement the life areas described by Jablonski (Jablonski, 2004) as being affected in the crisis phase. This study's findings offer a new perspective on QOL in patients and partners in early dialysis and suggests there are changes in QOL which warrant further investigation.

A limitation of this study is the small final sample size. The recruitment period of one year yielded a sample of 83 couples. However, due to significant drop-out between pre-dialysis assessment and subsequent follow-ups, we had a final sample of 39 couples. This limited our analysis of the data; however, using a random effects MLM allowed us to utilise all available data which increased the precision of our estimates (Curran et al., 2010). In addition, 93% of the participants were White British which may limit the generalizability of the findings. The follow-ups (6 and 12 weeks) may have been too soon after starting dialysis to detect significant changes in all the WHOQOL-BREF domains; however, these first 12 weeks are under-researched and were determined in consultation with a renal research patient-public involvement group and participants from a previous qualitative study.

In this study, only patients who were in a spousal-type relationship, and whose partner also consented to take part, were eligible. When screening potential patients, we experienced issues identifying those with a partner as this level of detail is often not routinely recorded. Furthermore, we found that the proportion of patients with partners was lower than we had estimated. We expected approximately 60% of patients to have partners but many sites found it to be as low as 30%. In most renal units, this type of information is not easily accessible and is not monitored at the national level. Without accurate and accessible data about partners, who are often primary informal caregivers to ERF patients, it is difficult for to form an accurate picture of the caregiving landscape in the ERF population. Therefore, we recommend that a mapping exercise be conducted across renal units in the UK to outline this area and that information on partners be routinely monitored and reported in a standardized way.

The major strength of our study is that it focuses on the changes in QOL during the crisis phase of dialysis. By zooming in on this time frame, we have exposed the complex effects of starting dialysis, improving patients’ QOL but initially impairing partners’ QOL, and demonstrated the need to include partners in research if we are to better understand the broader impact of treatments.

While this research provides a foundation to begin better understanding QOL in patients and their partners, future research with more couples conducted over a longer time frame may uncover additional changes that occur as they adjust to the treatment and could also look at factors which predict changes in QOL.

6.5.1 Conclusion

Our findings offer encouraging signs that patients' general and physical QOL improve after starting dialysis. However, it also indicated that patients have impaired QOL before starting dialysis and that the initial transition period negatively impacts their partners' general QOL. It is promising that starting dialysis did not negatively impact the domains of QOL in patients or partners.

Chapter 7: Discussion

7.1 Overview

The aims of this programme of research were to better understand quality of life (QOL) in established renal failure (ERF) patients and their partners over the period at which the patients started dialysis; to investigate the impact of dialysis on the dyadic relationship, and to identify psychological and dyadic relationship factors related to QOL. Features of the research which enable it to make an original contribution to the literature include the time periods over which participants were studied (which, across the studies, spanned from just prior to starting dialysis up until 2 years after starting dialysis) and the inclusion of spousal-type patient-partner dyads, enabling dyadic analysis at some levels. The present chapter of the thesis begins with a discussion of the novel contributions of each study's finding to the research questions outlined in the Introduction and in the context of the pre-existing literature. Then, the strengths and limitations of each study are considered, followed by the overall strengths and limitations of the programme of research. The clinical implications for this thesis and implications for future research are then presented.

7.2 Novel contributions to the literature

The first aims of this programme of research are stated below:

What do we know from the existing quantitative research about QOL in ERF patients and their partners?

What do we know from the existing qualitative studies about the experiences of ERF patients and their partners and how their experiences may relate to QOL?

To address these first research questions, a narrative literature review (Chapter 3) was conducted of existing empirical studies which had included samples of both patients and their partners, although not all participants in all studies were recruited as couples. The findings indicated that QOL in patients and their partners is impaired or affected in many ways by ERF, and in particular that dialysis treatment has an impact of their lives. Robust conclusions on patients and partners QOL, as defined in this thesis, could not be drawn as quantitative studies were lacking which actually assessed QOL as defined by the WHO, which was a guiding concept in this programme of research. Although 10 qualitative studies were included in the review, none were found that explored QOL in patient-partner dyads by gathering data from both members of the dyad and analysing using the structure of the dyadic pairings. In order to systematically describe the effects of ERF and dialysis on QOL, a novel approach was adopted in the narrative synthesis whereby the researcher mapped the findings of existing literature onto the WHOQOL structure. Mapping the findings in this way elucidated the experiences of patients and their partners in terms of the different facets and domains of QOL as described by the WHOQOL. This literature review offered a novel contribution as it is the first to summarise findings relating to QOL in ERF patients and their partners. Furthermore, it identified key areas that warrant further investigation, namely the impact of dialysis on QOL and the dyadic relationship. It also highlighted the dearth of research which includes patient-partner dyads in the early phases of dialysis (e.g., pre-dialysis and the first weeks of dialysis).

Further to this, a second aim of the thesis was to ascertain if there were differences in QOL between patients and their partners, which was addressed by this research question:

Are there differences in QOL between ERF patients and their partners?

The findings of the narrative synthesis indicated ERF and dialysis affected the facets and domains of QOL differently, and possibly that there were also differential effects on the two partners in the dyad. The effect of dialysis on overall QOL was difficult to assess as none of the studies directly asked how participants judged their overall QOL but reported a range of views on the impact of dialysis on their life and health and in general. However, an emerging finding from the review is that patients more commonly noted the positive effects of dialysis on their lives or health whereas partners did so less often. As discussed previously, mapping the findings of the qualitative studies onto the WHOQOL structure highlighted the way specific domains and facets of QOL were affected. It showed that health-related and physical QOL were discussed more frequently by patients, and that both patients and partners expressed significant impairments in their psychological QOL, with partners rarely identifying any positives effects on their psychological QOL. The narrative review of the quantitative studies suggested that patients and their partners had similar overall QOL (as measured by single item assessment of QOL), but partners generally had better QOL across the domains of the WHOQOL-BREF than patients.

In assessing how the review findings relate to the wider literature, it is necessary to draw conclusions from measures of QOL on the one hand (in the present literature review) and factors related to QOL, such as depression and health status on the other hand (as reviewed by Gilbertson et al., 2019). Gilbertson et al.'s (2019) review compared depression and health status in HD patients established on dialysis with that of their partners (data from a subset of the total review) and reported that partners were less depressed, had better physical functioning and similar mental functioning than patients (Gilbertson et al., 2019). The findings from the narrative review presented in the thesis and the review by Gilbertson et al. (2019) highlight that studies which assess QOL using recognised measures in patient-partner dyads, and also partner-centred research, is lacking.

The findings of the narrative literature review indicated that dialysis affected the dyadic relationship significantly. This finding informed the next research question:

What is the impact of early dialysis on the dyadic relationship between patients and their partners?

The narrative literature review highlighted the lack of analytic techniques used in the literature which capture the dyadic perspective of ERF patients and their partners. In Study 2, the method of analysis was dyadic thematic analysis (DTA), which had not been used in ERF research before. The analysis yielded a rich description of the impact of dialysis, and preparing for dialysis, at both the individual and dyadic level. Conducting a DTA allowed the theme 'Managing the relationship' to be identified. Within this theme, it was important that dyads worked together and highlighted the ways (e.g., being positive, accepting dialysis and normalising dialysis) in which they had minimised the impact of dialysis on their relationship, and ultimately their QOL. The findings from Study 2 complement those by Wise et al. (2010) where dyads in what were regarded as strong relationships, faced the stressors of ERF and dialysis together and had a sense of hope and optimism. This meant that they had adapted to the demands of short daily HHD better than other dyads. Wise et al.'s (2010) findings further underline the value in examining dyadic relationship factors when ERF patients and their partners are preparing for dialysis.

In contrast to the findings of the literature review, in Study 2 mode of dialysis was not a salient factor in how the relationship was impacted by dialysis. In Study 2, both patients and partners, irrespective of dialysis mode, described the significant ways dialysis impacted their lives. They stated that in the early phases of dialysis, the patient is prioritised and that partners took on the emotional and physical burdens of the dyad. This then led to changes in identities, within both partners and patients, and within the dyad. However, dyads who worked together and found ways to be positive, accepting or normalise dialysis were able to minimise the impact of all these changes on their relationship and lives. A possible reason why mode of dialysis was not a factor in how dialysis affected their lives could be because in Study 2 dyads were recruited who were in the early phases of dialysis. This differs from a majority of the studies which were included in the literature review which featured patients established on dialysis. It may be that in the early phases of dialysis the impact on their lives is significant, irrespective of mode.

Building on the interpretations drawn from Study 2, the next aim the programme of research was to address the following research question:

> *Drawing on their experience, what psychological and interpersonal factors do patients and partners relate to QOL during the early phases of dialysis?*

To address this research question, Study 3 was conducted, part of which entailed a secondary analysis of the semi-structured interviews with patients and their partners that had been obtained in Study 2. Three constructs were identified which appeared to drive differences in QOL across the dyads, these being: dialysis expectations, accepting dialysis and dyadic relationship characteristics. To our knowledge, these are the first psychological and interpersonal constructs related to QOL to be identified and defined in ERF patient-partner dyad research.

Proceeding from the previous research question was the following aim:

> *Can we develop a measure to assess these factors (the Starting Dialysis Questionnaire; SDQ)?*

Questions were designed on the basis of the insights gained from the semi-structured interviews (Study 2), and the secondary analysis of these interviews (Study 3), and were then assessed for comprehensibility, acceptability and applicability using cognitive interviews with a subset of Study 2 participants (Study 3.2). Study 3 adds a novel contribution to the field as it is a patient *and* partner-centred measure which addresses key factors that relate to QOL. Although other measures exist which assess topics related to those in the SDQ, such as the illness acceptance measure in the Illness Cognition Questionnaire (Evers et al., 2001), which assesses a person's own acceptance of their illness in general. In contrast, the SDQ questionnaire designed in the present programme of research was intended to capture patients and partners' level of acceptance of dialysis specifically. Also, the questions and participants' responses provide an indication of whether or not they are actively accepting of dialysis (i.e., making changes to their lives and reframing the effects of dialysis) which has been found to be positively correlated with QOL (Poppe et al., 2013). The preliminary evaluation of the psychometrics of the SDQ indicates that it is reliable, that the items within the domains are homogenous and the domains represent distinct constructs (Study 3).

The thesis commenced with an exploration of QOL in patients and their partners and concluded in a similar manner. The last two research questions focused on QOL at a specific, hitherto understudied, point in the ERF illness trajectory – the transition onto dialysis:

> *Does QOL change in patients and their partners as they transition from pre-dialysis to 12 weeks after starting dialysis?*

The quantitative strand of this programme of research made three novel contributions to literature. Firstly, it showed patterns of change in QOL in ERF patients and their partners over the transition onto dialysis, which has not been reported before. In the present study, patients and partners reported changes in their QOL, even over a short time frame. The most comparable study is that of Fan et al. (2008), who measured health status in PD patients and their partners both before starting PD and then again one year later, neither mental nor physical component scores changed in either group. However, as noted Fan et al., did not measure QOL as conceptualised in the present programme of research.

Secondly, patients' general and physical QOL improved from poor to good. This finding is consistent with the work of Wu et al., (2004) who found an improvement in QOL, at one year after starting dialysis (Wu et al., 2004). However, only the HD patients in their study reported improvements in overall QOL whereas QOL improved for both HD and PD patients in the present study. Thirdly, ours is the first study to report partners' QOL over the transitional period of starting dialysis. For partners, QOL was good overall, with QOL at 12 weeks recovering to pre-dialysis levels despite a slight worsening in QOL 6 weeks after the patient started dialysis. Finally, this study is the first to use the WHOQOL-BREF in patients and their partners in the early weeks of dialysis.

Closely related to the previous research questions is the following:

Are there differences between patients' and partners' QOL over this transition period?

Further to this, Study 4 allowed the examination of QOL between patients and their partners at this particular time in the ERF illness trajectory and featured patients and their spousal-type partners, or dyads. At pre-dialysis patients reported their QOL to be poor whereas partners reported their QOL to be good. However, after patients started dialysis, both patients and their partners reported their QOL the same.

7.3 Strengths and limitations

In this section, the strengths and limitations of each study will be discussed in turn and then in regard to the overall programme of research.

The first study in this thesis was the literature review which was conducted using a narrative style rather than following guidelines of a systematic review (e.g., searching multiple databases, providing assessments of the quality of the included studies). Rather than searching many different databases, it was decide to use Web of Science which integrates findings from all the standard relevant databases. It was decided to use broad and inclusive search terms and to sift through the hits obtained rather than using more selective search terms. There is, nevertheless, the possibility the search terms and databases used meant that studies which met the inclusion criteria and which could have informed the research question were not included in the review. However, hand searching on the basis of reference lists was carried out and did not suggest this to be the case. The literature review was updated in December 2019. This included a full review of all the ERF patient and partners studies that the researcher acquired over the programme of research and Web of Science was searched again, with two relevant recent studies being identified when the search was carried out again in December 2019.

Another limitation of the literature review was that firm conclusions could not be drawn from the findings reported in quantitative or qualitative studies. This was due to there being limited quantitative studies which met the inclusion criteria (i.e., measured QOL rather than health status), and within the five studies found, three different measures were used, thus, hindering generalizations across the studies. In the qualitative studies, it was difficult to assess overall QOL in the patients and their partners as it was a topic not directly addressed within the studies themselves. While the other facets and domains of the WHOQOL could be mapped, overall QOL was the most difficult and did not clearly indicate the effects of dialysis on patients or partners. However, despite these limitations, the WHOQOL provided a comprehensive structure onto which to map patients' and their partners' experiences. The interpretations made across the studies highlighted key areas of QOL affected by dialysis and ERF and effects that were mutual and different between patient-partner dyads.

The second study presented the findings from the semi-structured interviews on the impact of dialysis on the dyadic relationship between male patients and their female partners. Only 2 female ERF patients were recruited in the overall sample, despite the researcher aiming to recruit both male and female patients. During analysis, the experiences of the 2 male partners compared similarly to the experiences of the female partners. They too prioritized the patient, expressed worry and fears, which they sometimes kept to themselves, and assumed responsibilities in the household. On the other hand, during interviews, they showed less overt emotional distress and spoke less about changes in their identity. The first write up of this study included these two male partners. However, in order to facilitate comparisons between the dyads, and on the advice of the reviewers who read the paper prior to its publication in *Qualitative Health Research*, the two dyads with female patients and male partners were not included in the final analysis which is included in this thesis. The experiences of male partners and female patients should be researched to explore how their accounts may differ from those in this sample.

A strength of the dyadic relationship study was that the researcher obtained valuable insight into numerous areas of the participants' lives during the interviews. The participants openly, and often spontaneously, discussed personal topics, such as their intimate relationships, fears and worries. The richness of the interviews enabled the researcher to fully harness a dyadic perspective using DTA and to draw out the impact of dialysis on various aspects of the dyadic relationship.

The next study in the thesis was the development of the SDQ. The participants who assessed the comprehensibility and appropriateness of the SDQ in the cognitive interviews were a subset of those who took part in the study that informed its development (qualitative semi-structure interviews), which might be considered a limitation. The set of 5 couples who took part in the cognitive interviews, were those who responded to a letter from the researcher (therefore a self-selecting sample) and consisted of male patients and female partners. Although external validation of the content was confirmed by the renal research group, it may have provided additional insight if female patients or male partners, who had not participated in the previous study, were included in the cognitive interviews. Due to the number of completed questionnaires that were obtained, it was only possible to carry out preliminary psychometric testing. The sample size was not large enough to employ factor analysis or to assess convergent validity (Streiner & Norman, 2008).

The strengths of the SDQ are that is a patient- and partner-centred measure derived from interviews with the target population which uses patients' and partners' own language to assess relevant constructs. The preliminary evidence suggests that the SDQ has good psychometric properties (i.e., the items within the domains are similar in nature but not redundant, responses were overall normally distributed, and the domains had good internal consistency).

Finally, the last study in this thesis used a longitudinal, panel design to collect questionnaire data. Despite recruiting 10 research sites to take part in a multi-centre study, and even with the study being adopted onto the National Institute for Health Research (NIHR) portfolio, the target sample size was not achieved. Significant attrition occurred before the first follow-up (6 weeks after starting dialysis), with a small amount of additional attrition at the 12 week follow up. Due to the final sample being considerably smaller than had been anticipated, only the primary research questions could be addressed using multilevel modelling. This meant that the associations between the variables measured in the SDQ and changes in QOL could not be examined. It was also not possible to examine within-dyad effects on QOL. Recruitment issues will be discussed in relation to the overall programme of research in the following section.

A review of the attrition rates by research site indicates that on average three dyads per site were lost at follow-up due to non-response between pre-dialysis and the first follow-up. Four sites had high attrition rates. All four of these sites faced significant changes either to how renal care was delivered at their site or to the structure/workload of the renal research teams. Specifically, one site began running local clinics rather clinics based out of the main research hospital, which meant that the site investigator (SI) could not always meet potential participants; in the second site, the SI resigned and was replaced after two months; in the third site, the SI had intermittent periods of sick leave; and in the fourth site, the SI became the sole research nurse in the department and experienced a major increase in workload. Although the researcher was aware of these changes, and kept in touch with each of the sites on a regular basis, there were limited actions she could take to minimize the negative effects on recruitment and attrition. The researcher provided one-to-one training with the new SI and worked with the other SIs to create strategies to facilitate recruitment and minimize attrition (e.g., brainstorming sessions about which consultants to approach, ideas for prompting participants to return questionnaires, using the online questionnaire tool rather than sending out paper copies or trying to meet participants during clinical appointments).

Despite these limitations, the overall study had many strengths. Firstly, ERF patients and their partners state that QOL is important to them (Morton et al., 2011; Morton, Tong, et al., 2010), yet there is debate in the field as to how to measure it. Our study suggests that the WHOQOL-BREF addresses several areas of QOL important to ERF patients and their partners. Within the WHOQOL-BREF, the general QOL facet asks about overall QOL as well as health-related QOL, thus providing a simple summative measure of how the patient or partner rates their general QOL. Secondly, the items within the physical, psychological, social and environment domains of the WHOQOL-BREF address topics that ERF patients and partners have said are important to them (e.g., energy, sleep, travel and work) (Manera et al., 2019; Urquhart-Secord et al., 2016). Furthermore, this study provided valuable insight into QOL in both HD and PD patients and their partners over a crucial transition (from pre-dialysis onto dialysis). That 10 renal centres across England took part in it enhances the generalizations that can be drawn from the results.

It is also important to address the strengths and limitations in the overall programme of research. Due to QOL in patient-partner dyads being an emerging area of research in ERF, the initial stages of the research were very exploratory and took considerable time to pinpoint the key topics and questions that needed to be asked. The length of time to conduct and analyse the qualitative strands of the design may not have left sufficient time to recruit the target sample size, which then limited the analysis. However, an additional year was added to the programme of research, due to an approved interruption, and the research sites were given an additional six months to recruit participants. Recruiting dyads has been reported in the wider literature as requiring additional time, resources and multiple contacts (Revenson et al., 2016b) which should be taken into consideration in future dyadic research in ERF.

In Study 2, the target patients were in the care of a nephrologist but did not yet have a plan to start dialysis. During recruitment, some patients at this stage in pre-dialysis did not want to be associated with or think about ERF, or dialysis, more than they had to and were more difficult to recruit than patients already on dialysis and their partners (who often showed enthusiasm or an interest in giving back to the renal community). In the longitudinal study, the target patients had clinical evidence suggesting that they should start dialysis in the next two months; however, recruitment was difficult in this study too. Our target patients were more likely to feel too unwell, to be busy trying to prepare their life and work for dialysis, or simply overwhelmed. Furthermore, in some sites, patients never started dialysis despite their clinical evidence suggesting they would be starting soon. The decision to start dialysis in the UK is guided by the patient’s wishes, in consultation with the renal care team, and the clinical evidence (NICE, 2018). These patients who did not start dialysis may have been satisfied with their current health and may therefore have chosen not to start dialysis at that time. These are factors to be taken into account for future research conducted during this point in the ERF illness pathway.

A key strength of this programme of research was the inclusion of patients and the public in the design of the studies and study materials. The researcher met with renal patients who were part of the Manchester Royal Infirmary (MRI) patient and public renal research advisory group during the early stages of programme of research (May 2015) and presented her study aims. They provided feedback as to the timing of the qualitative interviews (they concurred with her view that she should interview people who were early in the ERF pathway) which was adopted into the study design. During the design phase of the quantitative study, the group reviewed the SDQ and provided feedback on the questions and the timings of the follow-ups. Their comments and feedback were incorporated into the study. The researcher also met with the MRI Kidney Patient Association board members and presented her study to them. They reviewed the WHOQOL-BREF and confirmed it captured their view of QOL. Throughout the programme of research, the researcher communicated the findings of the thesis to the key stakeholders. A lay version of the findings from the semi-structured interviews were mailed to all the participants and the PPI groups, and a poster outlining the key findings from the quantitative study will be sent to the research sites for distribution within their renal clinics. The accepted versions of the papers within the thesis were also disseminated to the clinical teams, and participants who requested copies.

Another strength of this programme of research is the focus on the patient-partner dyad from conception to conclusion. It was highlighted in the first study (literature review) that the patient-partner dyad and the dyadic perspective were under-represented in the ERF literature. Throughout the programme of research quantitative and qualitative methods were employed to better understand their experiences, QOL and the dyadic relationship which culminated in the creation of the SDQ. The SDQ was an unplanned outcome of this programme of research and reflects the iterative nature of this thesis and ties together the interpretations of the research while also providing a useful tool which that could be used in renal care.

7. 4 Conducting research with dyads

Conducting dyadic research comes with challenges, namely in regard to confidentiality and bias (recruitment has been discussed previously). An issue with confidentiality arose in Study 2 (impact of dialysis on the dyadic relationship) around how to disseminate the findings in a way that protected the internal confidentiality of the couples (i.e., that one member of the dyad would not recognise the comments of the other). Although the researcher had permission from participants to alter quotations or personally identifiable details, she did not need to take this step. Instead, she decided it best to only provide general identifiers alongside the quotations, as opposed to providing more detail about each participant, as is sometimes seen in qualitative research. This measure was necessary because it decreased the risk of breaking the internal confidentiality of the dyad, but it limited the researcher’s ability to fully report the dyad’s nuanced and complex experiences.

Although separate interviews facilitated the dyadic thematic analysis of the data, on three occasions couples preferred joint interviews which removed some of the complexity in presenting the data (i.e., the couples already knew what the other said so the researcher was not at risk of breaking internal confidentiality). When conducting dyadic qualitative research, researchers must consider how to handle confidentiality when designing the study and should make it clear in the study's documents that there is a risk that they may be able to recognise their partner's comments, and vice versus.

Furthermore, conducting dyadic research is emotionally and physically demanding because the researcher will often need to interview participants consecutively and the interviews may be about emotionally laden topics, such as chronic illness and the impact on the dyadic relationship. In Study 2, the researcher was affected by the experiences expressed during the interviews. To maintain her own well-being, the researcher debriefed with a member of her supervisory team and prioritised her own exercise and reflective time. To minimise inadvertently biasing the research, she kept field notes, used reflexivity practices (e.g., bracketing, journaling) and relied on the support of her supervisory team.

Research indicates that couples with higher relationship satisfaction and less negative affect participate in studies (Hagedoorn et al., 2015). To mitigate this bias, participants in the studies were not excluded on the basis of mental health issues. Some evidence that these measures may have reduced bias in Study 2 are that some participants spoke openly about their mental health challenges, and others discussed significant relationship issues (e.g., seeking couples' counselling, talking about the negative effects on their sex-life, expressing negative views about the other member of the dyad). If the sample recruited in Study 4 are biased as research suggests (i.e., higher relationship satisfaction and less negative affect), it is possible that the actual changes in QOL after starting dialysis may be greater than those reported by the recruited dyads.

7.5 Clinical implications

The qualitative study (Study 2) yielded rich insight into the complex way that ERF and dialysis impacts both patients and their spouses. It brought out the importance of positivity, accepting dialysis and normalising it in managing their relationship. It was found that, as early as the time around diagnosis of ERF, dyads are facing significant social, psychological and interpersonal changes. Being aware of these changes and the impact of the changes on both the patient and the partner may benefit renal health care professionals as it may assist them to better understand the daily lives of those in their care. In particular, it highlights the need for them to ask and listen to both patients and partners about their QOL.

The SDQ could be used in renal clinics to assist clinicians and nurses in identifying patients and partners who have high expectations, are having difficulty accepting dialysis or who have conflicting relationship dynamics. The recommended time to implement it would be during pre-dialysis but adapted versions of it could be used at any point in dialysis treatment. Conversations on expectations, being accepting of dialysis or how the dyad work together may be difficult to have even within couples, and more so between patients, their partners and the renal care team; therefore, the SDQ could provide a non-intrusive way of opening discussions on these topics which could benefit their overall adjustment and QOL.

The findings from the longitudinal study on QOL over the transition onto dialysis provide clinicians with a positive message to share with patients and their partners: in a sample of UK patients starting dialysis, patients' physical and general QOL improved and their partners report their QOL to be good overall. In light of the fact that the results also indicate that patients' QOL at pre-dialysis is poor and partners' QOL worsens over the initial weeks, renal services should consider providing additional support at the pre-dialysis stage. This support could be informative, such as ensuring patients and partners know who and where to go for advice or counselling, or one-to-one sessions with members of the renal care team who may be able to help dyads manage their expectations or to adapt their lifestyle to align with the demands of dialysis. These steps may help improve QOL over this transition period.

7.6 Implications for patients and their partners

Although starting dialysis may add stress and affect many areas of their QOL and dyadic relationship, QOL may improve for patients, and partners may be able to maintain their QOL. Patient-partner dyads who work together and are accepting, positive and normalise dialysis may be able to buffer the impact of dialysis on their relationship and their QOL.

7.7 Future Research

The findings from this thesis have highlighted areas for future research. Firstly, the SDQ needs to be further validated before it can be used in a clinical setting. Therefore, the next step in this research would be a large scale field trial to establish the measure's structure and validity (e.g., construct, convergent, divergent). Such a study would require an adequate sample size for each version (patient and partner); thus approximately 400 participants (200 of from each group) would need to be recruited in order to conduct a factor analysis.

Secondly, the findings from the dyadic thematic analysis in Study 2 indicate that couples who worked together as a team buffered their relationship from the negative effects of early dialysis. This finding echoes theories about how couples cope with chronic illness in in the dyadic coping literature, such as the relational coping (Kayser et al., 2007) and systemic-transactional models (Bodenmann, Meuwly, & Kayser, 2011). Future research that explores the coping styles of ERF couples may better our understanding of these dyadic processes. Additionally, it may be valuable to assess the relationship between coping styles and QOL, particularly in the early phases of dialysis.

Thirdly, the longitudinal quantitative study found that patients' and their partners' QOL changed over the transition onto dialysis. Future research should examine the associations of these changes in QOL in relation to psychological and relationship factors. Furthermore, there is potential to explore the data of the 39 couples who completed the study using qualitative approaches such a visual graphical analysis (Brown, McGuire, Beck, Peterson, & Mooney, 2007) which may expose patterns that could be informative.

Finally, this programme of research indicated that although partners often play a pivotal role in ERF patients' care, they are not integrated into the current renal care service. Supporting and including renal patients' partners is in line with the 2014 National Health Service's forward view. In order to integrate them and offer effective support, the first step would be to conduct a mapping exercise to better understand who the partners of ERF patients are and what their needs are.

This initiative should be conducted across the UK and may best be conducted in collaboration with Kidney Care UK and the UK Renal Registry. This body of work would lay the groundwork for ensuring renal services meet the needs of the patients and those who provide informal, voluntary care and support to them. A further step in this mapping exercise should also be to standardise how and what details about patients' caregivers, informal or formal, are reported across all UK renal units. Currently, renal units only systematically record if a patient has a 'next of kin' and often no further details are kept electronically. Standardising, recording and linking this information about patients' caregivers to the UK Renal Registry may be beneficial as it could then be accessed and reviewed by policymakers, researchers and healthcare providers.

7.8 Summary and conclusion

This thesis has made a significant and novel contribution to the ERF field by providing insight into how ERF, and dialysis, affect QOL and the relationship between patients and their partners in the early phases of dialysis. The interpretations drawn from the qualitative strand of this research indicated that ERF and dialysis significantly impact many areas of QOL and also the dyadic relationship, but these may be minimised by psychological and relationship characteristics of the dyad, especially in the early phases. An outcome of this research is the SDQ which may offer clinicians a practical tool to identify patient-partner dyads who would benefit from additional support or counselling as they prepare to start dialysis. Furthermore, this thesis provided evidence as to the impact of starting dialysis on QOL in patients and their partners during the initial weeks of adjustment. The quantitative results showed that patients' QOL improved after starting dialysis, and their partners reported theirs to be good, although it worsened initially. In conclusion, the findings of this programme of research offer a positive message that good QOL may achieved over the transition onto dialysis, that dyads who work together can minimise the impact on their relationship, and that by recognizing and addressing psychological and interpersonal factors we may be able to improve QOL in ERF patient-partner dyads.

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Appendices

Appendix A

Chapter 3: Literature Review

Overview of articles included in the literature review

Quantitative studies

Author (year) *Title, Country*	*Purpose*	*Design*	*Sample*		*Analysis*	*Measures*	*Results*		*Conclusions*
			Patients	*Partners*			*Patients* *M* *SD* *p value*	*Partners* *M* *SD* *p value*	
Al-Rawashdeh, Alshraifeen, Rababa & Ashour (2020) "Hope predicted quality of life in dyads of community-dwelling patients receiving hemodialysis and their family caregivers" Jordan	To examine the associations between hope and QOL in HD patients and their partners using the actor-partner interdependence model (APIM).	Cross-sectional Dyadic	123 HD patients receiving outpatient dialysis from a Ministry of Health, military or university-led hospital in Jordan. Length of time on dialysis: >3 months	123 of their partners. Spouses: 26% (32) Child: 36% (44) Parent: 12% (15) Sibling: 11% (14) Other family member: 2% (3)	Paired *t*-tests, Pearson's Product Moment Correlations, Multilevel modelling to test the APIM	Hope: Herth Hope Index (HHI) 12 items 1-4 response scale (1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree) QOL: WHOQOL-BREF Physical	32.06 (3.81)	33.47 (4.06) *p*=0.002	Patients had poor QOL in the physical, psychological and environment domains and rated their social QOL to be moderate. Partners had good QOL in the physical, psychological and social domains and

Males: 57% (70)	(missing data for 15 partners) Female: 52% (64)	Psychological	46.54 (20.76)	63.65 (21.6) *p*<0.001	moderate QOL in the environment domain. Partners had a statistically higher QOL scores than patients in every domain. Significant actor effects were found between hope and QOL domain in both patient and their partners. Patients' hope scores had a significant positive association with partners'
		Social	49.68 (18.7)	55.6 (17.75) *p*=0.003	
		Environment	53.54 (22.13)	59.8 (23.36) *p*=0.017	
			48.56 (17.86)	52.46 (16.19) *p*=0.04	

									environment domain scores.
Anees, Hameed, Mumtaz, Ibrahim and Khan (2011) “Dialysis-related factors affecting quality of life in patients on hemodialysis” Pakistan	To assess health-related QOL of dialysis patients and dialysis-related factors affecting it.	Cross-sectional Not matched	125 HD patients from 3 dialysis units in Lahore. Length of time on dialysis: 58% (72, more than 8 months) 42% (53, less than 8 months)	50 of their partners (family caregivers). Female: NA	Descriptive statistics (M, SD) Inferential statistics (Pearson correlation coefficient, Student t test – independent samples, 1-way ANOVA)	WHOQOL-BREF: Physical	10.30 3.48	14.96 3.04 p<0.001	Patients’ QOL is poorer than their partners in physical, psychological and social domains.
						Physical (transformed score)*	39.4	68.5	
						Psychological	12.22 2.83	14.08 2.85 p=0.003	
						Psychological (transformed score)*	51.4	63	
						Social	12.18 4.22	14.64 3.74 p=0.007	
						Social (transformed score)*	51.1	66.5	
						Environment	12.18 4.22	12.76 2.93 p=0.51	

						Environment (transformed score)*	51.1	54.8	
Ferri and Pruchno (2009) “Quality of life in end-stage renal disease patients: Differences in patient and spouse perceptions” USA	To examine similarities and differences in spouse and patient ratings of the QOL of patients with ERF.	Longitudinal (1 year follow-up) Dyadic	315 patients on HD recruited from dialysis centres across the USA. 211 patients participated at the one year follow-up. Length of time on dialysis: 70 months (average) Male: 73%	315 of their partners at baseline. 211 of their partners at follow-up. Female: Data not reported	Two regressions were calculated to assess the associations of baseline and follow-up variables on patients’ QOL (self-reported) and patients’ proxy rating of QOL (partner-rated). Paired sample *t*-tests were used to compare patients’ and partner’ scores.	QOL: One item “How would you rate [your/the patient’s] overall QOL at present?” 1=Poor, 2=Fair, 3=Good, 4=Very good, 5=Excellent	Baseline: 3.35 1.06 Follow-up: 3.30 0.97	(proxy) Baseline: 2.9 1.08 $p<0.000$ Follow-up: 2.98 1.07 $p<0.001$	Patients reported better QOL, health, mood, functional ability and less symptoms than their partners’ proxy assessments. Patients and partners’ QOL scores were positively correlated at baseline and follow-up. Patients’ baseline QOL and improvement
						Health: One item “In general, would you say that [your/the patient’s] health is: 1=Poor, 2=Fair, 3=Good, 4=Very good, 5=Excellent”	Baseline: 2.78 1.06 Follow-up: 2.79 1.03	Baseline: 2.4 1.08 $p<0.000$ Follow-up: 2.29 1.04 $p<0.001$	
						Kidney disease symptoms:			

15 symptoms commonly associated with kidney disease (from the CHOICE Health Experience Questionnaire)	Baseline: 13.05 7.36	Baseline: 15.57 7.34 p<0.000	s in health and mood were predictors of QOL at follow-up. Partners' rating of the patients' QOL at follow-up were predicted by patients' baseline QOL and improvements in patients' health, functional ability, mood and partners' QOL.
	Follow-up: 11.03 6.94	Follow-up: 13.48 7.21 p<0.000	
Mood: 10 item Philadelphia Geriatric Center Positive Affect and Negative Affect Scale	Baseline: 37.65 5.60	Baseline: 34.35 6.36 p<0.000	
	Follow-up: 38.12 5.68	Follow-up: 34.21 6.48	
Functional ability: 10 items from the National Health Interview Survey	Baseline: 21.28 6.41	Baseline: 18.80 6.56 p<0.000	
At baseline and follow-up, patients completed each	Follow-up: 21.79 6.00	Follow-up: 18.94 6.58	

						measure. Partners completed each measure rating their assessment of the patient and also reported their QOL.		p<0.000	
Khaira, Mahajan, Khatri, Bhowmik, Gupta and Agarwal (2012) “Depression and marital dissatisfaction among Indian hemodialysis patients and their spouses: A cross-sectional study” India	To explore incidence and degree of depression, marital dissatisfaction, and QOL in Indian ERF patients and their spouses and to assess factors that contribute to these.	Cross-sectional Dyadic	49 patients on HD from a tertiary care hospital in northern India. Length of time on dialysis: 14 months (average) Male: 65% (32)	49 of their partners. Spouses: 100% Female: 65% (32)	Pearson’s correlation coefficient and t-tests were used to explore relationships in the data. Individual stepwise multiple regression was used to assess the predictors of depression and marital dissatisfaction.	QOL: One item asking them to rate their QOL, Poor-Excellent	Male: 2.8 1.0 Female: 2.5 1.1 p=0.42	Male: 2.8 1.1 Female: 2.7 1.2 p=0.83	Patients’ scores for depression were negatively correlated with QOL. Partners’ scores for depression and marital satisfaction were negatively correlated with QOL.
						Depression: 21 item Beck Depression Inventory	Male: 13.7 10.8 Female: 22.0 10.6 p=0.015	Male: 13.6 9.8 Female: 11.5 10.0 p=0.50	
						Marital Satisfaction:	Male: 25.0	Male: 28.6	

						14 item Revised Dyadic Adjustment Scale	16.7 Female: 30 18.9 p=0.35	16.7 Female: 19.4 13.6 p=0.04	
						Socioeconomic status: Kuppuswamy Urban Index	-	-	
						Social support: Nuclear or joint family	-	-	
							(t-tests between the scores of male and female patients)	(t-tests between the scores of male and female partners)	

Mixed methods studies

Author (year), Title, Country	*Purpose*	*Design*	*Sample*		*Analysis*	*Measures*	*Results*		*Conclusions*
			Patients	*Partners*			*Patients M SD/Range*	*Partners M SD/Range*	
Courts (2000)	To examine anxiety, stress,	Dyadic	14 HHD patients from	14 of their partners	Descriptive statistics	Clinical Anxiety Scale	15 Range: 0-43	9 Range: 2-19	The patients' and partners' scores

"Psychosocial adjustment of patients on home hemodialysis and their dialysis partners" USA	depression and psychological adjustment in patients and carers. To explore patient and carers HHD decision-making process.	Surveys were mailed to the participants. Interviews were conducted by the researcher in the participants' homes.	multiple dialysis facilities within a southern USA state. Average length of time on HHD: Not reported. Male: -	Spouse: 71% Family member: 21% Friend: 7% Female: 93% (13)	were reported. A descriptive, narrative reporting style was used for the qualitative data.	Generalized Contentment Scale	20.7 Range: 9-56	20.3 Range: 6-29	revealed low levels of anxiety, depression, and dialysis related stress, and positive adjustment to the illness. The interviews indicated that overall both patients and partners recommend HHD and listed its many benefits. However, the partners discussed the negative effects of HHD more than the patients.
						Hemodialysis Stressor Scale^{+}	33 Range: 8-62	-	
						Psychosocial Adjustment to Illness Scales Self-Report^{+}	49.1 Range: 32-67	-	
						Spielberger Anxiety Scale: State	37.6 Range: 23-56	31.8 Range: 20-52	
						Trait	37.4 Range: 30-56	33.8 Range: 20-48	

							Psychosocial Interviews: Patients chose HHD either on advice from their health professional or stated it was their personal preference. HHD allowed was more convenient to them. Their partners stated that they had felt stressed in the beginning and that HHD required commitment and a strong relationship.		
Ferrario, Zotti, Baroni, Cavagnino and Fornara (2002) "Emotional reaction and practical problem of the caregivers of hemodialysed patients" Italy	To investigate the personality traits of patients and their partners and compare these to a healthy population. To evaluate the relationship	Cross-sectional Dyadic	50 HD patients from 2 dialysis centres in north-western Italy. Average length of time on dialysis:	50 of their partners Spouse: 70% Son/daughter: 14% Parent: 8% Women: 80%	Critical ratio was used to compare participants' questionnaire scores with the healthy population. Student's t-test for paired data and Pearson's correlation for	Anxiety: State-Trait Anxiety Inventory			Patients and partners' scores on the SWLS were not correlated. Patients had higher levels of anxiety and depression compared to a healthy population, unlike
						State	42.46 11.07	41.16 11.05	
						Trait	43.76 11.84	41.16 9.15	
						Personality: Eysenck Personality Questionnaire			
						Extraversion	8.12 3.47	8.28 2.98	
						Neuroticism	5.98	5.42	

between personality and caregiving stress and satisfaction with life.	55 months (range 2-245 months) Male: 66%	relationships between the variables. Frequency distribution was used to analyse the qualitative interview data.	Psychoticism	3.00 3.02 1.50	3.23 2.58 1.36	partners who did not have higher levels of negative affect compared to a healthy population.
			Depression: Depression Questionnaire	8.90 5.98	5.28 3.85	
			Quality of life: Satisfaction with Life Scale	-	-	
			Family environment: Family Strain Questionnaire	-	-	
			Semi-structured interview (partners only)	Semi-structured Interview: 25% reported financial problems; 12% bothered by patient’s symptoms 10% experienced social distress; Significant impact to social life; 58% thought about the patient’s possible death but did not speak about it to them; 94% found reward in their caregiving duty		

Qualitative studies

Author (year), Title, Country	*Purpose*	*Design*	*Sample*		*Analysis*	*Data collection method*	*Results*	*Conclusions*
			Patients	*Partners*				
Andrew (2001) "The pre-dialysis experience – Are individual needs being met?"(Andrew, 2001) UK	To expand knowledge regarding what patients and their families need during pre-dialysis care and provide direction for renal units	Cross-sectional Not matched	10 patients (No further details provided)	Patients' family members (Number not specified)	Grounded theory	Semi-structured interviews	Eight categories about the pre-dialysis experience: 1) Information provision 2) Reaction 3) Coping strategies 4) Learning and understanding 5) Ability to be positive 6) Acceptance 7) Sharing and support 8) The way forward.	The pre-dialysis experience is a journey that consists of many changes. Renal units must adopt holistic approaches necessary to meet patients and families' needs.
Baillie and Lankshear (2014) "Patient and family perspectives on peritoneal dialysis at home: Findings from an	To explore the perspective and experiences of PD patients and their families	Cross-sectional Not matched	16 patients recruited from a large Welsh NHS health board. Length of time on PD:	9 of their partners Spouse: 6 Daughter: 2 Family member: 1 (2 partners – a wife and a	Thematic analysis	Ethnographic interviews and observations	Four themes describing the experiences of initiating PD, the constraints imposed by PD, the uncertainty of managing a crisis and patient's deterioration, and seeking freedom through creativity or hope for a transplant.	Despite PD posing significant challenges in the lives of patients and their partners, they

ethnographic study”(Baillie & Lankshear, 2015) UK			12 patients >2 years 3 patients 1-2 years 1 patient 6-12 months Male: 12 (75%)	daughter – were related to 1 patient) Female: 100%				described how they managed these.
Ekelund and Andersson (2010) “I need to lead my own life in any case” – A study of patients in dialysis with or without a partner” Sweden	To elicit patients’ and partners’ experiences of living with ERF and explore how they coped with ERF.	Longitudinal Not matched	39 patients who had started HD or PD in the last year at a major renal clinic in southern Sweden. 29 patients participated in the follow-up 12 months after the initial interview. Length of time on	21 of their partners (spouses or cohabitating partner) 15 of their partners participated in the interview at 12 months. Female: 75% (16)	Phenomenological with biographical perspective and discursive approach	Questionnaire based semi-structured interviews	Themes were explored across the patient-partner dyads and patients without a partner: 1) Importance of treatment being individualized 2) Dependency on an apparatus 3) Consequences of the disease and its treatment 4) Hopes for the future 5) Thoughts on life and death Additional themes include The psychosocial dyad, Living alone, and Evaluation of the interview.	Similar experiences were reported across HD and PD modalities and between patient-partner dyads and single patients.

			dialysis: > 12 months Male: 93% (30)					
Monaro, Stewart, and Gullick (2014) “A ‘lost life’: Coming to terms with haemodialysis” Australia	To explore early experiences of close family members and people with ERF starting HD.	Cross-sectional Other	11 HD patients from a tertiary referral hospital in Sydney, Australia. (3 patients did not have a partner, 4 patients’ partners did not participate in the interviews). Length of time on dialysis: < 3 months	5 partners (1 partner’s patient did not participate in the interviews) Spouse: 3 Daughter: 1 Mother: 1 Female: 80%	Phenomenological analysis	Semi-structured interviews	The common experience was a sense of loss and described by the themes Shock and grief, Loss of sense of self, Loss of spontaneity and personal freedom, Changed body feelings, Reframing family roles, and Loss of social connectedness.	Early dialysis is a time in the treatment when both patients and their families members experience significant changes or loss physically, emotionally and socially.

			Male: 45% (5)					
Wellard and Street (1999) “Family issues in home-based care”(Wellard & Street, 1999) Australia	To explore how families cope with home-based dialysis.	Case studies Other	3 patients on home dialysis. Length on dialysis: Not reported Male: 100% (3)	5 their family members. Spouse: 3 Other family member: 2 Female: Not reported.	Critical ethnographic approach	In-depth interviews, informal conversations, and observations	The issues the families confronted with home-based dialysis included the home becoming a clinic, placing expectations on the wives’ to act as caregivers, a changed social life, difficulties with local medical staff, and a process of learning to work the health-care system.	The findings of this study identified a number of areas that families could benefit from more support.
White and Grenyer (1999) “The biopsychosocial impact of end-stage renal disease: The experience of dialysis patients and their partners” Australia	To investigate the biopsychosocial impact of ERF on both patients and partners using a phenomenological approach.	Cross-sectional Dyadic	22 patients on HD or PD, recruited from a single tertiary dialysis facility. Length of time on dialysis: 3.5 years (range 6 months-8 years)	22 of their partners. Spouses: 95% (21) Daughter: 5% (1) Female: 55% (12)	Husserlian phenomenological approach	Interviews (open response to two item topic guide)	Patient perspective: 1) Anxiety about the uncertainty of their health 2) Major changes in lifestyle since the commencement of dialysis 3) Negative emotional responses to dialysis 4) Positive aspects of their relationship 5) A sense of indebtedness to their partners Partner perspective: 1) Lifestyle changes since the commencement of dialysis 2) Fatigue	Both patients and partners reported lifestyle changes that impacted their emotional and physical health. Although both identified positives in their relationship,

			Male: 50% (11)				3) Negative reactions to the partners’ situation 4) Positive relationship with partners 5) Loss within the relationship	partners reported a sense of loss in the relationship.
Wise, Schatelll, Klicko, Burdan and Showers (2010) “Successful daily home hemodialysis patient-care partner dyads: Benefits outweigh burdens”(Wise et al., 2010) USA	To explore patient and carers experiences on SDHD and what individual, relationship and social factors influence their experience.	Cross-sectional Dyadic	13 patients recruited via 5 dialysis centres. Average length of time on SDHHD: 17 months Male: 69% (9)	13 of their partners Spouse or cohabitating: 100% (13) Female: 69% (9)	Grounded theory	In-depth Interviews	Four relationship profiles were identified: Thriving, Surviving, Martyrdom and Seeking. Profiles which had higher levels of congruence between their narratives and who shared the responsibilities of SDHD were more successful in managing it and spoke more positively of their circumstances. Across each profile, patients stated that SDHD had improved their health-related well-being whereas carers’ views of SDHD and its impact on their lives often varied across each profile and between themselves and their patient-partner.	The impact of SDHD on patients and partners is complex and affects each member of the dyad uniquely.

Wright and Kirby (1999) "Deconstructing Conceptualizations of 'adjustment' to chronic illness"(Wright & Kirby, 1999) UK	To develop a theoretical framework within which to understand 'adjustment' in ERF.	Cross-sectional Not matched	10 PD patients. Length of time on dialysis: 5 patients 6-8 weeks; 5 patients 12 months Male: 60%	8 of their partners. Spouses: 50% (5) Daughter: 13% (1) Nurses: 37% (3) Female: -	Grounded theory	Semi-structured interviews	Five themes were identified related to adjustment and acceptance: 1. Adopting a new approach to being and living 2. Getting back to life 3. Adapting life to accommodate illness and treatment 4. Coping skills 5. Processing losses	Adjustment to ERF and the illness were marked by patients being able to adopt a new approach to living and being. Successfully adjusting was impacted by external, internal, illness factors and occurred over time.

Notes. ERF – established renal failure, HD – haemodialysis, HHD – Home haemodialysis, PD – peritoneal dialysis, QOL – Quality of life, SDHD – Short daily home haemodialysis, SWLS – Satisfaction with life scale, WHOQOL – World Health Organization Quality of Life Scale.

- Indicates that the data was not reported in the article.

* Anees et al. 2011 did not transform the domain scores of the WHOQOL-BREF, as recommended by the scoring guidelines. The transformations provided in the table were conducted by the researcher in accordance with these guidelines.

Appendix B

Supporting quotations from qualitative synthesis

	Quotes	Contributing studies	Author's interpretation:
Overall QOL	"[T]his is the best I've ever felt…I feel like I have a life again." Patient (Wise et al., 2010) "I've got no life. I've got to come here three times a week." Patient (Monaro et al., 2014) "[it's] the only way to live" Partner (Courts, 2000) "I always have to consider the dialysis." Partner (Wise et al., 2010)	(Andrew, 2001; Baillie & Lankshear, 2015; Courts, 2000; Ekelund & Andersson, 2010; Ferrario et al., 2002; Monaro et al., 2014; White & Grenyer, 1999; Wise et al., 2010; Wright & Kirby, 1999)	Dialysis had both a positive and negative impact on QOL in patients and partners. Patients reported more benefits to their QOL than partners who noted some positives but who more often described how it negatively impacted their lives and lifestyle.
Health	"Now I feel much better I'm just going to try getting on with things —like before, you know." Patient (Wright & Kirby, 1999) "We cope as long as I stay healthy. Otherwise, heaven knows what would happen if I were sick." Partner (White & Grenyer, 1999) "He's alive and still going. I suppose that is the main thing." Partner (White & Grenyer, 1999) "It isn't a disease or disability. . .that's going to get better, you know, there's more	(Ekelund & Andersson, 2010; Monaro et al., 2014; Wright & Kirby, 1999)	Overall patients stated dialysis improved their health, although some noted they still felt tired or had other side-effects. Partners rarely commented on their health but recognized the importance of them staying well to look after the patient. Both patients and partners reflected on dialysis' part keeping the patient alive and the terminal nature of ERF.

	possibility of it getting worse rather than better." Patient (Baillie & Lankshear, 2015)		
Physical Domain			
Pain and discomfort	"It got rid of all the fluid... the sick feeling." Patient (Monaro et al., 2014) "I have this terrible itching." Patient (Ekelund & Andersson, 2010)	(Ekelund & Andersson, 2010; Monaro et al., 2014; Wise et al., 2010)	Pain and discomfort were only mentioned by patients, and dialysis had mixed effects on it.
Energy and fatigue	"Well, you cannot imagine being so tired for so long. You feel too tired to breathe —it is just as though you cannot be bothered to live." Patient (Wright & Kirby, 1999) "I just get very tired. We're just tired." Partner (White & Grenyer, 1999)	(Ekelund & Andersson, 2010; Monaro et al., 2014; White & Grenyer, 1999; Wise et al., 2010; Wright & Kirby, 1999)	Generally, patients and partners reported being tired; however, patients in Wise et al. (2010) stated they had more energy. These patients had switched from conventional, in-centre HD to HHD.
Sleep and rest	"The dialysis drains you right out. . . I go home and sit in my armchair and go to sleep." Patient (Monaro et al., 2014)	(Monaro et al., 2014)	Sleep and rest were not frequently commented on. This quotation indicates that patients may have disturbed sleep patterns on dialysis.
Psychological Domain			
Positive feelings	"Now . . . I feel a lot more hope. It has really made a difference in how I view everything." Patient (Wise et al., 2010)	(Andrew, 2001; Baillie & Lankshear, 2015; Courts, 2000; Ekelund & Andersson, 2010;	Patients reported feeling less depressed and having a positive view of life. Partners

		Ferrario et al., 2002; Wise et al., 2010; Wright & Kirby, 1999)	did not report any positive feelings as a result of dialysis, but Ferrario et al. (2002) reported that 94% of partners “felt better as a result of the fact that they were caring for their loved one.”
Thinking, learning, memory and concentration	“It affected me cognitively —thinking through things. I could not quite get it out of my mind. I felt anxious and uptight thinking about it —my head was just full of kidney disease.” Patient (Wright & Kirby, 1999)	(Andrew, 2001; Monaro et al., 2014; Wright & Kirby, 1999)	Only discussed by patients and infrequently but this quotation suggests impairments in this facet.
Self-esteem	“I feel like I’m no more than a package that’s being carried around. I don’t have any goals at all anymore.” Patient (Ekelund & Andersson, 2010)	(Ekelund & Andersson, 2010; Monaro et al., 2014; Wright & Kirby, 1999)	Patients described themselves as useless and without a clear sense of purpose. Monaro et al. (2014) reported that partners had a lost sense of self.
Body image and appearance	“I used to have quite a good figure before this. That sometimes gets me upset you know. . . I feel like Michelin woman as I now get so big around here (abdomen), so you have to wear more baggy things like this.” Patient (Wright & Kirby, 1999)	(Wright & Kirby, 1999)	Only patients discussed the negative impact of ERF on their body image and appearance. Some patients covered up their fistulas whereas some were accepting of it.

Negative Feelings	“. . . Feeling useless, that they’re no good for anybody. . . F—ng useless! I should have died [crying] and it would have been better for everybody ‘cause it’s so hard on everyone now.” Patient (Monaro et al., 2014) “It [dialysis] affects me to the point of frustration. It doesn't matter how much I do for my wife, we know there is no light at the end of the tunnel.” Partner (White & Grenyer, 1999)	(Andrew, 2001; Baillie & Lankshear, 2015; Courts, 2000; Ekelund & Andersson, 2010; Ferrario et al., 2002; Monaro et al., 2014; White & Grenyer, 1999; Wise et al., 2010; Wright & Kirby, 1999)	Both patients and partners reported negative feelings about ERF and the impact of dialysis on their lives.
Level of Independence Domain			
Mobility	Not discussed by the patients or partners.		
Activities of daily living	“I’ve always been independent. . . Ever since I’ve been sick I’ve been relying on the family to keep me going.” Patient (Monaro et al., 2014)	(Monaro et al., 2014)	Very few of patients mentioned not being able to take care of their basic needs.
Dependence on medication and treatment	“The most difficult change has been from feeling free to being bound to an apparatus.” Patient (Ekelund & Andersson, 2010) “has more freedom … can do what he wants” Patient (Courts, 2000) “[Home dialysis] is more work on my part than it was when he was at the center. Sometimes it gets a little hairy, like if I need	(Andrew, 2001; Courts, 2000; Ekelund & Andersson, 2010; Wise et al., 2010)	Being physically tied to the dialysis machine was difficult for many patients. However, patients on home dialysis and their partners stated it gave them freedom, and their QOL was better because they had more independence. However,

	to do something, well, I always have to consider the dialysis.” Partner (Wise et al., 2010)		partners of HHD patients stated that the dialysis machine and regime were burdensome and ever present in their lives.
Working capacity	“It was very important for me to get back to a life, get back to working, then in that way I still have a normal existence and feel better about myself” (Wright & Kirby, 1999) “It is tough trying to get work done while she’s on the machine. It pretty much rules the house.” Partner (Wise et al., 2010)	(Courts, 2000; Wellard & Street, 1999; Wise et al., 2010; Wright & Kirby, 1999)	Although HHD gave some patients the opportunity to work, most patients reported that their ability to work was limited by dialysis but was important to their well-being. Partners of HHD patients found it difficult to work when patients were dialysing and stated HHD created more work for them.
Social Relationships Domain			
Personal relationships	“I’m very blessed. I was so sick. I could barely walk. But I’ve got [Partner]. . . if you have a good caretaker and a person that loves you, you have to care for them too.” Patient (Wise et al., 2010) “We have been married for 45 years. We've had our ups and downs but I think in reality this dialysis has brought us closer together.” Partner (White & Grenyer, 1999)	(Courts, 2000; Ekelund & Andersson, 2010; Monaro et al., 2014; Wellard & Street, 1999; White & Grenyer, 1999; Wise et al., 2010; Wright & Kirby, 1999)	Patients and partners stated the importance of a strong relationship and mutual love and respect. For these dyads, dialysis did not negatively impact their relationship, and in some cases strengthened it. However, dialysis brought worry whether they could cope with it and in some cases

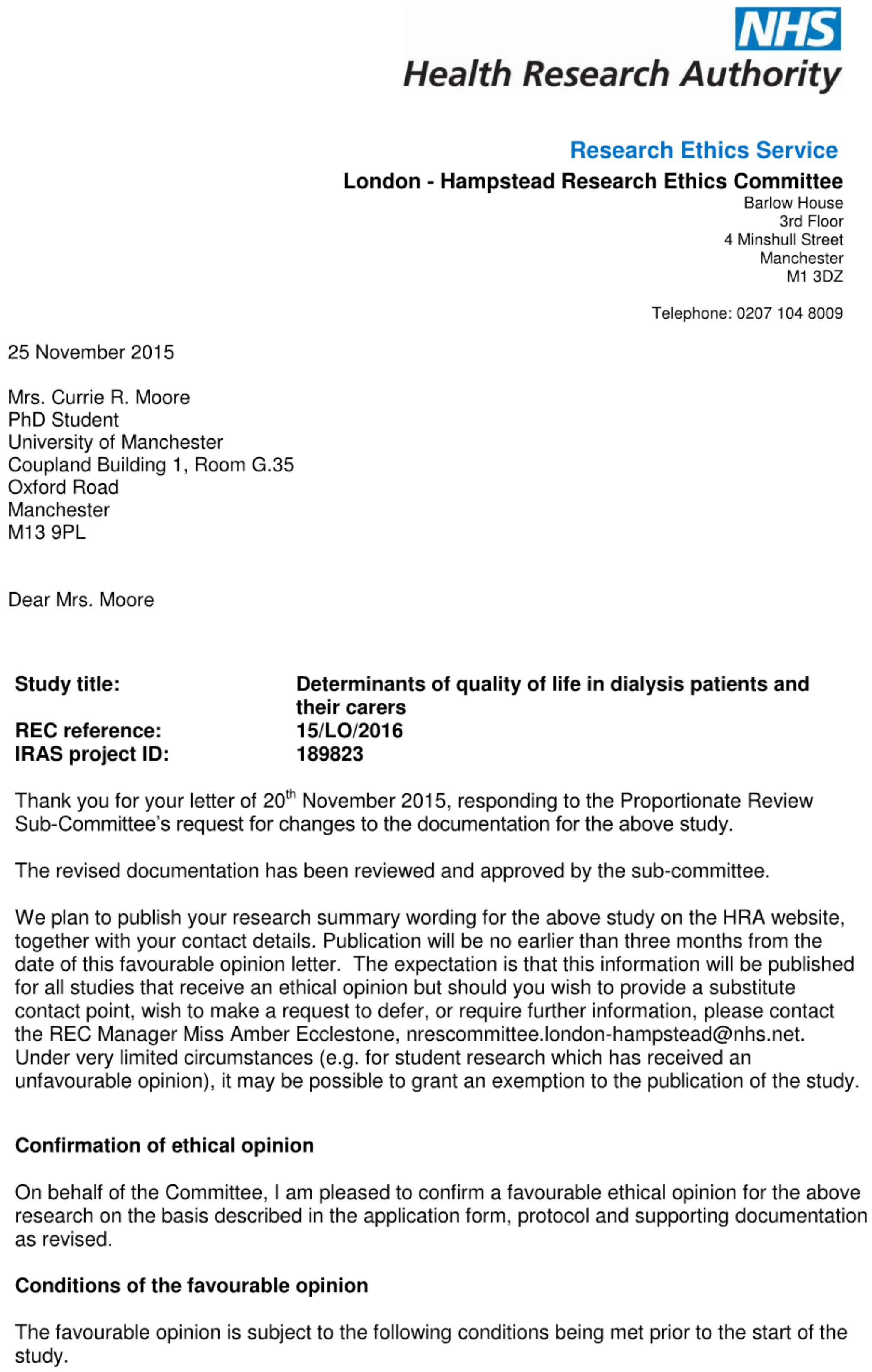
	"I was worried.. . we've been married 28 years... I thought it might be too much for him and he might leave me.. . if he did that, I'd just be devastated... but he sort of got into it." Patient (Monaro et al., 2014) "I don't like him. No, I don't like him. I want to keep him alive. . . we've been together for [many] years. I can love him without liking him." Partner (Wise et al., 2010)		exacerbated relationships which were already fraught.
Practical social support	"You've lost your independence... you depend on other people all the time. . . I've got to now ask for help from my friends. . . I'm finding it difficult to do." Patient (Monaro et al., 2014) "She [wife] was involved in the training, so she knew, so if I sort of broke my legs and couldn't move, she'd know what to do." Patient (Baillie & Lankshear, 2015) "I want to have a second person trained so she can get time off." Patient (Wise et al., 2010)	(Andrew, 2001; Baillie & Lankshear, 2015; Ekelund & Andersson, 2010; Monaro et al., 2014; Wellard & Street, 1999)	Patients relied mostly on their partners for practical support with dialysis. Those who had to ask friends or non-spousal family members had more difficulty getting and asking for the help. Partners did not comment directly on the practical support they received. One patient, however, noted the importance of having someone trained so the partner could have respite.
Sex life	"My sexual longing is reduced." Patient (Ekelund & Andersson, 2010)	(Ekelund & Andersson, 2010; Monaro et al., 2014; White & Grenyer, 1999)	Partners spoke about their sex-life more readily than patients,

	“It's affected our sex life. We had a very good sex life, and now we're too tired half the time. I hope that comes back. He feels the same as I do.” Partner (White & Grenyer, 1999)		but both stated it was impaired.
Environment Domain			
Physical safety and security	Not commented on by patients or partners.		
Home environment	“He transformed [my] sunroom into a dialysis center.” Partner (Wise et al., 2010)	(Courts, 2000; Wellard & Street, 1999; Wise et al., 2010)	Only home dialysis partners discussed the impact of dialysis on the home environment, which was often negative.
Financial resources	“I’m not working.. . I get part superannuation and part disability. . . I have liabilities like mortgages, investments so I’m going to have to re-look at my finances.” Patient (Monaro et al., 2014)	(Ekelund & Andersson, 2010; Ferrario et al., 2002; Monaro et al., 2014)	Patients more frequently discussed their financial concerns and problems accessing disability benefits. Ferrario et al. (2002) reported that 25% of partners had financial problems.
Health and social care availability and quality	“The treatment personnel should realize that they’re dealing with a person, and not simply with a patient.” Patient (Ekelund & Andersson, 2010) “I did finally talk to people at the center. . . It really did help for me to talk to them. They were real honest with me. I wish I had talked to them sooner.” Partner (Wise et al., 2010)	(Andrew, 2001; Baillie & Lankshear, 2015; Ekelund & Andersson, 2010; Monaro et al., 2014; Wellard & Street, 1999; Wise et al., 2010)	Patients and partners highlighted the importance of person-centred care. Accessing reliable treatment outside of dialysis was repeatedly discussed as an issue as so few doctors understand the complexity of ERF.

Opportunities for new information and skills	“I didn’t recognise it [peritonitis] at the time. . . but once it’s happened once, you’re looking for [it], you’re aware then.” Partner (Baillie & Lankshear, 2015)	(Baillie & Lankshear, 2015; Monaro et al., 2014)	Home dialysis patients and partners learned many new skills related to dialysis, including recognizing the signs of infection.
Participation and opportunities for recreation/leisure	“There was a table [in the hotel room]... that was marble so I could wipe it down and put the bag on there, and I said “Oh dear what am I gonna hang it up with?”... found a hook in the bathroom, hooked it on there .. . and it worked out great.” Patient (Baillie & Lankshear, 2015) “We . . . had to make arrangements with multiple dialysis units. We had to follow a schedule, no flexibility. They did not deliver the supplies. We had to wait.” Partner (Wise et al., 2010)	(Baillie & Lankshear, 2015; Courts, 2000; Ekelund & Andersson, 2010; Ferrario et al., 2002; Monaro et al., 2014; White & Grenyer, 1999; Wright & Kirby, 1999)	Patients on HHD spoke most positively about their ability to travel and partake in leisure activities. Some PD and their partners grew in confidence in doing their treatments outside of the home which increased their opportunities for recreation and leisure. Overall, partners reported that dialysis complicated their ability to take part in previously enjoyed recreational activities or to travel.
Physical environment	Not discussed by patients or partners.		
Transport	Not discussed by patients or partners.		
Spirituality, Religion, Personal Beliefs Domain			

Spiritual, Religion, Personal Beliefs	"You just get on with it now . . . that's it really. If you have adjusted you try and get back to what's normal as far as you can." Patient (Wright & Kirby, 1999) "When he was ready to give up, I told him, 'Oh, no. You're not giving up! You just put your trust in God and I'll do the rest'." Partner (Wise et al., 2010)	(Wise et al., 2010; Wright & Kirby, 1999)	Patients and partners expressed their belief in themselves, their partner or their religious beliefs to overcome obstacles related to dialysis.

Appendix C



NHS
Health Research Authority

Research Ethics Service
London - Hampstead Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8009

25 November 2015

Mrs. Currie R. Moore
PhD Student
University of Manchester
Coupland Building 1, Room G.35
Oxford Road
Manchester
M13 9PL

Dear Mrs. Moore

Study title:	**Determinants of quality of life in dialysis patients and their carers**
REC reference:	**15/LO/2016**
IRAS project ID:	**189823**

Thank you for your letter of 20th November 2015, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Miss Amber Ecclestone, nrescommittee.london-hampstead@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Confirmation of Insurance Coverage]		12 October 2015
Interview schedules or topic guides for participants [Topic Guide]	V3	16 October 2015
IRAS Checklist XML [Checklist_04112015]		04 November 2015
Letter from funder [MRC]		16 May 2014
Letter from sponsor [UoM Sponsorship Confirmation]		12 October 2015
Letters of invitation to participant	V3	16 October 2015

Other [CV.Suzanne Skevington]		14 October 2015
Other [CV.Sandip Mitra]	1	02 November 2015
Other [Uni Manchester Liability]		01 June 2015
Other [Uni Manchester- Prof Indemnity]		29 May 2015
Other [Uni Manchester Public Employer Product Liability]		03 June 2015
Other [Training.GCP.Currie]		03 March 2015
Other [Training.GCP.Sandip]		14 June 2015
Other [Data Management Plan]	3	28 October 2015
Other [Email Correspondence - re: pre-validation Q&A]		06 November 2015
Other [Distress Policy]	1	06 November 2015
Other [Lone Worker Policy.Escalation Procedure]	V1	19 November 2015
Other [Lone Worker Policy.Considerations Manchester]	V1	19 November 2015
Other [Lone Worker Policy.Procedures]	V1	19 November 2015
Other [Lone Worker Policy.Risk Asmt Checklist]	V1	19 November 2015
Other [Lone Worker Policy.Safety Check Template]	V1	19 November 2015
Other [Researcher response to Provisional Approval]	V1	20 November 2015
Participant consent form [Patient]	V4	27 October 2015
Participant consent form [Carer]	V4	27 October 2015
Participant information sheet (PIS) [Patient]	V6	27 October 2015
Participant information sheet (PIS) [Carer]	V5	27 October 2015
Participant information sheet (PIS) [PIS.Patient]	V7	19 November 2015
Participant information sheet (PIS) [PIS.Carer]	V6	19 November 2015
REC Application Form [REC_Form_04112015]		04 November 2015
Referee's report or other scientific critique report [PAN MAN]		22 September 2015
Research protocol or project proposal [Protocol]	2	16 October 2015
Summary CV for Chief Investigator (CI) [CV.Currie Moore]		02 November 2015
Summary CV for supervisor (student research) [CV.Alison Wearden (PI)]	1	18 September 2015
Validated questionnaire [WHOQOL-Bref]		
Validated questionnaire [WHQQOL Importance Scale]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/LO/2016	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Signed on behalf
of Miss Stephanie Ellis
Chair

Email: nrescommittee.london-hampstead@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Ms Lynne Macrae*

Dr. Lynne Webster, Central Manchester University Hospitals NHS Foundation Trust

Appendix D

[Printed on Trust's Letterhead]

Invitation to Participate in a Research Study:

Quality of life in dialysis patients and their carers

Dear *Patient Name*,

You are invited to take part in a research study at the Manchester Royal Infirmary. Research is an important part of the work that we do at the Trust and helps us to provide better care to our patients and those close to them.

You have been sent this letter because you may be eligible to take part in this research study. The study is about your quality of life during the early stages of dialysis care. We are keen to interview people who are preparing for dialysis or who have started dialysis in the last 6 months. The study also seeks to understand more about the impact of dialysis on those close to you. If you are interested in taking part, you will be asked to invite the person who you think gives you the most support in your daily life (your "carer") to take part as well.

The study consists of an interview and completing 3 short surveys. The interviews will be conversational and held with you and the person you nominate separately. Please be assured that everything said in the interviews will remain confidential and will not be shared with your healthcare team or the other person who takes part.

Next steps:

- You can contact any of the people listed below to confirm your interest in taking part or ask to not be contacted further about this study:
    - Mrs. Currie Moore, Researcher, 01612758300, currie.moore@manchester.ac.uk
    - Clinical Research Nurses, 0161276 4485, *[nurse inserts email address*]
    - Dr. Sandip Mitra, 07900242651, sandip.mitra@cmft.nhs.uk
- If we do not hear from you in 3 working days, one of your clinical care team will be in touch by telephone.
- If you would like to take part in this study, the researcher team would also like to speak with your "carer". Please check that your "carer" gives his or her permission to be contacted by the research team.

If you have any questions about the study or taking part in research, we will be happy to answer them for you. Thank you for your time and for considering to take part in this study.

Best regards,

Dr. Sandip Mitra	*[Nurse Inserts Name]*
Consultant Nephrologist	Clinical Research Nurses
CMFT – MRI Renal Care	CMFT – MRI Renal Research

Appendix E

CMFT Logo here

PARTICIPANT INFORMATION LEAFLET
Quality of life in dialysis patients and their carers: Interview Study
(Patient Version)

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives or anyone else you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?
More and more people require dialysis every year. Dialysis provides people with a way of removing the toxins from their bodies when their kidneys are no longer able to perform this function. Although it is life sustaining, it is also a complex medical treatment and requires people to spend a considerable amount of time undergoing dialysis and rigorously adhering to diets, medication and schedules. Therefore, its impact on peoples' lives is not limited to just the individual on dialysis' physical health but also to many other areas of their lives and to the lives of their families and friends.

With all medical treatments, it is important to know how they affect people's quality of life. A large amount of research has been done to assess the quality of life of people on dialysis; however, there is very little known about how dialysis impacts peoples' quality of life just before they start dialysis and over the first 9 months on it. The aim of this study is to conduct interviews with patients and a person close to them who assists with their care (carer) over this time period. The information collected from this study will provide future dialysis patients and carers, health care professionals and governing bodies with a better understanding of how dialysis affects your quality of life.

Why have I been invited?
You have been asked to take part in this study because you are currently in the care of the renal team at Manchester Royal Infirmary. People who are planning to use dialysis OR who have just started dialysis OR who have been on dialysis for less than 6 months are invited to participate in this study. We are also interested in better understanding how dialysis affects people close to you. We would like to ask that you nominate a person (a member of your family or a close friend) who provides you with emotional,

physical or practical support. We will invite them to take part in the study as well.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

a. You may contact the researcher directly (contact details provided on page 3) or one of the doctors or nurses listed in the Letter of Invitation. Alternatively, a member of your renal care team will contact you by phone in 3 days time to see if you are interested in taking part in the study. They will also ask if you give your permission to be contacted by the researcher. If you give your permission, the researcher will contact you and answer any questions you have about the study.
b. If you decide to participate, an interview will be arranged with you. The interview can be arranged at the hospital (in a private meeting room) or at your own home. The duration of the interview will be about one hour and will be arranged at a time most convenient to you.
c. Before the interview, the researcher will make sure you are happy to participate in the study. She will then review your rights as a participant with you. Lastly, the researcher will obtain your informed consent in writing.
d. The interviews will be audio-recorded to allow the researcher to review the conversation.
e. If the any aspect of the study is distressing to you, we will pause the interview and you may decide if you would like to continue or not. If necessary, the researcher can offer you information on support available to you.
f. After the interview, you will be asked to complete 3 short surveys.
g. At the conclusion of the study, the researcher will confirm how the findings will be shared with you. She will also ask if you are interested in providing feedback on her analysis of the study's findings. This would involve either another meeting or phone call.
h. You have the right to withdraw from this study at any point, without explanation. Taking part in this study will not affect any aspect of your health care.

What are the possible benefits of taking part?

There are no direct and immediate benefits to you personally for participating in this study. However, the information you provide will be invaluable in studying quality of life during a very critical period of time. The findings of the study will influence the care provided to patients and their carers in the future, and you would have made an important contribution.

Will my taking part in this study be kept confidential?
Everything that you say in the interview and in the surveys will be confidential and will not be released to anyone outside of the study or to your carer. However, if it is revealed through the interview that you are at risk of harm to yourself or another person, the researcher will ask your permission to put you in contact with the relevant health care professional. When the results of the study are reported and published, your name will not be released and it will not be possible to identify you or any other participants' data.

Who will have access to the information obtained in the study?
Individuals from the University of Manchester, regulatory authorities or NHS Trust may need to look at the data collected during the study to make sure the research is being carried out as planned. With your permission, the information they look at will include identifiable data (they will be able to see who it belongs to). Only authorised individuals will look at the data and all will have a duty of confidentiality to you as a research participant.
Please note a professional transcription service, which is approved by the University of Manchester, will be hired to transcribe the audio-recordings. The transcripts will be anonymised by the researcher to ensure that you cannot be identified from them.

The researcher will request permission to access your medical records in order to obtain further details about your medical history that may influence your responses. Examples of the type of information that she may look at are your level of renal functioning, time in pre-dialysis care, the origin of your kidney disease or changes in your renal care.

With your permission, anonymous versions of your data will be shared with other research teams (e.g., the World Health Organization). Sharing data in research is a way of maximising the valuable information you provide and will be shared inline with the Medical Research Council UK's policy on sharing data.

What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study?
The participant would be withdrawn from the study and all identifiable data already collected with consent would be retained and used in the study. No further data would be collected.

What will happen to the results of the study?
The study may take up to 1 year to be completed. The findings from this study will be published in health psychology and medical journals. You will not be identified in any of these publications. The audio-recordings will be digitally archived in a confidential manner for the duration of the study and deleted 5 years after publication or 10 years, whichever is longer, in a secure archive at the University of Manchester. If you wish for your data to be removed from the study, please contact Mrs. Currie Moore.

Who is funding the research?
The study is being funded by the Medical Research Council (UK) through the University of Manchester.

Who has reviewed this study?
This research study has been given a favourable ethical opinion for conduct in the NHS by the Research Ethics Committee (15/LO/2016). The University of Manchester and the CMFT R&D Department have also reviewed this study. They monitor research projects to ensure that they are being conducted properly, according to the best practice in research.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions; the contact details are at the end of this sheet. Alternatively, if you wish to contact someone independent of the research team, please contact the Patient Advisory Liaison Service (PALS) on 0161 276 426. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk

If you are distressed by the topics discussed in the interview, please contact the British Kidney Patient Association (http://www.britishkidney-pa.co.uk/, 01420 541 424) who offers free counselling and support services.

Contact for further information
If you wish to know more about the study please contact the researcher:
Mrs. Currie Moore
Tel: 0161 275 8300
Email: currie.moore@postgrad.manchester.ac.uk

Research Team:
Dr. Sandip Mitra, Consultant Nephrologist, Manchester Royal Infirmary
Dr. Alison Wearden, Prof. of Health Psychology, University of Manchester
Dr. Suzanne Skevington, Prof. of Health Psychology, University of Manchester

Appendix F

CMFT Logo here

PARTICIPANT INFORMATION LEAFLET

Quality of life in dialysis patients and carers: Interview Study

(Carer Version)

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives or anyone else you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

More and more people require dialysis every year. Dialysis provides its people with a way of removing the toxins from their bodies when their kidneys are no longer able to perform this function. Although it is life sustaining, it is also a complex medical treatment and requires people to spend a considerable amount of time undergoing dialysis and rigorously adhering to diets, medication and schedules. Therefore, its impact on peoples' lives is not limited to just the individual on dialysis' physical health but also to many other areas of their lives and to the lives of their families and friends.

With all medical treatments, it is important to know how they affect people's quality of life. A large amount of research has been done to assess the quality of life of people on dialysis; however, there is very little known about how dialysis impacts peoples' quality of life just before they start dialysis and over the first 9 months on it. The aim of this study is to conduct interviews with patients and a person close to them who assists with their care (carer) over this time period. The information collected from this study will provide future dialysis patients and carers, health care professionals and governing bodies with a better understanding of how dialysis affects your quality of life.

Why have I been invited?

You have been asked to take part in this study because someone close to you is currently receiving renal care at the Manchester Royal Infirmary. This patient has been invited to participate in this study and has invited you to join the study. This person has nominated you to take part in this study as you provide the most support to him or her. We are interested in better understanding how dialysis affects people close to the patient during the early stages of care. Your participation would be very valued.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time without giving a reason. This will not affect the standard of care the patient receives or how you are treated at clinical appointments.

What will happen to me if I take part?

a. You may contact the researcher directly (Mrs. Currie Moore – her contact details are provided on page 3). Alternatively, if you have given permission for your contact details to be shared with her, she will contact you in 3 days time to speak to you about the study and answer any questions you have about it.
b. If you decide to participate, an interview will be arranged with you. The interview can be arranged at the hospital (in a private meeting room) or at your own home. The duration of the interview will be about one hour and will be arranged at a time most convenient to you.
c. Before the interview, the researcher will make sure you are happy to participate in the study. She will then review your rights as a participant with you. Lastly, the researcher will obtain your informed consent in writing.
d. The interviews will be audio-recorded to allow the researcher to review the conversation.
e. If the any aspect of the study is distressing to you, we will pause the interview and you may decide if you would like to continue or not. If necessary, the researcher can offer you information on support available to you.
f. After the interview, you will be asked to complete 3 short surveys.
g. At the conclusion of the study, the researcher will confirm how the findings will be shared with you. She will also ask if you are interested in providing feedback on her analysis of the study's findings. This would involve either another meeting or phone call.
h. You have the right to withdraw from this study at any point, without explanation. Taking part in this study will not affect any aspect of the patient's health care.

What are the possible benefits of taking part?
There are no direct and immediate benefits to you personally for participating in this study. However, the information you provide will be

invaluable in studying quality of life during a very critical period of time. The findings of the study will influence the care provided to patients and their carers in the future, and you would have made an important contribution.

Will my taking part in this study be kept confidential?
Everything that you say in the interview and in the surveys will be confidential and will not be released to anyone outside of the study or to the renal patient. However, if it is revealed through the interview that you are at risk of harm to yourself or another person, the researcher will ask your permission to put you in contact with the relevant health care professional. When the results of the study are reported and published, your name will not be released and it will not be possible to identify you or any other participants' data.

Who will have access to the information obtained in the study?
Individuals from the University of Manchester, regulatory authorities or NHS Trust may need to look at the data collected during the study to make sure the research is being carried out as planned. With your permission, the information they look at will include identifiable data (they will be able to see who it belongs to). Only authorised individuals will look at the data and all will have a duty of confidentiality to you as a research participant.
Please note a professional transcription service, which is approved by the University of Manchester, will be hired to transcribe the audio-recordings. The transcripts will be anonymised by the researcher to ensure that you cannot be identified from them.

With your permission, anonymous versions of your data will be shared with other research teams (e.g., the World Health Organization). Sharing data in research is a way of maximising the valuable information you provide and will be shared inline with the Medical Research Council UK's policy on sharing data.

What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study?
The participant would be withdrawn from the study. Identifiable data already collected with consent would be retained and used in the study. No further data would be collected.

What will happen to the results of the study?
The study may take up to 1 year to be completed. The findings from this study will be published in health psychology and medical journals. You will not be personally identified in any of these publications. The audio-recordings will be digitally archived in a confidential manner for the duration of the study and deleted 5 years after publication or 10 years, whichever is

longer, in a secure archive at the University of Manchester. If you wish for your data to be removed from the study, please contact Mrs. Currie Moore.

Who is funding the research?

The study is being funded by the Medical Research Council (UK) through the University of Manchester.

Who has reviewed this study?

This research study has been given a favourable ethical opinion for conduct in the NHS by the Research Ethics Committee (15/LO/2016). The University of Manchester and the CMFT R&D Department have also reviewed this study. They monitor research projects to ensure that they are being conducted properly, according to the best practice in research.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions; the contact details are at the end of this sheet. Alternatively, if you wish to contact someone independent of the research team, please contact the Patient Advisory Liaison Service (PALS) on 0161 276 426. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk

If you are distressed by the topics discussed in the interview, please contact the British Kidney Patient Association (http://www.britishkidney-pa.co.uk/, 01420 541 424) who offer free counselling and support services.

Contact for further information

If you wish to know more about the study, please contact the researcher:
Mrs. Currie Moore
Tel: 0161 275 8300
Email: currie.moore@postgrad.manchester.ac.uk

Research Team:
Dr. Sandip Mitra, Consultant Nephrologist, Manchester Royal Infirmary
Dr. Alison Wearden, Prof. of Health Psychology, University of Manchester
Dr. Suzanne Skevington, Prof. of Health Psychology, University of Manchester

Appendix G

Initial questions by theme, quotation and code

Theme and code	*Example quotation*	*Questions*
Dialysis Expectations		
Quality of life	*Hopeful it will improve my quality of life (Patient)*	What kind of effect do you think dialysis will have on your QOL?
Health	*So I think really just probably worried about what's going to happen and worried about how long it might take until a kidney's found, and then sort of thinking, well, hopefully when he's had it done he's going to feel much better (Partner)*	What do you think your health will be like 6 weeks from now?
Accepting dialysis		
Dialysis and ERF		
Dialysis	*There again that's [dialysis] going to alter your life, but you have to accept that, you know. No, you don't have to, but we would. I would, I've accepted it. That's our life for the next three months (Partner)*	How able are you to accept dialysis?
ERF	*there's not a lot I can do about my body. I try to, you know, maintain a bit of a healthy diet but you've just got to get on with it, yeah. (Patient)*	Have you come to terms with ERF?
Regime/routine of dialysis	*But, as I say, you just get a new routine, don't you, because there's nothing else you can do. But you just get in a routine, don't you? You've got to get on with it, what else can you do?. . . You've got no option, have we. (Partner)*	How accepting are you of the routine and amount of time spent on dialysis?

Context	*I think because we're older as well, I think as you get older you just – well, you're together and you love one another and illnesses and things happen, don't they, that are always there to test you. (Partner)*	How have previous medical experiences influenced your ability to accept dialysis?
Lifestyle		
Limitations	*We can't do that anymore, you know, we have to go to places that it's safe to go to with [patient]. But, I've been looking into other, sort of, holidays and you know, as long as we can get away, you know, it's not a huge disappointment that really. (Partner)*	How able are you to accept the limitations of you/your partner due to dialysis?... ERF?
Adjustment	*You just accept, well at some stage it's going to happen. (Patient)*	How much are you able to accept the changes to your life that dialysis may bring?
Adaptation	*I'm hoping that we'll be able to fit dialysis around our life as opposed to the other way around. (Partner)*	How much are you able to accept dialysis because you are confident you can adapt dialysis to your life?
Actively accepting & control of dialysis		
Difficulties accepting	*I never wanted to have dialysis but I'm going to have no choice, by the look of it. . . I'm not looking forward to dialysis. (Patient)*	How hard have you found it to accept dialysis as part of your life?
Lack of choice	*What can you do, you're stuck. . . Because there's no choice. (Partner)*	To what extent do you accept dialysis as part of your life because you feel you had no other choice?

Benefits	*you must… it's burden or no burden, but you must do it to keep alive. There's no way out. If you don't do it you'll go downhill, it's that straight-forward.(Patient)*	To what extent do you accept dialysis because it will lead to benefits for you or your partner (health, positive future)?
Ownership/Control	*But it is fantastic when the option is there, that you can have it at home and you can kind of control your own disease. . . And you taking over it, not that your disease is taking over you. (Partner)*	Does your dialysis give you the ownership and control of your life that you would like?
Future		
Transplant	*I try and make the best of it in the hope that I'm going to get a kidney. Because I reckon that if I get a kidney and it's all alright, I should get some of my life back then. (Patient)*	How hopeful are you that you/your partner will receive a transplant in the near future?
Dyadic Factors		
Team-like		
Togetherness	*I mean emotionally we've always been there together (Patient)*	To what extent do you feel like you and your partner are a team when it comes to handling your dialysis?
Steadfastness	*Because I decide I'm married to her and whatever happens, whether good or bad, I'll be there for her 100 plus percent, no matter what. (Partner)*	How much do you and your partner share the belief that no matter what happens you will do your best to look after each other?
Role in Relationship	*I'm one of these people that do everything. You know, I do all the house, the gardening and C04 works and so I always did everything. . .So it's not fair really, I don't think, that he should have to do it, but he does. (Patient)*	To what extent has dialysis changed your role in the relationship?

Role in dialysis	*I think that changes, because you become a carer, not his partner. I'm his carer. (Partner)*	How content are you with the roles each of your have in relation to dialysis?
Being a couple	*Sometimes you'll see couples out doing stuff and it's always me on my own just doing everything by myself and.. I think it doesn't get to me all the time but sometimes I just think, 'oh, wouldn't it be nice if we could share these things?' (Partner)*	How important to you is it that you and your partner make time to do things as couple?
Communication		
Communication style	*"I've been told to communicate quite a lot" (Patient)*	How would you describe your communication with your partner about dialysis
Fears	*It's the fear factor of that next level of…well, he's stable now. We're going to upset the apple cart. What's going to happen, what's…it's the fear factor. (Partner)*	To what extent are you able to share your fears about dialysis or the future with your partner?
Worry	*[Whispers to me] I don't let him know that I worry. Don't let him see me worried. (Partner)*	How often do you limit what you tell your partner about dialysis to prevent her/him from worrying?
Listening	*And taking on board what I say. I think before he used to not listen. 'Cause it's been like all the things you say, you say something and it works for a few days or weeks and then it all drifts back to how it was before. (Partner)*	Does your partner listen to you and take your point of view on board?
Positivity		

Positive	*I'm trying to twist things for him to make it look more positive. As I say, you know, you're only doing three days, you're not doing four, and you can still go out of a morning. (Partner)*	How much does your partner rely on you to feel positive about dialysis?
Strength	*And, as I said, [patient] is very strong and I'm able to leech his strength and together we get through it. (Partner)*	How much do you rely on your partner for strength or positivity?
Humour	*Yeah, because we've been through so much and we can laugh about it. (Partner)*	How often are you and your partner able to find humour in small things and have a laugh?
Awareness of self and other		
Pressure	*there were times that I felt out of my depth and I wasn't comfortable. I was out of my comfort zone, looking after him (Partner)*	How often you feel overwhelmed by the pressure to manage dialysis related tasks as well as your other everday tasks?
Burden	*it's like having another baby for her, having me (Patient)*	How much of a burden is dialysis on you? How much of a burden is dialysis on your partner?
Burden	*When I've got energy...I can do my fair share of the jobs that need to be done. . . [but I'm not satisfied because] I'm not delivering my share of the bargain (Patient)*	How much do you worry that you are a burden to your partner because of dialysis?
Loneliness/Isolation	*if the girls didn't come, you know, I'd be quite honest it's a bit lonely. (Partner)*	How has dialysis effected the level of loneliness or isolation you feel?
Time for self	*I can relax. So, yeah, I make cards and I knit and I've got into doing word searches. I just find that is a chilling out thing, sort of thing. (Partner)*	How often are you able to get the time you need for yourself?

Appendix H

Originals questions assessed in cognitive interviews, actions and final questions

	Original core question	Actions	Final questions
1.	What do you expect your **QOL** will be like 6 weeks from now? [question phrasing on pre-dialysis version] What do you think your **QOL** will be like 6 weeks from now?	QOL is a personally defined term and that was deemed acceptable. On partners' questionnaire packs, use emphasis on the words 'your' or 'your' to assure them that we are interested in their experiences and thoughts. that the questions are about them. In the instructions, state the time frame for all of these questions (i.e., We ask that you think about your life **in the last two weeks**). Included.	In 6 weeks, what do you think your **quality of life** will be like? In 12 weeks, what do you think your **quality of life** will be like?
1b.	[on pre-dialysis version only] What do you expect your **QOL** will be like 12 weeks from now?	Change phrasing to match dialysis version. Add question to dialysis SDQ.	
2.	What do you think your *health* will be like 6 weeks from now?	Emotional health reported as important by participants and viewed differently from overall health, especially in early dialysis.	In 6 weeks, what do you think your *physical health* will be like?

		Included.	In 12 weeks, what do you think your *emotional health* will be like?
2b.	[on pre-dialysis version only] What do you expect your *health* will be like 12 weeks from now?	Change phrasing to match dialysis version.	
3.	[No expectation question on pre-dialysis versions] Overall, has your experience of starting dialysis lived up to your expectations?	At pre-dialysis, add a question about expectations. At follow-ups (after patient has started dialysis) remove 'lived up.' Included.	How would you rate your expectations of dialysis? How much has dialysis met your expectations?
4.	[No open-ended expectation question on pre-dialysis versions] Please write down in what ways your expectations were fulfilled:	Included.	Please write down in what ways you expect dialysis will benefit you or your partner: Please write down in what ways your expectations have been fulfilled:
5.	Please write down in what ways your expectations were not fulfilled:	Included.	Please write down in what ways you expect dialysis will **not** benefit you or your partner:

			Please write down in what ways your expectations have **not** been fulfilled:
6.	Have you come to terms with being on dialysis?	Included.	How much have you come to terms with starting dialysis? How much have you come to terms with being on dialysis?
7.	To what extent are you able to fit dialysis into your life?	Deleted.	
8.	To what extent are you able to accept changes to your lifestyle due to dialysis?	Deleted.	
9.	To what extent are you able to carry on with your normal life?	Move to after Q6 and change normal to daily. Included.	To what extent do you think you will be able to carry on with your daily life when you start dialysis? To what extent have you been able to carry on with your daily life since starting dialysis?
10.	Does your dialysis give you the control of the treatment that you would like?	Delete 'of the treatment' Included.	To what extent do you think you will have the control of dialysis that you would like?

			To what extent do you have the control of dialysis that you would like?
11.	How satisfied are you that dialysis is the best option for you at this time?	None of the other participants had issues with this question so retained in PFQ. Included.	How satisfied are you that dialysis is the best option for you at this time? How satisfied are you that dialysis is the best option for you at this time?
12.	How bothered would you be if dialysis is a long-term treatment for your kidney disease?	No other participants had difficulty with the item or disliked the word bothered. The scoring was flipped to keep it in line with the other items. Included.	How bothered would you be if dialysis became a long-term treatment for your kidney disease? How bothered would you be if dialysis became a long-term treatment for your kidney disease?
13.	How involved is your partner in your dialysis?	Changed the initial wording. Included.	How much do you expect that your partner will be involved in your dialysis? How much is your partner involved in your dialysis?
14.	Does your partner's involvement in your dialysis match your needs?	Included.	How much do you think your partner's involvement in your dialysis will match your needs?

			How much does your partner’s involvement in your dialysis match your needs?
15.	Has dialysis changed your role in the relationship?	Other participants stated ‘role’ was acceptable. Included.	How much do you expect dialysis will change your role in the relationship? How much has dialysis changed your role in the relationship?
16.	How bothered are you by dialysis related tasks?	Move to different section of the questionnaire. Added a question on how bothersome dialysis is for partners. Included.	How much do you think you will be bothered by dialysis? How much are you bothered by dialysis?
17	How bothersome is dialysis for your partner?	Move to different section of the questionnaire. Included.	How bothersome do you expect dialysis to be for your partner? How bothersome is dialysis for your partner?
18.	Has dialysis affected your ability to manage your everyday tasks?	Deleted.	
19.	Do you and your partner act as a team when it comes to handling your dialysis?	Included.	How much do you think you and your partner will act as a

			team when it comes to handling your dialysis? How much do you and your partner act as a team when it comes to handling dialysis?
20.	How much are you and your partner are “on the same page” (share similar attitudes and beliefs) about dialysis?	Included.	How much do you think that you and your partner will be “on the same page” (share similar views) about dialysis? How much are you and your partner are “on the same page” (share similar views) about dialysis?
21.	How much does your partner rely on you to feel positive about dialysis?	Change question to directly ask about their own positivity. Included.	How positive do you think you will be about dialysis? How positive are you about dialysis?
22.	How much do you rely on your partner to feel positive about dialysis?	Change question to directly ask about their own positivity. Included.	How positive do you think your partner will be about dialysis? How positive is your partner towards dialysis?

23.	Are you able to express your feelings about dialysis to your partner?	Included.	How well do you think you will be able to express your *feelings* about dialysis to your partner? How well are you able to express your *feelings* about dialysis to your partner?
24.	How comfortable are you discussing issues related to dialysis with your partner?	To highlight distinction between questions, emphasis added on key words. Included.	How comfortable do you think you will be discussing *issues* related to dialysis with your partner? How comfortable are you discussing *issues* related to dialysis with your partner?
25.	Is your partner reluctant to talk about dialysis?	Emphasis added and question re-phrased. Included.	How comfortable do you think your partner will be to talk about dialysis-related *issues*? How comfortable is your partner talking about dialysis-related *issues*?
26.	How willing is your partner to share his/her feelings about dialysis with you?	Emphasis added. Included.	How willing do you think your partner will be to share his/her *feelings* about dialysis with you?

			How willing is your partner to share his/her *feelings* about dialysis with you?
27.	Does your communication with your partner about dialysis match your needs?	Deleted.	
28.	Does your partner listen to your views on dialysis related topics?	Included.	How much do you think that your partner will listen to your views on dialysis related topics? How much does your partner listen to your views on dialysis related topics?
29.	How often do you get time for yourself since dialysis started?	Question removed from patient versions. Included.	How often do you think you will you get time for yourself once dialysis starts? How often do you get time for yourself since dialysis started?
30.	How often do you feel lonely because of dialysis?	Added a question on isolation. Included.	How often do you think you will feel lonely because of dialysis? How often do you feel lonely because of dialysis?

			How often do you think you will feel isolated because of dialysis? How often do you feel isolated because of dialysis?
31.	How often do you limit what you say to your partner about dialysis to prevent her/him from worrying?	Deleted.	
32.	How often do you and your partner make time to do things together?	Changed phrasing. Included.	How often do you think that you and your partner will do activities you enjoy together? How often do you and your partner do activities you enjoy together?
33.	How often do you and your partner find humour in small things or have a laugh?	Included.	How often do you expect that you and your partner will be able to find humour in small things or have a laugh? How often do you and your partner find humour in small things or have a laugh?
34.	How satisfied are you with your relationship?	Separated spatially in questionnaire with reminder to think about their life over the last two weeks.	How satisfied are you with your relationship?

<table>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Note. The items presented here are the patient versions. The partner versions differ slightly in their wording but address the same topics. The partner items assessed in the cognitive interviews are in Appendix L & N and the final partner version of the SDQ are in Appendix Q.
Response scales with their coordinating question number:
1=Much worse than now, 2=Worse than now, 3=The same, 4=A little better than now, 5=Much better than now – Q1-6
1=Very low, 2=low, 3=No expectations, 4=High, 5=Very high – Q7
1=Not at all, 2=Not much, 3=Moderately, 4=A great deal, 5=Completely – Q10-14, Q17-28
1=Very dissatisfied, 2=Dissatisfied, 3=Neither satisfied or dissatisfied, 4=Satisfied, 5=Very satisfied – Q15, Q34
1=An extreme amount, 2=Very much, 3=A moderate amount, 4=A little, 5=Not at all – Q16
1=Never, 2=Seldom, 3=Quite often, 4=Very often, 5=Always – Q29-33

Response scales taken from “Designing response scales for cross-cultural use in health care: Data from the development of the UK WHOQOL” by S. M. Skevington and C. Tucker, 1999, *British Journal of Medical Psychology, 72*(1), 51-61.</td></tr>
</table>

Appendix I

NHS
Health Research Authority

London - Hampstead Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 02071048127

09 June 2017

Ms Lynne Macrae
Faculty Research Practice Co-ordinator
FMHS Research Office, 3.53 Simon Building
University of Manchester
M13 9PL

Dear Ms Macrae

Study title:	**Determinants of quality of life in dialysis patients and their carers**
REC reference:	**15/LO/2016**
Amendment number:	**Amendment 2 date 17.05.2017**
Amendment date:	**17 May 2017**
IRAS project ID:	**189823**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee were happy to approve the amendment on the following conditions:

- The Sub-Committee was satisfied that the study extension be considered as an amendment, rather than a separate application, as it does not appear to be too much of an additional burden. The Sub-Committee did however feel that this was a close run thing, and would be happy to accept the amendment on the condition that any future extensions of this nature be submitted as new study applications.

- The Sub-Committee raised a concern that your amendment intended to place the burden of responsibility on participants to tell you if they do not wish to take part in the extension. It was the Sub-Committee's view that participants who do not respond should be assumed to not wish to take part.

You responded to confirm your agreement with these conditions, and supplied amended documentation as requested.

The Sub-Committee gave a favourable opinion of the amendment, based upon the revisions.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Letters of invitation to participant [Letter of Invitation.Follow Up]	2	08 June 2017
Non-validated questionnaire [PFQ.CKD.C]	1	15 May 2017
Non-validated questionnaire [PFQ.CKD.C Patients]	1	15 May 2017
Non-validated questionnaire [PFQ.CKD]	1	15 May 2017
Non-validated questionnaire [PFQ.CKD.P]	1	15 May 2017
Notice of Substantial Amendment (non-CTIMP) [NoSA]	Amendment 2 date 17.05.2017	17 May 2017
Participant consent form [IC Follow Up]	1	04 May 2017
Participant information sheet (PIS) [PIS Follow up]	1	04 May 2017
Research protocol or project proposal [Protocol]	6	08 June 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/LO/2016:	**Please quote this number on all correspondence**

Yours sincerely

Miss Stephanie Ellis, BEM
Chair

E-mail: nrescommittee.london-hampstead@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr. Lynne Webster, Central Manchester University Hospitals NHS Foundation Trust*
Mrs. Currie R. Moore, University of Manchester

London - Hampstead Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 29 May 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Miss Stephanie Ellis, BEM	Former Civil Servant	Yes	
Dr Francesca Silverton	Statistics Teacher	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Nafeesa Khanam	REC Assistant
Mr Matt Rogerson	REC Manager

Appendix J

Invitation to Participate in a Follow-up Task:

Quality of life in dialysis patients and their carers

Dear *Patient Name*,

Last year, you took part in a study about your quality of life. Now, you are invited to take part in a follow-up task related to that study.

This follow-up task concerns topics that were found to be important to your quality of life. The areas that people stated as important to their quality of life were related to accepting dialysis, expectations, and how patients and their partners work together. There are limited questionnaires which ask about these areas. Therefore, the research team has created a new questionnaire. Your feedback on this questionnaire would provide valuable insight as to how the questions are understood and answered.

This follow-up project consists of completing a questionnaire. While you are completing the questionnaire, you will be asked to say anything you are thinking about the questions (the words or phrasing) or how you decide to answer them (i.e., where the response options suitable?). The researcher may ask for you about the words used, the order of the questions or how to make the questions better. The task will last approximately 30 minutes.

Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information leaflet carefully and discuss it with friends, relatives or anyone else you wish. Please do not hesitate to ask if there is anything that is not clear or if you would like more information.

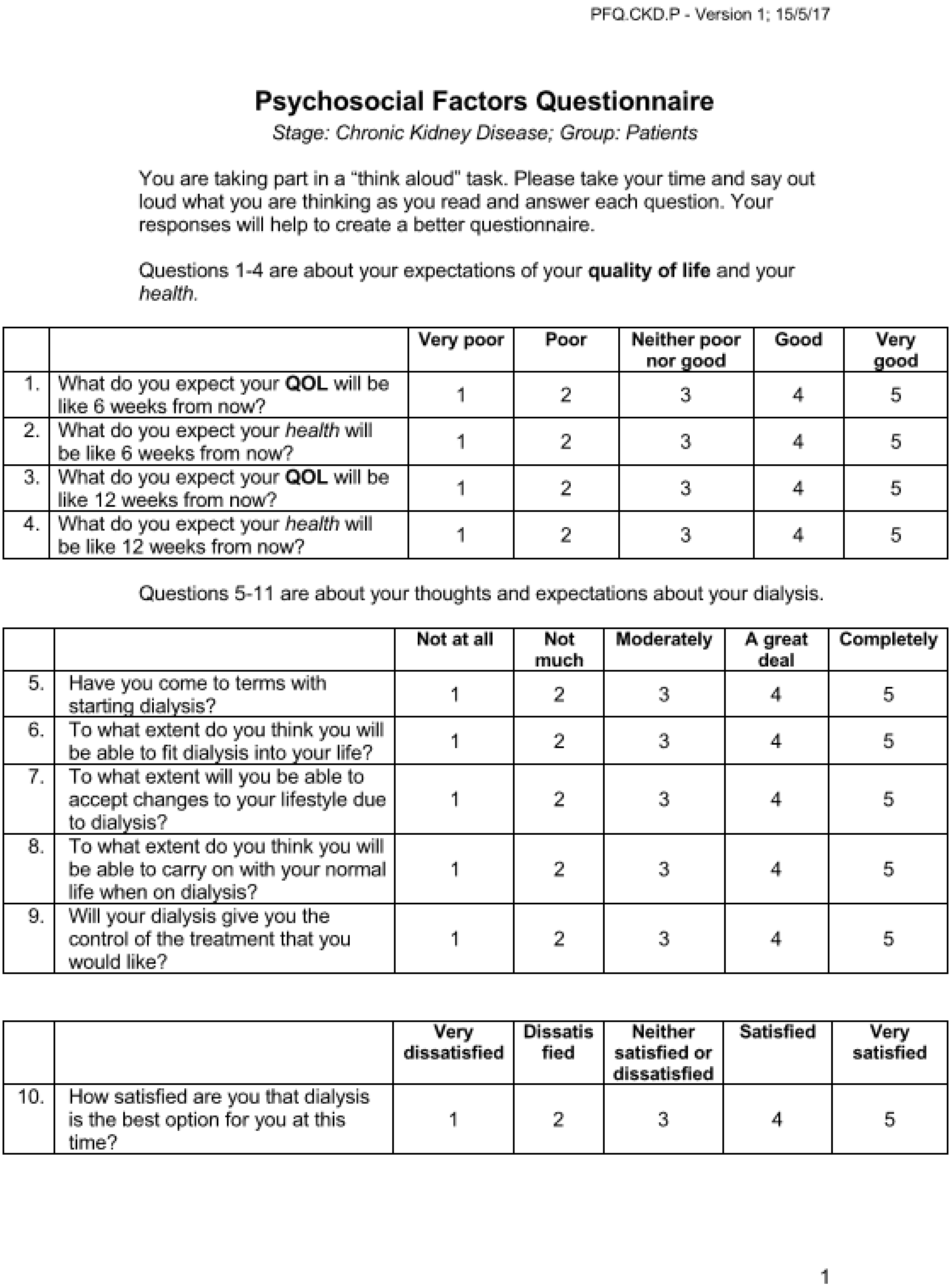
Next steps:

If you would like to take part in this task, please contact me on:
Email: currie.moore@postgrad.manchester.ac.uk
Office: 0161 275 8300
Thank you for your time and for considering to take part in this project.

Best regards,

Currie Moore
PhD Student
University of Manchester

Appendix K
*Starting Dialysis Questionnaire was originally called the Psychosocial Factors Questionnaire



PFQ.CKD.P - Version 1; 15/5/17

Psychosocial Factors Questionnaire

Stage: Chronic Kidney Disease; Group: Patients

You are taking part in a “think aloud” task. Please take your time and say out loud what you are thinking as you read and answer each question. Your responses will help to create a better questionnaire.

Questions 1-4 are about your expectations of your **quality of life** and your *health*.

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	What do you expect your **QOL** will be like 6 weeks from now?	1	2	3	4	5
2.	What do you expect your *health* will be like 6 weeks from now?	1	2	3	4	5
3.	What do you expect your **QOL** will be like 12 weeks from now?	1	2	3	4	5
4.	What do you expect your *health* will be like 12 weeks from now?	1	2	3	4	5

Questions 5-11 are about your thoughts and expectations about your dialysis.

		Not at all	Not much	Moderately	A great deal	Completely
5.	Have you come to terms with starting dialysis?	1	2	3	4	5
6.	To what extent do you think you will be able to fit dialysis into your life?	1	2	3	4	5
7.	To what extent will you be able to accept changes to your lifestyle due to dialysis?	1	2	3	4	5
8.	To what extent do you think you will be able to carry on with your normal life when on dialysis?	1	2	3	4	5
9.	Will your dialysis give you the control of the treatment that you would like?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied or dissatisfied	Satisfied	Very satisfied
10.	How satisfied are you that dialysis is the best option for you at this time?	1	2	3	4	5

1

		Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
11.	How bothered would you be if your dialysis is a long-term treatment for your kidney disease?	1	2	3	4	5

Questions 12-27 are about **how much** you expect dialysis to affect areas of your life or your relationship with your partner:

		Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
12.	How much do you expect that your partner will be involved in your dialysis?	1	2	3	4	5
13.	Do you expect that your partner's involvement in your dialysis will match your needs?	1	2	3	4	5
14.	Do you expect dialysis to change your role in the relationship?	1	2	3	4	5
15.	How bothered do you expect to be by dialysis related tasks?	1	2	3	4	5
16.	Do you expect dialysis to affect your ability to manage your everyday tasks?	1	2	3	4	5
17.	How bothersome do you expect dialysis to be for your partner?	1	2	3	4	5
18.	Do you think you and your partner will be a team when it comes to handling your dialysis?	1	2	3	4	5
19.	How much do you think that you and your partner are "on the same page" (share similar attitudes and beliefs) about dialysis?	1	2	3	4	5
20.	How much do you think your partner will rely on you to feel positive about dialysis?	1	2	3	4	5
21.	How much do think you will rely on your partner to feel positive about dialysis?	1	2	3	4	5
22.	Do you think you will be able to express your feelings about dialysis to your partner?	1	2	3	4	5
23.	How comfortable do you think you will be discussing issues related to dialysis with your partner?	1	2	3	4	5
24.	Do you think your partner will be reluctant to talk about dialysis?	1	2	3	4	5

		Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
25.	How willing do you think your partner will be to share his/her feelings about dialysis with you?	1	2	3	4	5
26.	How much do you expect your communication with your partner about dialysis will match your needs?	1	2	3	4	5
27.	How much do you expect your partner will listen to your views on dialysis related topics?	1	2	3	4	5

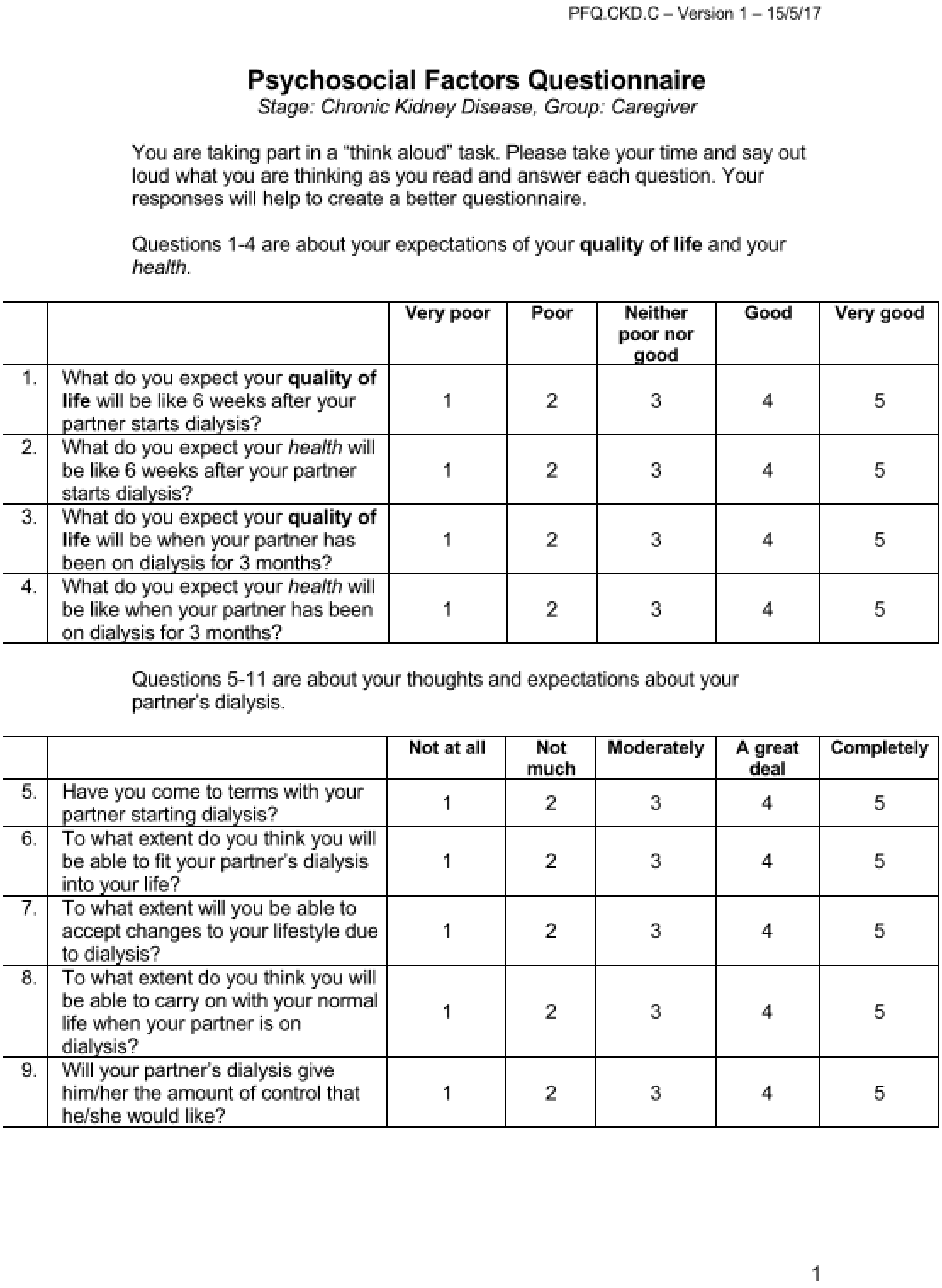
Questions 28-33 are about **how often** you think or expect these experiences after starting dialysis:

		Never	**Seldom**	**Quite often**	**Very often**	**Always**
28.	How often do you think you will you get time for yourself once dialysis starts?	1	2	3	4	5
29.	How often do you think you will feel lonely because of dialysis?	1	2	3	4	5
30.	How often do you think you will limit what you say to your partner about dialysis to prevent her/him from worrying?	1	2	3	4	5
31.	How often do you think that you and your partner will make time to do things together?	1	2	3	4	5
32.	How often do you expect that you and your partner will be able to find humour in small things or have a laugh?	1	2	3	4	5

		Very dissatisfied	**Dissatisfied**	**Neither satisfied or dissatisfied**	**Satisfied**	**Very satisfied**
33.	How satisfied are you with your relationship?	1	2	3	4	5

Appendix L

*Starting Dialysis Questionnaire was originally called the Psychosocial Factors Questionnaire



PFQ.CKD.C – Version 1 – 15/5/17

Psychosocial Factors Questionnaire

Stage: Chronic Kidney Disease, Group: Caregiver

You are taking part in a “think aloud” task. Please take your time and say out loud what you are thinking as you read and answer each question. Your responses will help to create a better questionnaire.

Questions 1-4 are about your expectations of your **quality of life** and your *health*.

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	What do you expect your **quality of life** will be like 6 weeks after your partner starts dialysis?	1	2	3	4	5
2.	What do you expect your *health* will be like 6 weeks after your partner starts dialysis?	1	2	3	4	5
3.	What do you expect your **quality of life** will be when your partner has been on dialysis for 3 months?	1	2	3	4	5
4.	What do you expect your *health* will be like when your partner has been on dialysis for 3 months?	1	2	3	4	5

Questions 5-11 are about your thoughts and expectations about your partner’s dialysis.

		Not at all	Not much	Moderately	A great deal	Completely
5.	Have you come to terms with your partner starting dialysis?	1	2	3	4	5
6.	To what extent do you think you will be able to fit your partner’s dialysis into your life?	1	2	3	4	5
7.	To what extent will you be able to accept changes to your lifestyle due to dialysis?	1	2	3	4	5
8.	To what extent do you think you will be able to carry on with your normal life when your partner is on dialysis?	1	2	3	4	5
9.	Will your partner’s dialysis give him/her the amount of control that he/she would like?	1	2	3	4	5

1

		Very dissatisfied	Dissatis fied	Neither satisfied or dissatisfied	Satisfied	Very satisfied
10.	How satisfied are you that dialysis is the best option for your partner at this time?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	An extreme amount
11.	How bothered would you be if dialysis is a long-term treatment for your partner's kidney disease?	1	2	3	4	5

Questions 12-27 are about **how much** you expect dialysis to affect areas of your life or your relationship with your partner:

		Not at all	Not much	Moderately	A great deal	Completely
12.	Do you expect that your partner will involve you in his/her dialysis?	1	2	3	4	5
13.	How much do you think your involvement in your partner's dialysis will match how much you want to be involved?	1	2	3	4	5
14.	Do you expect dialysis to change your role in the relationship?	1	2	3	4	5
15.	How bothered do you expect to be by dialysis related tasks?	1	2	3	4	5
16.	Do you expect dialysis to affect your ability to manage your everyday tasks?	1	2	3	4	5
17.	How bothersome do you expect dialysis to be for your partner?	1	2	3	4	5
18.	Do you think you and your partner will be a team when it comes to handling your dialysis?	1	2	3	4	5
19.	How much do you think that you and your partner are "on the same page" (share similar attitudes and beliefs) about dialysis?	1	2	3	4	5
20.	How much do you think your partner will rely on you to feel positive about dialysis?	1	2	3	4	5
21.	How much do think you will rely on your partner to feel positive about dialysis?	1	2	3	4	5
22.	Do you think you will be able to express your feelings about dialysis to your partner?	1	2	3	4	5

		Not at all	Not much	Moderately	A great deal	Completely
23.	How comfortable do you think you will be discussing issues related to dialysis with your partner?	1	2	3	4	5
24.	Do you think your partner will be reluctant to talk about dialysis?	1	2	3	4	5
25.	How willing do you think your partner will be to share his/her feelings about dialysis with you?	1	2	3	4	5
26.	How much do you expect that your communication with your partner about dialysis will match your needs?	1	2	3	4	5
27.	How much do you expect your partner will listen to your views on dialysis related topics?	1	2	3	4	5

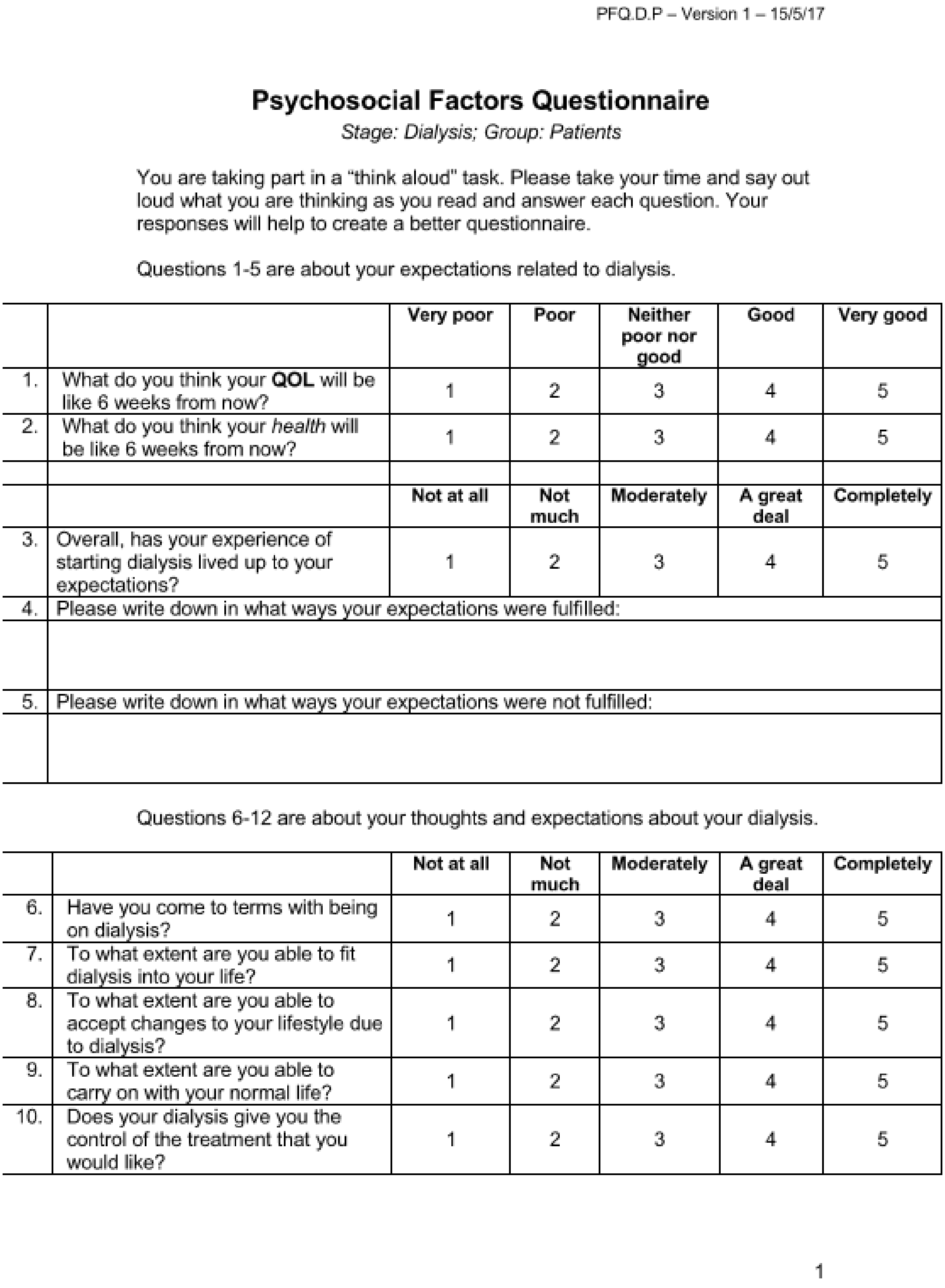
Questions 28-33 are about **how often** you think or expect these experiences after starting dialysis:

		Never	Seldom	Quite often	Very often	Always
28.	How often do you think you will you get time for yourself once dialysis starts?	1	2	3	4	5
29.	How often do you think you will feel lonely because of dialysis?	1	2	3	4	5
30.	How often do you think you will limit what you say to your partner about dialysis to prevent her/him from worrying?	1	2	3	4	5
31.	How often do you think that you and your partner will make time to do things together?	1	2	3	4	5
32.	How often do you expect that you and your partner will be able to find humour in small things or have a laugh?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied or dissatisfied	Satisfied	Very satisfied
33.	How satisfied are you with your relationship?	1	2	3	4	5

Appendix M

*Starting Dialysis Questionnaire was originally called the Psychosocial Factors Questionnaire



PFQ.D.P – Version 1 – 15/5/17

Psychosocial Factors Questionnaire

Stage: Dialysis; Group: Patients

You are taking part in a "think aloud" task. Please take your time and say out loud what you are thinking as you read and answer each question. Your responses will help to create a better questionnaire.

Questions 1-5 are about your expectations related to dialysis.

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	What do you think your **QOL** will be like 6 weeks from now?	1	2	3	4	5
2.	What do you think your *health* will be like 6 weeks from now?	1	2	3	4	5
		Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
3.	Overall, has your experience of starting dialysis lived up to your expectations?	1	2	3	4	5
4.	Please write down in what ways your expectations were fulfilled:					
5.	Please write down in what ways your expectations were not fulfilled:					

Questions 6-12 are about your thoughts and expectations about your dialysis.

		Not at all	Not much	Moderately	A great deal	Completely
6.	Have you come to terms with being on dialysis?	1	2	3	4	5
7.	To what extent are you able to fit dialysis into your life?	1	2	3	4	5
8.	To what extent are you able to accept changes to your lifestyle due to dialysis?	1	2	3	4	5
9.	To what extent are you able to carry on with your normal life?	1	2	3	4	5
10.	Does your dialysis give you the control of the treatment that you would like?	1	2	3	4	5

1

		Very dissatisfied	**Dissatis fied**	**Neither satisfied or dissatisfied**	**Satisfied**	**Very satisfied**
11.	How satisfied are you that dialysis is the best option for you at this time?	1	2	3	4	5

		Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
12.	How bothered would you be if dialysis is a long-term treatment for your kidney disease?	1	2	3	4	5

Questions 13-28 are about **how much** you expect dialysis to affect areas of your life or your relationship with your partner:

		Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
13.	How involved is your partner in your dialysis?	1	2	3	4	5
14.	Does your partner's involvement in your dialysis match your needs?	1	2	3	4	5
15.	Has dialysis changed your role in the relationship?	1	2	3	4	5
16.	How bothered are you by dialysis related tasks?	1	2	3	4	5
17.	Has dialysis affected your ability to manage your everyday tasks?	1	2	3	4	5
18.	How bothersome is dialysis for your partner?	1	2	3	4	5
19.	Do you and your partner act as a team when it comes to handling your dialysis?	1	2	3	4	5
20.	How much are you and your partner are "on the same page" (share similar attitudes and beliefs) about dialysis?	1	2	3	4	5
21.	How much does your partner rely on you to feel positive about dialysis?	1	2	3	4	5
22.	How much do you rely on your partner to feel positive about dialysis?	1	2	3	4	5
23.	Are you able to express your feelings about dialysis to your partner?	1	2	3	4	5
24.	How comfortable are you discussing issues related to dialysis with your partner?	1	2	3	4	5

		Not at all	Not much	Moderately	A great deal	Completely
25.	Is your partner reluctant to talk about dialysis?	1	2	3	4	5
26.	How willing is your partner to share his/her feelings about dialysis with you?	1	2	3	4	5
27.	Does your communication with your partner about dialysis match your needs?	1	2	3	4	5
28.	Does your partner listen to your views on dialysis related topics?	1	2	3	4	5

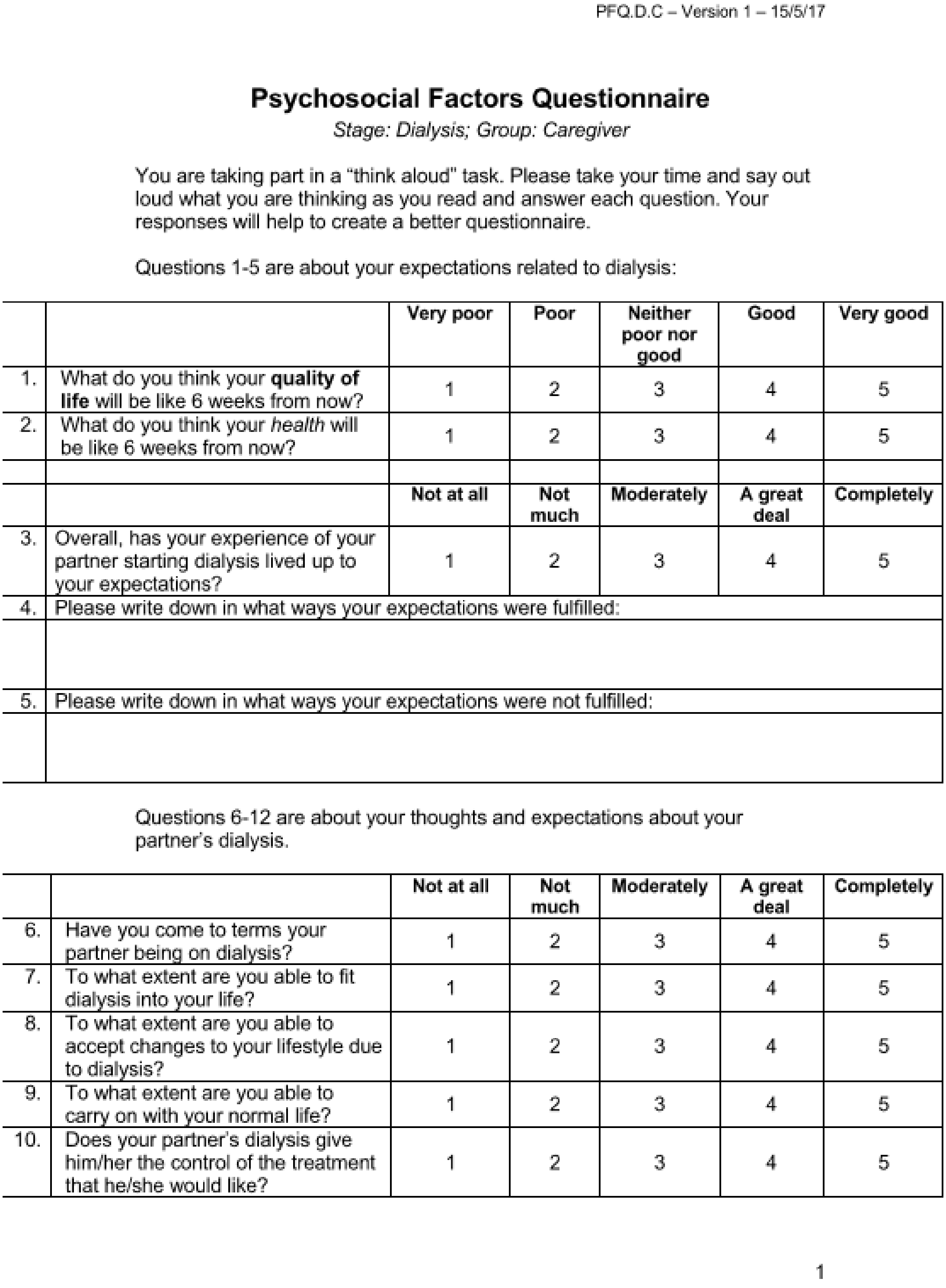
Questions 29-34 are about **how often** you think or expect these experiences after starting dialysis:

		Never	Seldom	Quite often	Very often	Always
29.	How often do you get time for yourself since dialysis started?	1	2	3	4	5
30.	How often do feel lonely because of dialysis?	1	2	3	4	5
31.	How often do you limit what you say to your partner about dialysis to prevent her/him from worrying?	1	2	3	4	5
32.	How often do you and your partner make time to do things together?	1	2	3	4	5
33.	How often do you and your partner find humour in small things or have a laugh?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied or dissatisfied	Satisfied	Very satisfied
34.	How satisfied are you with your relationship?	1	2	3	4	5

Appendix N

*Starting Dialysis Questionnaire was originally called the Psychosocial Factors Questionnaire



PFQ.D.C – Version 1 – 15/5/17

Psychosocial Factors Questionnaire

Stage: Dialysis; Group: Caregiver

You are taking part in a "think aloud" task. Please take your time and say out loud what you are thinking as you read and answer each question. Your responses will help to create a better questionnaire.

Questions 1-5 are about your expectations related to dialysis:

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	What do you think your **quality of life** will be like 6 weeks from now?	1	2	3	4	5
2.	What do you think your *health* will be like 6 weeks from now?	1	2	3	4	5
		Not at all	Not much	Moderately	A great deal	Completely
3.	Overall, has your experience of your partner starting dialysis lived up to your expectations?	1	2	3	4	5
4.	Please write down in what ways your expectations were fulfilled:					
5.	Please write down in what ways your expectations were not fulfilled:					

Questions 6-12 are about your thoughts and expectations about your partner's dialysis.

		Not at all	Not much	Moderately	A great deal	Completely
6.	Have you come to terms your partner being on dialysis?	1	2	3	4	5
7.	To what extent are you able to fit dialysis into your life?	1	2	3	4	5
8.	To what extent are you able to accept changes to your lifestyle due to dialysis?	1	2	3	4	5
9.	To what extent are you able to carry on with your normal life?	1	2	3	4	5
10.	Does your partner's dialysis give him/her the control of the treatment that he/she would like?	1	2	3	4	5

		Very dissatisfied	**Dissatis fied**	**Neither satisfied or dissatisfied**	**Satisfied**	**Very satisfied**
11.	How satisfied are you that dialysis is the best option for your partner at this time?	1	2	3	4	5

		Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
12.	How bothered would you be if dialysis is a long-term treatment for your kidney disease?	1	2	3	4	5

Questions 13-28 are about **how much** you expect dialysis to affect areas of your life or your relationship with your partner:

		Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
13.	Does your partner involve you in his/her dialysis?	1	2	3	4	5
14.	Does your involvement in your partner's dialysis match how much you want to be involved?	1	2	3	4	5
15.	Has dialysis changed your role in the relationship?	1	2	3	4	5
16.	How bothered are you by dialysis related tasks?	1	2	3	4	5
17.	Has dialysis affected your ability to manage your everyday tasks?	1	2	3	4	5
18.	How bothersome is dialysis for your partner?	1	2	3	4	5
19.	Do you and your partner act as a team when it comes to handling your dialysis?	1	2	3	4	5
20.	How much are you and your partner are "on the same page" (share similar attitudes and beliefs) about dialysis?	1	2	3	4	5
21.	How much does your partner rely on you to feel positive about dialysis?	1	2	3	4	5
22.	How much do you rely on your partner to feel positive about dialysis?	1	2	3	4	5
23.	Are you able to express your feelings about dialysis to your partner?	1	2	3	4	5
24.	How comfortable are you discussing issues related to dialysis with your partner?	1	2	3	4	5

		Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
25.	Is your partner reluctant to talk about dialysis?	1	2	3	4	5
26.	How willing is your partner to share his/her feelings about dialysis with you?	1	2	3	4	5
27.	Does your communication with your partner about dialysis match your needs?	1	2	3	4	5
28.	Does your partner listen to your views on dialysis related topics?	1	2	3	4	5

Questions 29-34 are about **how often** you think or expect these experiences after starting dialysis:

		Never	**Seldom**	**Quite often**	**Very often**	**Always**
29.	How often do you get time for yourself since dialysis started?	1	2	3	4	5
30.	How often do feel lonely because of dialysis?	1	2	3	4	5
31.	How often do you limit what you say to your partner about dialysis to prevent her/him from worrying?	1	2	3	4	5
32.	How often do you and your partner make time to do things together?	1	2	3	4	5
33.	How often do you and your partner find humour in small things or have a laugh?	1	2	3	4	5

		Very dissatisfied	**Dissatis fied**	**Neither satisfied or dissatisfied**	**Satisfied**	**Very satisfied**
34.	How satisfied are you with your relationship?	1	2	3	4	5

Appendix O

Psychometric properties of the pre-dialysis version of the Starting Dialysis Questionnaire

	Patients (n=83)							*Partners* (n=83)						
	Mean	SD	Skew	Kurtosis	Item-domain correlation	Alpha (α) if item removed	Alpha (α)	Mean	SD	Skew	Kurtosis	Inter-domain correlation	Alpha (α) if item removed	Alpha (α)
Expectations	3.35	0.67	0.31	0.23			0.90	3.17	0.48	0.00	0.00			.86
1. In 6 weeks, what do you think your quality of life will be like?	3.29	0.69	0.09	0.45	0.77	0.88		3.06	0.50	0.63*	0.00	0.65	0.84	
2. In 6 weeks, what do you think your *physical health* will be like?	3.27	0.71	0.42	0.87*	0.75	0.88		3.07	0.49	0.00	0.00	0.56	0.85	
3. In 6 weeks, what do you think your *emotional health* will be like?	3.23	0.80	0.53*	0.37	0.72	0.88		3.02	0.54	0.06	0.01	0.79	0.82	

4.	In 12 weeks, what do you think your quality of life will be like?	3.43	1.02	0.75*	0.00	0.87	0.86		3.24	0.79	0.00	0.22	0.83	0.80	
5.	In 12 weeks, what do you think your *physical health* will be like?	3.35	0.99	0.62*	0.00	0.81	0.87		3.13	0.68	0.00	0.00	0.77	0.82	
6.	In 12 weeks, what do you think your *emotional health* will be like?	3.33	0.94	0.33	0.62*	0.78	0.88		3.15	0.80	0.00	0.06	0.78	0.81	
7.	How would you rate your expectations of dialysis?	3.48	0.69	0.07	0.74*	0.25~	0.93^		3.50	0.71	0.00	0.08	0.15~	0.90^	
Accepting dialysis		3.29	0.61	0.46	.05			0.75	3.41	0.67	0.22	0.66*			0.81

10	How much have you come to terms with starting dialysis?	3.35	1.15	0.95*	0.04	0.62	0.68	3.78	1.04	0.28	0.01	0.70	0.77
11	To what extent do you think you will be able to carry on with your daily life when you start dialysis?	3.26	0.75	0.32	0.12	0.55	0.71	3.30	0.83	0.73*	0.21	0.49	0.80
12	How much do you think you will be bothered by dialysis?	3.05	0.87	0.01	0.62*	0.67	0.68	3.20	0.99	0.26	0.59*	0.48	0.80
13	How bothersome do you expect dialysis to be for your partner?	3.04	0.95	0.86*	0.84*	0.22~	0.77^	2.70	0.98	0.00	0.25	0.61	0.77

14	To what extent do you think you will have the control of dialysis that you would like?	3.14	1.02	0.82*	0.38	0.30~	0.76^	3.32	1.02	0.48	0.04	0.49	0.80
15	How satisfied are you that dialysis is the best option for you at this time?	4.02	0.79	0.00	0.01	0.43	0.73	4.28	0.69	0.02	0.49	0.44	0.80
16	How bothered would you be if dialysis became a long-term treatment for your kidney disease?	3.18	1.19	0.86*	0.02	0.55	0.70	3.28	1.25	0.79*	0.00	0.65	0.77

Dyadic relationship characteristics		3.95	.06	0.03	0.58			0.92	3.85	0.59	0.08	0.64*			0.90
17	How much do you expect that your partner will be involved in your dialysis?	3.58	1.03	0.48	0.03	0.57	0.91		3.93	0.89	0.13	0.14	0.46	0.90	
18	How much do you think your partner’s involvement in your dialysis will match your needs?	3.89	0.94	0.01	0.62	0.62	0.91		3.94	0.97	0.02	0.87*	0.54	0.90	
19	How much do you expect dialysis will change your role in the relationship ?	3.78	1.09	0.05	0.20	0.13~	0.93^		3.76	1.11	0.03	0.19	0.34~	0.90	

20	How much do you think you and your partner will act as a team when it comes to handling your dialysis?	4.16	0.87	.00	0.06	0.74	0.91	4.12	1.08	0.00	0.03	0.53	0.89
21	How much do you think that you and your partner will be “on the same page” (share similar views) about dialysis?	4.0	0.87	0.19	0.01	0.72	0.91	4.11	0.86	0.01	0.84*	0.57	0.90
22	How positive do you think you will be about dialysis?	3.88	0.85	0.61*	0.01	0.60	0.91	4.20	0.75	0.05	0.45	0.40~	0.90
23	How positive do you think your partner	3.94	0.93	0.17	0.01	0.66	0.91	3.78	0.94	0.17	0.06	0.58	0.90

	will be about dialysis?												
24	How well do you think you will be able to express <u>your</u> *feelings* about dialysis to your partner?	4.12	1.00	0.00	0.79*	0.71	0.91	3.95	1.04	0.00	0.53*	0.68	0.89
25	How comfortable do you think <u>you</u> will be discussing *issues* related to dialysis with your partner?	4.30	0.87	0.00	0.36	0.70	0.91	4.24	0.90	0.00	0.07	0.69	0.89
26	How comfortable do you think your partner will be to talk	4.20	0.87	0.01	0.46	0.71	0.91	4.00	1.16	0.00	0.38	0.80	0.89

	about dialysis-related *issues*?												
27	How willing do you think your partner will be to share his/her *feelings* about dialysis with you?	3.98	1.06	0.01	0.32	0.73	0.91	3.98	1.20	0.00	0.49	0.762	0.89
28	How much do you think that your partner will listen to your views on dialysis related topics?	4.20	0.88	0.01	0.31	0.74	0.91	3.88	0.86	.99*	0.00	0.49	0.90
29	*Partner only* How often do you think you will you get time for yourself once	-	-	-	-	-	-	3.00	0.78	0.21	0.31	0.38~	0.90

	dialysis starts?												
30	How often do you think you will feel lonely because of dialysis?	3.80	0.81	0.07	0.17	0.56	0.91	3.60	1.05	0.20	0.24	0.57	0.90
31	How often do you think you will feel isolated because of dialysis?	3.70	0.91	0.08	0.88*	0.49	0.92	3.67	1.00	0.10	0.83*	0.51	0.90
32	How often do you think that you and your partner will do activities you enjoy together?	3.27	1.04	0.24	0.03	0.59	0.91	3.04	0.86	0.01	0.47	0.52	0.90

33	How often do you expect that you and your partner will be able to find humour in small things or have a laugh?	3.91	0.96	0.19	0.00	0.55	0.91	3.73	1.06	0.21	0.18	0.53	0.90
34	How satisfied are you with your relationship?	4.43	0.87	0.00	0.08	0.54	0.93^	4.38	0.73	0.00	0.56*	0.53	0.90

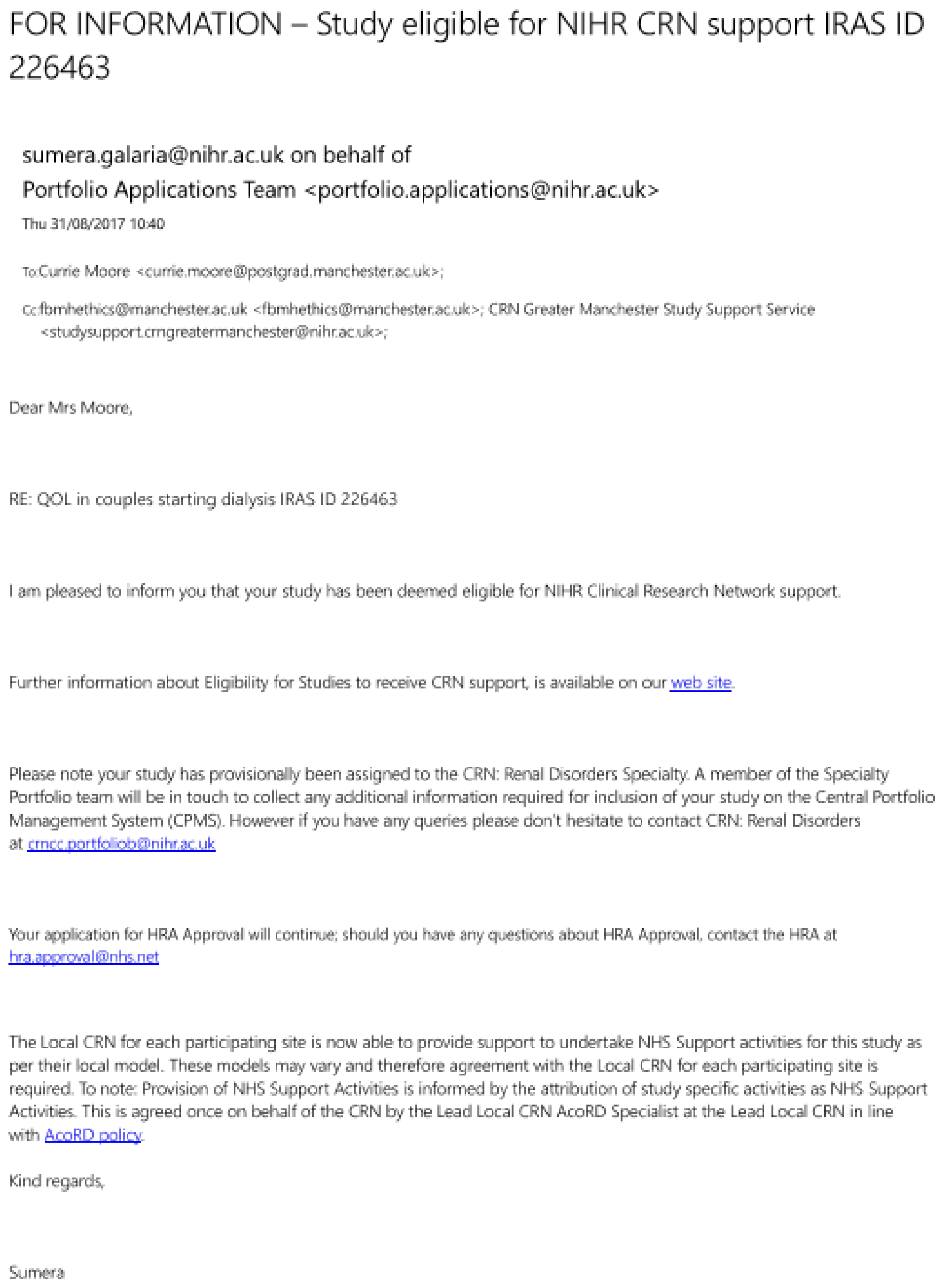
Note. The wording of the items presented here are taken from the pre-dialysis patient version of Starting Dialysis Questionnaire. Items for on the pre-dialysis partner version differ slightly in phrasing (see Additional File 4).

* Item with minor skew or kurtosis, values >0.5

^ Item, that if removed, the internal consistency of the domain improves

~ Item with low correlation with other items within the domain, values <0.40

Appendix P



FOR INFORMATION – Study eligible for NIHR CRN support IRAS ID 226463

sumera.galaria@nihr.ac.uk on behalf of
Portfolio Applications Team <portfolio.applications@nihr.ac.uk>
Thu 31/08/2017 10:40

To:Currie Moore <currie.moore@postgrad.manchester.ac.uk>;

Cc:fbmhethics@manchester.ac.uk <fbmhethics@manchester.ac.uk>; CRN Greater Manchester Study Support Service <studysupport.crngreatermanchester@nihr.ac.uk>;

Dear Mrs Moore,

RE: QOL in couples starting dialysis IRAS ID 226463

I am pleased to inform you that your study has been deemed eligible for NIHR Clinical Research Network support.

Further information about Eligibility for Studies to receive CRN support, is available on our web site.

Please note your study has provisionally been assigned to the CRN: Renal Disorders Specialty. A member of the Specialty Portfolio team will be in touch to collect any additional information required for inclusion of your study on the Central Portfolio Management System (CPMS). However if you have any queries please don't hesitate to contact CRN: Renal Disorders at crncc.portfoliob@nihr.ac.uk

Your application for HRA Approval will continue; should you have any questions about HRA Approval, contact the HRA at hra.approval@nhs.net

The Local CRN for each participating site is now able to provide support to undertake NHS Support activities for this study as per their local model. These models may vary and therefore agreement with the Local CRN for each participating site is required. To note: Provision of NHS Support Activities is informed by the attribution of study specific activities as NHS Support Activities. This is agreed once on behalf of the CRN by the Lead Local CRN AcoRD Specialist at the Lead Local CRN in line with AcoRD policy.

Kind regards,

Sumera

Appendix Q

NHS
Health Research Authority

Mrs Currie Moore
PhD Student
University of Manchester
Coupland Building 1, Room G.35
Oxford Road
Manchester
M13 9PL

Email: hra.approval@nhs.net

12 October 2017

Dear Mrs Moore

Letter of HRA Approval

Study title: **Determinants of quality of life in dialysis patients and their carers**
IRAS project ID: **226463**
REC reference: **17/NW/0501**
Sponsor **University of Manchester**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

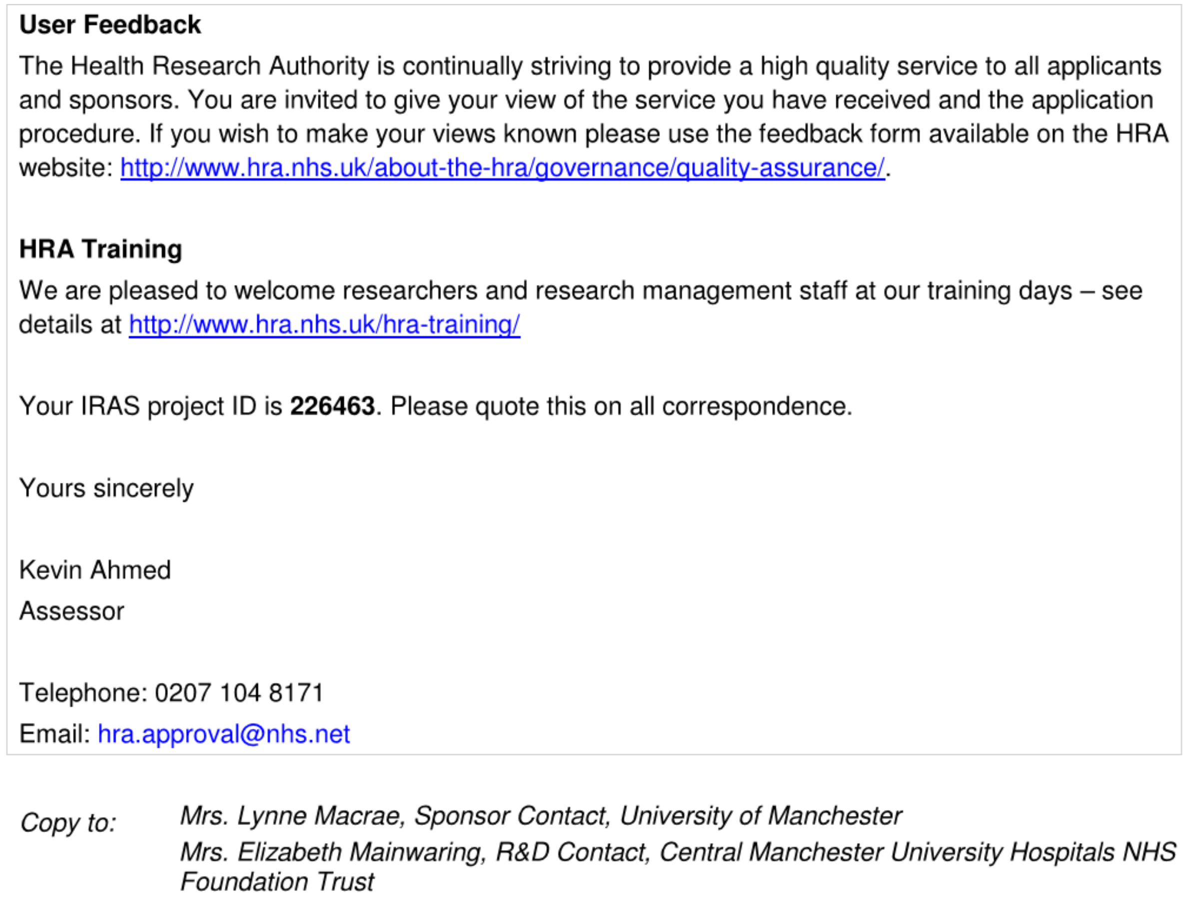
- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.



User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **226463**. Please quote this on all correspondence.

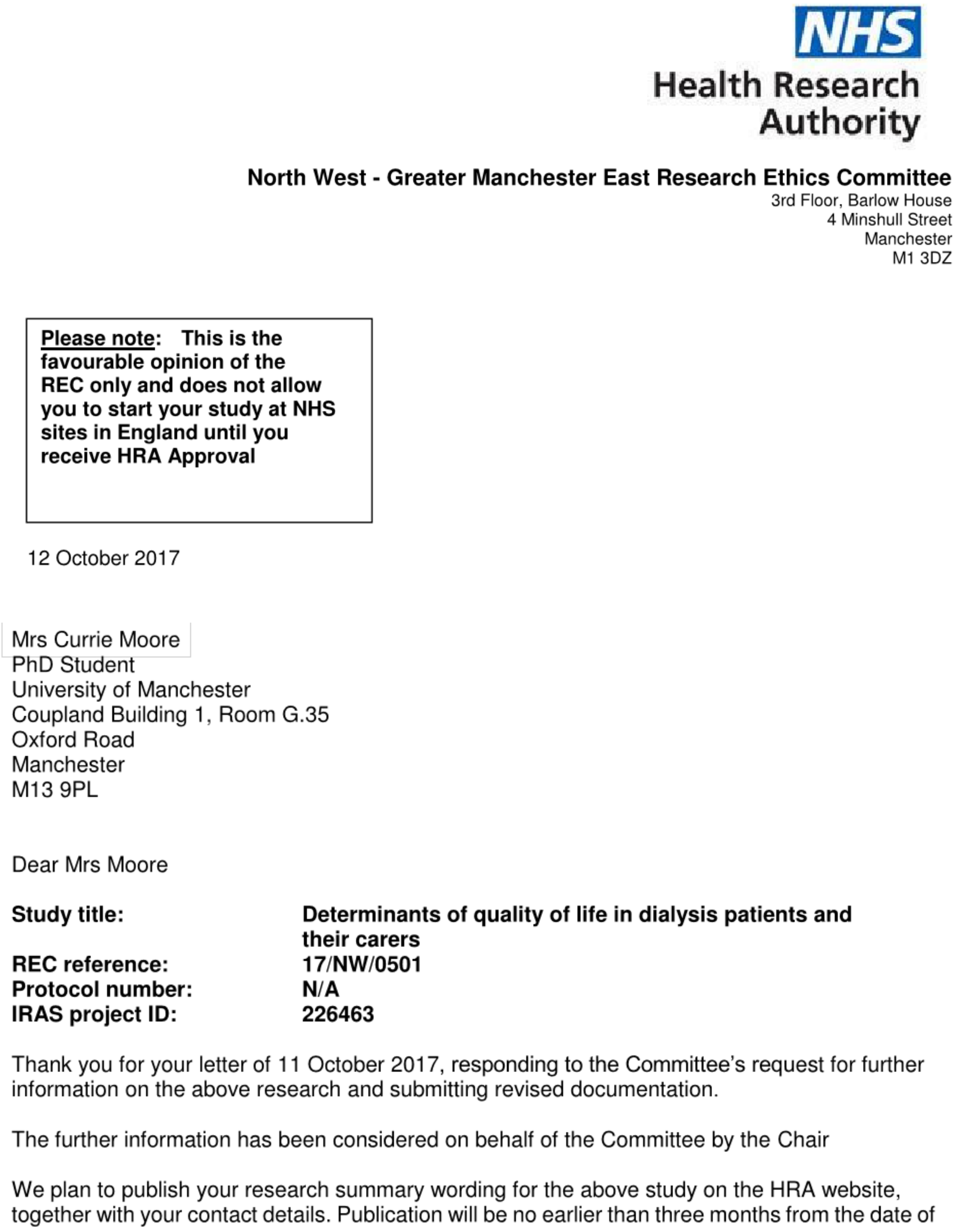
Yours sincerely

Kevin Ahmed
Assessor

Telephone: 0207 104 8171
Email: hra.approval@nhs.net

Copy to: *Mrs. Lynne Macrae, Sponsor Contact, University of Manchester*
Mrs. Elizabeth Mainwaring, R&D Contact, Central Manchester University Hospitals NHS Foundation Trust

Appendix R



NHS
Health Research
Authority

North West - Greater Manchester East Research Ethics Committee
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

12 October 2017

Mrs Currie Moore
PhD Student
University of Manchester
Coupland Building 1, Room G.35
Oxford Road
Manchester
M13 9PL

Dear Mrs Moore

Study title: **Determinants of quality of life in dialysis patients and their carers**
REC reference: **17/NW/0501**
Protocol number: **N/A**
IRAS project ID: **226463**

Thank you for your letter of 11 October 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Public liability 2017-18]		30 May 2017
IRAS Application Form [IRAS_Form_03082017]		03 August 2017
IRAS Checklist XML [Checklist_11102017]		11 October 2017
Letter from funder [MRC Doctoral Training Programme - Confirmation]		16 May 2014
Letter from sponsor [Moore_NHS001263_03.08.17]		03 August 2017
Letters of invitation to participant [Letter of invitation]	1	05 June 2017
Non-validated questionnaire [Psychosocial Factors Questionnaire - Patients T1]	1	05 June 2017
Non-validated questionnaire [Psychosocial Factors Questionnaire - Patients T2]	1	05 June 2017
Non-validated questionnaire [Psychosocial Factors Questionnaire - Patients T3]	1	05 June 2017
Non-validated questionnaire [Psychosocial Factors Questionnaire - Partners T1]	1	05 June 2017
Non-validated questionnaire [Psychosocial Factors Questionnaire - Partners T2]	1	05 June 2017
Non-validated questionnaire [Psychosocial Factors Questionnaire - Partners T3]	1	05 June 2017
Other [Letter from sponsor confirming insurance coverage]		03 August 2017
Other [Distress Policy]	1	29 July 2017
Other [Protocol]	3	06 October 2017
Other [Cover Letter.Provisional Opinion]	1	11 October 2017
Other [CI responses to provisional opinion]	1	06 October 2017
Other [Consent to Contact Form]	1	06 October 2017
Other [Recipe Reminder.Letter]	1	06 October 2017
Participant consent form [Participant consent form]	2	29 July 2017
Participant information sheet (PIS) [Participant Information Sheet]	2	29 July 2017
Participant information sheet (PIS) [Participant Informaiton Sheet]	3	06 October 2017
Referee's report or other scientific critique report [Evidence of external peer-review]	1	29 July 2017
Research protocol or project proposal [Protocol]	2	29 July 2017
Sample diary card/patient card [Case Report Form.V2]	2	29 July 2017
Summary CV for Chief Investigator (CI) [Moore, Currie CV]		12 June 2017
Summary CV for supervisor (student research) [WEARDEN, Alison CV (Principle Investigator)]		12 June 2017
Validated questionnaire [WHOQOL-BREF]		29 July 2017
Validated questionnaire [HADS]	1	02 July 2017
Validated questionnaire [POS-Symptoms-Generic (Partners)]	1	
Validated questionnaire [POS-Symptoms-Renal (Patients)]	1	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/NW/0501	**Please quote this number on all correspondence**

With the Committee’s best wishes for the success of this project.

Yours sincerely

Signed on behalf of:
Mr Simon Jones
Chair
Email:nrescommittee.northwest-gmeast@nhs.net

Enclosures:	“After ethical review – guidance for researchers”
Copy to:	Mrs. Lynne Macrae Mrs. Elizabeth Mainwaring, Central Manchester University Hospitals NHS Foundation Trust

Appendix S

[To be printed on each site's NHS letterhead]
Invitation to Participate in a Research Study:
Quality of life in couples starting dialysis

Dear *Patient Name*,

You are invited to take part in a research study on quality of life that is being run at your renal centre. Research is an important part of the work that the *[insert name of NHS Trust]* does because it helps us provide better care to our patients and those close to them.

You have been given this letter because you may be eligible to take part in this research study. The study is about quality of life in couples as you prepare to start dialysis and over your first 12 weeks on dialysis. Quality of life in people like yourselves is not known, so we are attempting to find out.

The study is a questionnaire study (you do NOT need to have extra bloods taken or attend additional hospital or clinical appointments). Both you and your partner will be asked to complete 3 questionnaires on 3 occasions: before starting dialysis, 6 weeks after starting dialysis and 12 weeks after starting dialysis. The questionnaires may be completed at your planned clinical appointments or dialysis sessions. Please be assured that everything you write in the questionnaires will remain confidential to the research team.

Next steps:

- You can contact either of the people listed below to confirm your interest in taking part:
    - Mrs. Currie Moore, Researcher, 0161 275 8300 currie.moore@postgrad.manchester.ac.uk
    - [Insert Site Investigator Details]
- If we do not hear from you in 1 week, a member of your care team will be in touch by telephone to check if you have any questions about the study.
- If you would like to take part in this study, the researcher will invite your partner to join too. Please check that your partner is happy to participate in this study and to be contacted by the research team.

Before you decide if you would like to take part, it is important for you to understand the study and what it will involve. Please take time to read the following information sheet carefully and discuss it with friends, relatives or anyone else you wish. Please do not hesitate to ask if there is anything that is not clear or if you would like more information.

Thank you for your time and for considering to take part in this study.

Best regards,

Currie Moore	[Name]
PhD Student	[Site investigator's job title]
University of Manchester	[NHS Renal Centre]

Appendix T

Research Site Logo here

MANCHESTER
1824
The University of Manchester

Participant Information Sheet

Quality of life
Starting dialysis

What is the purpose of study?

The main purpose of this study is to better understand quality of life (QOL) in couples as one of them prepares for and starts on dialysis. We are interested in QOL of patients and also the person closest to them (for example, a spouse or partner) during this time period. The other purpose of the study is to look at factors that may be related to better and poorer QOL.

Why have I been invited?

You have been invited because you or your partner may be preparing to start on haemodialysis or peritoneal dialysis.

Do I have to take part?

You decide whether or not to take part. Because we are interested in the QOL of patients *and* their partners, both of you would need to agree to join the study.
Even if you decide to take part, you or your partner are still free to withdraw at any time without giving a reason.

What are the possible benefits of taking part?

There are no direct and immediate benefits to you personally for participating in this study. However, your participation will be valuable to us in understanding how dialysis affects your QOL.

Who is funding this study?
The study is being funded by the Medical Research Council (UK) awarded to the University of Manchester as part of their Doctoral Training Programme. This study is part of a programme of research for a PhD.

What will happen to me if I take part in this study?

1. If you decide to participate, you will be asked to complete 3 questionnaires. The study is collecting this information at 3 occasions – before starting dialysis, 6 weeks after starting dialysis, and 12 weeks after starting dialysis. You may complete the questionnaires at clinical appointments or dialysis sessions.
2. Before completing the questionnaire, the researcher will make sure you are happy to participate in the study. She will then review your rights as a participant with you. If you are still happy to take part, the researcher will ask you to initial, sign and date a Consent Form.
3. The researcher will give you the option of completing the questionnaires on paper or online. If you need any assistance completing the questionnaires, please ask the researcher. The questionnaires take approximately 20 minutes to fill in.
4. When you are finished, you simply return the questionnaires to the researcher. She will then ask if you are interested in taking part again in about 6 weeks and again at 12 weeks. If so, the researcher will ask how you prefer to be contacted. You will complete a similar set of questionnaires at the next occasion.
5. You have the right to withdraw from this study at any point, without explanation.
6. Taking part in this study will not affect any aspect of your, or your partner's, health care.
7. The contact details you provide will be transferred out of the Trust and stored securely at the University purely for sending out the questionnaires. These will be deleted when your participation in the study is over.

Will my taking part in this study be kept confidential?
Everything in the questionnaires will be confidential and will not be released to anyone outside of the research team. When the results of the study are reported and published, your name will not be released and it will *not* be possible to identify you or any other participants' data.

Who will have access to the information obtained in the study?
Individuals from the University of Manchester, regulatory authorities or NHS Trust may need to look at the data collected during the study to make sure that it is being carried out as planned. With your permission, the information they look at will include identifiable data (they will be able to see who it belongs to). Only authorised individuals will look at the data and all will have a duty of confidentiality to you as a research participant. With your permission, anonymous versions of the data will be shared with other

research teams (e.g., the World Health Organization Quality of Life Group). Sharing data in research is a way of maximising the valuable information you provide and will be shared in line with the Medical Research Council UK's policy on data sharing. *For patients:* The researcher requests permission to access your medical records in order to obtain further details about your medical history that may help us understand your experience. Examples of the type of information might be looked at are your time in pre-dialysis care, the origin of your kidney disease or changes in your renal care.

What happens if a participant (who has given informed consent) loses the ability to give consent during the study?

The participant would be withdrawn from the study and all identifiable data already collected with consent would be retained and used in the study. The couple would not take part in any further follow ups.

What will happen to the results of the study?

The study will take up to 2 years to be completed. The findings from it will be published as part of a PhD thesis and in academic journals. You will *not* be identifiable in any of these publications. The data collected will be locked in a secure archive at the University of Manchester for a minimum of 5 years after the date of any publication which based on the results or 10 years, whichever is longer. If you wish for your data to be removed from the study, please contact Mrs. Currie Moore.

Who has reviewed this study?

This research study has been given a favourable ethical opinion for conduct in the NHS by the Research Ethics Committee (17/NW/0501) and Health Research Authority. The University of Manchester and the MFT R&D Department have also reviewed this study. They monitor research projects to ensure that they are being conducted properly, according to the best practice in research

Who is supervising this study?

- Dr. Sandip Mitra, Consultant Nephrologist, Manchester Royal Infirmary
- Dr. Alison Wearden, Prof. of Health Psychology, University of Manchester
- Dr. Suzanne Skevington, Prof. of Health Psychology, University of Manchester
- Dr. Lesley-Anne Carter, Lecturer of Biostatistics, University of Manchester

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to a senior member of the research team who will do her best to answer your questions:

Prof. Alison Wearden, alison.wearden@manchester.ac.uk, **0161 275 2684**

How to join the study:

Contact either the researcher or local clinical research nurse:

Mrs. Currie Moore, Researcher
0161 275 8300
currie.moore@postgrad.manchester.ac.uk

Insert Local Site Investigator
Renal Research Nurse, xxxxxxx
xxxxxxxxxx@xxxxxxxxx

Contact details for further information:

Questions or minor complaints:

If you wish to know more about the study or have a minor complaint, please contact the researcher, **Mrs. Currie Moore, Manchester Centre for Health Psychology, Coupland Building I, University of Manchester, Oxford Road, Manchester, M13 9PL** or by the contact details listed above.

Formal complaints:

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact the Research Governance and Integrity Manager, Research Office, University of Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

General information:

If you would like more information on kidney disease or dialysis, please contact Kidney Care UK by telephone on 01420 541 424 or visit their website: http://www.kidneycareuk.org

Appendix U

Quality of life
Starting dialysis

QUESTIONNAIRE PACK

PATIENT VERSION

Instructions

This questionnaire asks how you feel about **your** quality of life, health and other areas of your life.

Please answer all the questions.
If you are unsure about which response to give to a question, please choose the **ONE** that appears most appropriate. This can often be your first response.
You should **circle** the number that best fits your response.

Please keep in mind your standards, hopes, pleasures and concerns.
We ask that you think about your life **in the last two weeks**.

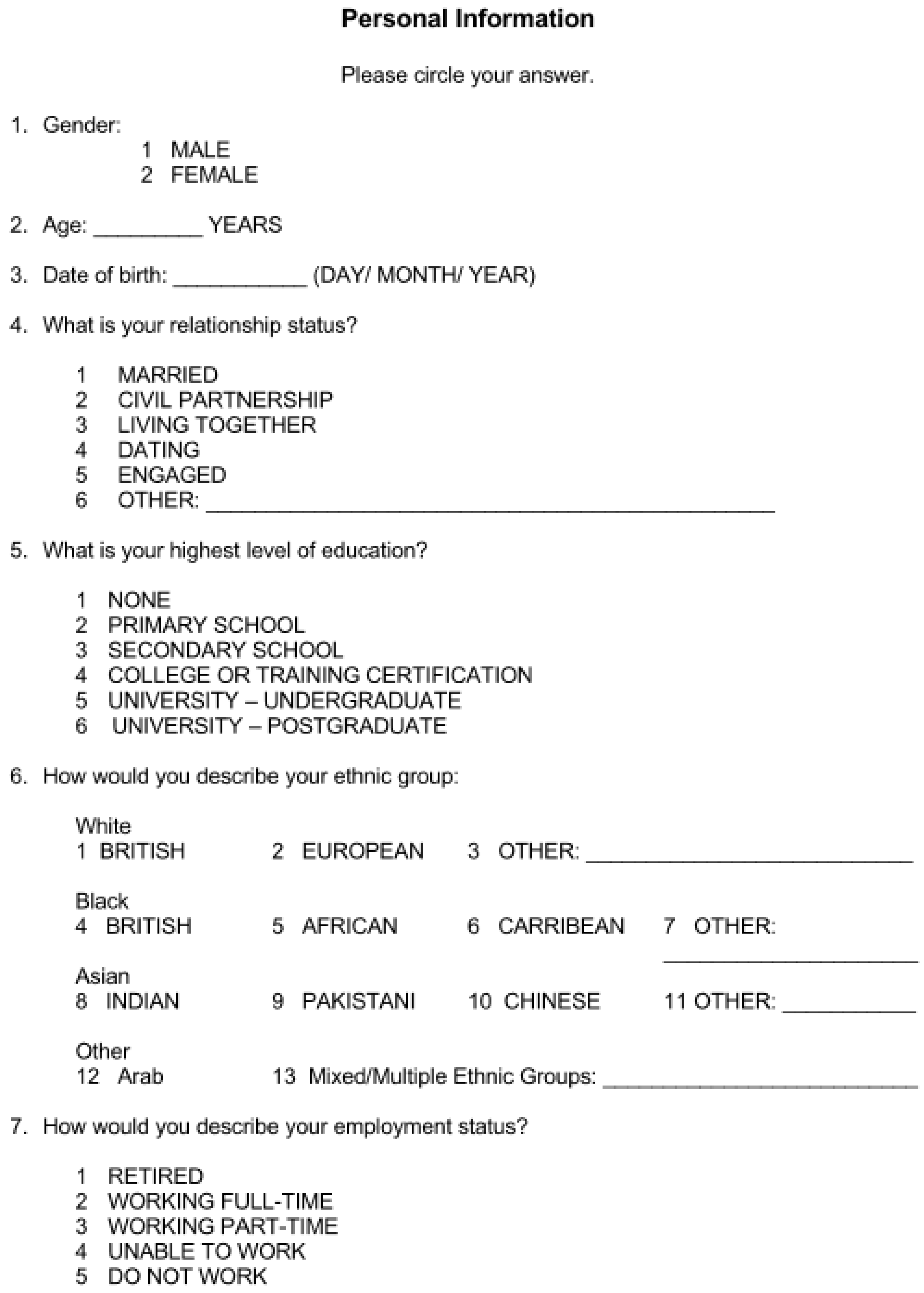
Please read each question, assess your feelings,
and **circle** the number on the scale for each question that gives the best answer for you.

Research Team Contact Details:
Mrs. Currie Moore
PhD Researcher
Manchester Centre for Health Psychology
G.35, Coupland Building I
Oxford Road
University of Manchester
Manchester M13 9PL
Email: Currie.moore@postgrad.manchester.ac.uk
Telephone: 0161 275 8300

MANCHESTER
1824
The University of Manchester

IRAS ID: 226463

Questionnaires Patients T1.V2
06/10/17



Personal Information

Please circle your answer.

1. Gender:
    1 MALE
    2 FEMALE

2. Age: __________ YEARS

3. Date of birth: ____________ (DAY/ MONTH/ YEAR)

4. What is your relationship status?

    1 MARRIED
    2 CIVIL PARTNERSHIP
    3 LIVING TOGETHER
    4 DATING
    5 ENGAGED
    6 OTHER: ____

5. What is your highest level of education?

    1 NONE
    2 PRIMARY SCHOOL
    3 SECONDARY SCHOOL
    4 COLLEGE OR TRAINING CERTIFICATION
    5 UNIVERSITY – UNDERGRADUATE
    6 UNIVERSITY – POSTGRADUATE

6. How would you describe your ethnic group:

    White
    1 BRITISH   2 EUROPEAN   3 OTHER: ______________________________

    Black
    4 BRITISH   5 AFRICAN   6 CARRIBEAN   7 OTHER: ________________________

    Asian
    8 INDIAN   9 PAKISTANI   10 CHINESE   11 OTHER: ____________

    Other
    12 Arab   13 Mixed/Multiple Ethnic Groups: _____________________________

7. How would you describe your employment status?

    1 RETIRED
    2 WORKING FULL-TIME
    3 WORKING PART-TIME
    4 UNABLE TO WORK
    5 DO NOT WORK

Quality of life and Health

Question 1-2 are about your current quality of life and health. Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks**.

		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	**Dissatisfied**	**Neither satisfied or dissatisfied**	**Satisfied**	**Very satisfied**
2.	How satisfied are you with your health?	1	2	3	4	5

The following set of questions is about your expectations of your quality of life and your health **in the future**.

		Much worse than now	**Worse than now**	**The same**	**A little better than now**	**Much better than now**
3.	In 6 weeks, what do you think your **quality of life** will be like?	1	2	3	4	5
4.	In 6 weeks, what do you think your *physical health* will be like?	1	2	3	4	5
5.	In 6 weeks, what do you think your *emotional health* will be like?	1	2	3	4	5
6.	In 3 months, what do you think your **quality of life** will be like?	1	2	3	4	5
7.	In 3 months, what do you think your *physical health* will be like?	1	2	3	4	5
8.	In 3 months, what do you think your *emotional health* will be like?	1	2	3	4	5

		Very low	**Low**	**No expectations**	**High**	**Very high**
9.	How would you rate your expectations of dialysis?	1	2	3	4	5

Some people have expectations of dialysis, and some people do not.
To give us a better idea of what patients think about dialysis before starting on it, could you please write down any thoughts you have on the following:

10.	Please write down in what ways you expect dialysis will benefit you or your partner:
11.	Please write down in what ways you expect it will **not** benefit you or your partner:

The following questions are about your thoughts and expectations about dialysis.

		Not at all	Not much	Moderately	A great deal	Completely
12.	How much have you come to terms with starting dialysis?	1	2	3	4	5
13.	To what extent do you think you will be able to carry on with your daily life when you start dialysis?	1	2	3	4	5
14.	How much do you think you will be bothered by dialysis?	1	2	3	4	5
15.	How bothersome do you expect dialysis to be for your partner?	1	2	3	4	5
16.	To what extent do you think you will have the control of dialysis that you would like?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied or dissatisfied	Satisfied	Very satisfied
17.	How satisfied are you that dialysis is the best option for you at this time?	1	2	3	4	5

		An extreme amount	Very much	A moderate amount	A little	Not at all
18.	How bothered would you be if dialysis became a long-term treatment for your kidney disease?	1	2	3	4	5

The following questions are about **how much** you expect dialysis to affect areas of your life or your relationship with your partner.

		Not at all	Not much	Moderately	A great deal	Completely
19.	How much do you expect that your partner will be involved in your dialysis?	1	2	3	4	5
20.	How much do you think your partner's involvement in your dialysis will match your needs?	1	2	3	4	5
21.	How much do you expect dialysis will change your role in the relationship?	1	2	3	4	5
22.	How much do you think you and your partner will act as a team when it comes to handling your dialysis?	1	2	3	4	5
23.	How much do you think that you and your partner will be "on the same page" (share similar views) about dialysis?	1	2	3	4	5
24.	How positive do you think you will be about dialysis?	1	2	3	4	5
25.	How positive do you think your partner will be about dialysis?	1	2	3	4	5
26.	How well do you think you will be able to express <u>your</u> *feelings* about dialysis to your partner?	1	2	3	4	5

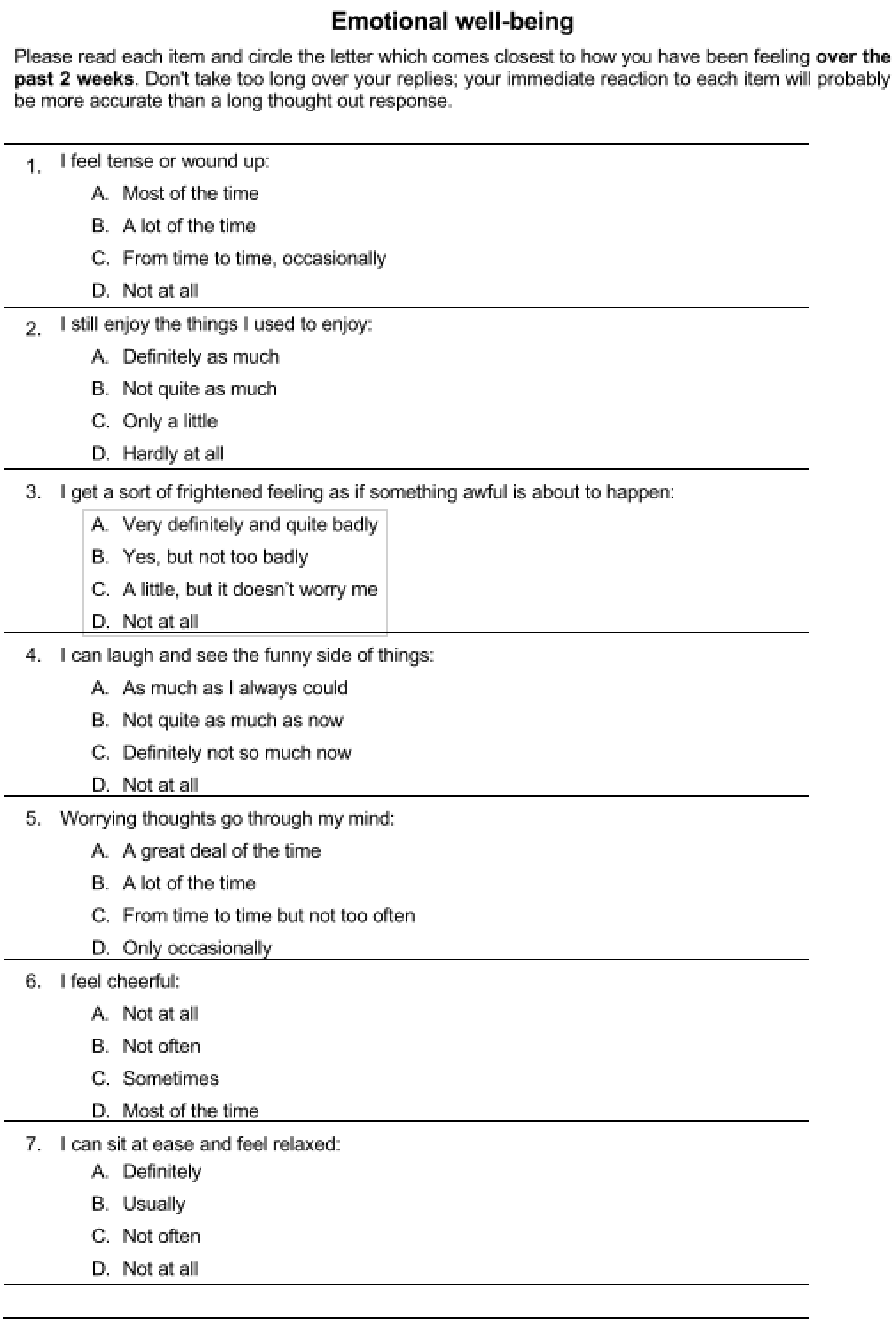
		Not at all	Not much	Moderately	A great deal	Completely
27.	How comfortable do you think you will be discussing *issues* related to dialysis with your partner?	1	2	3	4	5
28.	How comfortable do you think your partner will be to talk about dialysis-related *issues*?	1	2	3	4	5
29.	How willing do you think your partner will be to share his/her *feelings* about dialysis with you?	1	2	3	4	5
30.	How much do you think that your partner will listen to your views on dialysis related topics?	1	2	3	4	5

The following questions about **how often** you think or expect these experiences after starting dialysis.

		Never	Seldom	Quite often	Very often	Always
31.	How often do you think you will feel lonely because of dialysis?	1	2	3	4	5
32.	How often do you think you will feel isolated because of dialysis?	1	2	3	4	5
33.	How often do you think that you and your partner will do activities you enjoy together?	1	2	3	4	5
34.	How often do you expect that you and your partner will be able to find humour in small things or have a laugh?	1	2	3	4	5

The following question asks you to think about **how satisfied** you are with aspects of your life **over the last two weeks**.

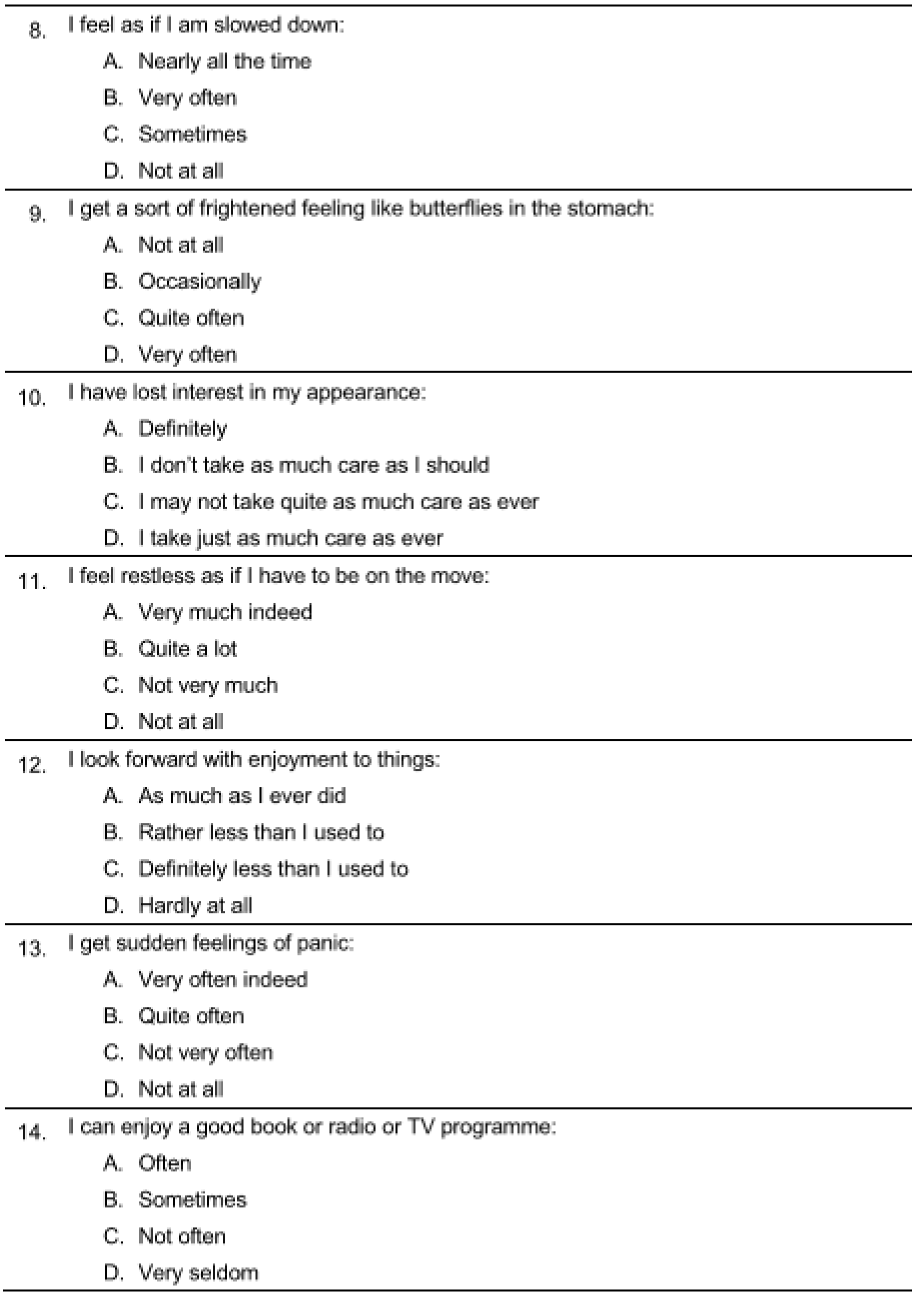
		Very dissatisfied	Dissatisfied	Neither satisfied or dissatisfied	Satisfied	Very satisfied
35.	How satisfied are you with your relationship?	1	2	3	4	5



Emotional well-being

Please read each item and circle the letter which comes closest to how you have been feeling **over the past 2 weeks**. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or wound up:
    - A. Most of the time
    - B. A lot of the time
    - C. From time to time, occasionally
    - D. Not at all
2. I still enjoy the things I used to enjoy:
    - A. Definitely as much
    - B. Not quite as much
    - C. Only a little
    - D. Hardly at all
3. I get a sort of frightened feeling as if something awful is about to happen:
    - A. Very definitely and quite badly
    - B. Yes, but not too badly
    - C. A little, but it doesn't worry me
    - D. Not at all
4. I can laugh and see the funny side of things:
    - A. As much as I always could
    - B. Not quite as much as now
    - C. Definitely not so much now
    - D. Not at all
5. Worrying thoughts go through my mind:
    - A. A great deal of the time
    - B. A lot of the time
    - C. From time to time but not too often
    - D. Only occasionally
6. I feel cheerful:
    - A. Not at all
    - B. Not often
    - C. Sometimes
    - D. Most of the time
7. I can sit at ease and feel relaxed:
    - A. Definitely
    - B. Usually
    - C. Not often
    - D. Not at all



8. I feel as if I am slowed down:
   - A. Nearly all the time
   - B. Very often
   - C. Sometimes
   - D. Not at all

9. I get a sort of frightened feeling like butterflies in the stomach:
   - A. Not at all
   - B. Occasionally
   - C. Quite often
   - D. Very often

10. I have lost interest in my appearance:
    - A. Definitely
    - B. I don't take as much care as I should
    - C. I may not take quite as much care as ever
    - D. I take just as much care as ever

11. I feel restless as if I have to be on the move:
    - A. Very much indeed
    - B. Quite a lot
    - C. Not very much
    - D. Not at all

12. I look forward with enjoyment to things:
    - A. As much as I ever did
    - B. Rather less than I used to
    - C. Definitely less than I used to
    - D. Hardly at all

13. I get sudden feelings of panic:
    - A. Very often indeed
    - B. Quite often
    - C. Not very often
    - D. Not at all

14. I can enjoy a good book or radio or TV programme:
    - A. Often
    - B. Sometimes
    - C. Not often
    - D. Very seldom

Other areas related to your current quality of life

The following questions ask about **how much** you have experienced certain things **in the last two weeks.**

		Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	How much do you feel that pain prevents you from doing what you need to do?	1	2	3	4	5
2	How much do you need medical treatment to function in your daily life?	1	2	3	4	5
3	How much do you enjoy life?	1	2	3	4	5

		Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**
4	To what extent do you feel life to be meaningful?	1	2	3	4	5
5	How well are you able to concentrate?	1	2	3	4	5
6	How safe do you feel in your daily life?	1	2	3	4	5
7	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things **in the last two weeks**.

		Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
8	Do you have enough energy for everyday life?	1	2	3	4	5
9	Are you able to accept your bodily appearance?	1	2	3	4	5
10	To what extent do you have enough money to meet your needs?	1	2	3	4	5
11	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
12	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

The following questions ask you to say **how good or satisfied** you have felt about various aspects of your life **over the last two weeks**.

		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
13	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
14	How satisfied are you with your sleep?	1	2	3	4	5
15	How satisfied are you with your ability to perform daily living activities?	1	2	3	4	5
16	How satisfied are you with your capacity for work? Note: Work is defined as any major activity including paid work, unpaid work, voluntary or community work, full-time study, care of children and household duties.	1	2	3	4	5
17	How satisfied are you with yourself?	1	2	3	4	5
18	How satisfied are you with your personal relationships?	1	2	3	4	5
19	How satisfied are you with your sex life?	1	2	3	4	5
20	How satisfied are you with the support you get from your friends?	1	2	3	4	5
21	How satisfied are you with the conditions of your living place?	1	2	3	4	5
22	How satisfied are you with your access to health services?	1	2	3	4	5
23	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things **in the last two weeks**.

		Never	**Seldom**	**Quite often**	**Very often**	**Always**
24	How often do you have negative feelings, such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Symptoms

Below is a list of symptoms, which you may or may not have experienced.
Please circle the number to show how you feel each of these symptoms has affected you
and how you have been feeling over the **past 2 weeks.**

	Not at all No effect	**Slightly** but not bothered to be rid of it	**Moderately** limits some activity or concentration	**Severely** activities or concentration markedly affected	**Overwhelmingly** unable to think of anything else
Pain	0	1	2	3	4
Shortness of breath	0	1	2	3	4
Weakness or lack of energy	0	1	2	3	4
Nausea (feeling like you are going to be sick)	0	1	2	3	4
Vomiting (being sick)	0	1	2	3	4
Poor appetite	0	1	2	3	4
Constipation	0	1	2	3	4
Mouth problems	0	1	2	3	4
Drowsiness	0	1	2	3	4
Poor mobility	0	1	2	3	4
Itching	0	1	2	3	4
Difficulty sleeping	0	1	2	3	4
Restless legs or difficulty keeping legs still	0	1	2	3	4
Feeling anxious	0	1	2	3	4
Feeling depressed	0	1	2	3	4
Changes in skin	0	1	2	3	4
Diarrhoea	0	1	2	3	4

Any other symptoms:					
1.	0	1	2	3	4
2.	0	1	2	3	4
3.	0	1	2	3	4

Which symptom has affected you the most? ____

Which symptom has improved the most? ____

Thank you for answering these questions. Your contribution is greatly appreciated.

Is there anything else you would like to tell us about?
Also, any comments that you think may help us to understand dialysis patients
and their partners would be most appreciated.
Please feel free to use this space for this purpose.

To be completed by the person who gives you the questionnaire pack:

Participant Id: ____________________________ Renal Centre: ____________________________

Date completed: _____________ (dd/mm/yy) Approximate time to complete: __________ (minutes)

How was the questionnaire completed:
_____ Completed without assistance from researcher or investigator
_____ Assisted by researcher or investigator (read aloud)
_____ Other – please provide details:___________________________
Where was the questionnaire completed:
____ At a clinical appointment
____ Before a dialysis session
____ During a dialysis session
____ At home
____ Other: ____________________________________

Appendix V

Quality of life
Starting dialysis

QUESTIONNAIRE PACK

PARTNER VERSION

Instructions

This questionnaire asks how you feel about **your** quality of life, health and other areas of your life.
Your needs matter even as your partner prepares for dialysis.
By completing this questionnaire, you will help us understand your experience
and how we can better support you both.

Please answer all the questions.
If you are unsure about which response to give to a question, please choose the **ONE** that appears most appropriate. This can often be your first response.
You should **circle** the number that best fits your response.

Please keep in mind your standards, hopes, pleasures and concerns.
We ask that you think about your life **in the last two weeks**.

Please read each question, assess your feelings,
and **circle** the number on the scale for each question that gives the best answer for you.

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MANCHESTER 1824
The University of Manchester

IRAS ID: 226463

Questionnaires Partners T1.V2
Date: 06/10/17

Personal Information

Please circle your answer.

1. Gender:
    1 MALE
    2 FEMALE

2. Age: _________ YEARS

3. Date of birth: ___________ (DAY/ MONTH/ YEAR)

4. What is your relationship status?

    1 MARRIED
    2 CIVIL PARTNERSHIP
    3 LIVING TOGETHER
    4 DATING
    5 ENGAGED
    6 OTHER: ____

5. What is your highest level of education?

    1 NONE
    2 PRIMARY SCHOOL
    3 SECONDARY SCHOOL
    4 COLLEGE OR TRAINING CERTIFICATION
    5 UNIVERSITY – UNDERGRADUATE
    6 UNIVERSITY – POSTGRADUATE

6. How would you describe your ethnic group:

    White
    1 BRITISH   2 EUROPEAN   3 OTHER: ___________________________

    Black
    4 BRITISH   5 AFRICAN   6 CARRIBEAN   7 OTHER: _____________________

    Asian
    8 INDIAN   9 PAKISTANI   10 CHINESE   11 OTHER: ___________

    Other
    12 ARAB   13 Mixed/Multiple Ethnic Groups: __________________________

7. How would you describe your employment status?

    1 RETIRED
    2 WORKING FULL-TIME
    3 WORKING PART-TIME
    4 UNABLE TO WORK
    5 DO NOT WORK

Quality of life and Health

Question 1-2 are about your current quality of life and health. Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks**.

		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	**Dissatisfied**	**Neither satisfied or dissatisfied**	**Satisfied**	**Very satisfied**
2.	How satisfied are you with your health?	1	2	3	4	5

The following set of questions is about your expectations of your quality of life and your health **in the future**.

		Much worse than now	**Worse than now**	**The same**	**A little better than now**	**Much better than now**
3.	In 6 weeks, what do you think your **quality of life** will be like?	1	2	3	4	5
4.	In 6 weeks, what do you think your *physical health* will be like?	1	2	3	4	5
5.	In 6 weeks, what do you think your *emotional health* will be like?	1	2	3	4	5
6.	In 3 months, what do you think your **quality of life** will be like?	1	2	3	4	5
7.	In 3 months, what do you think your *physical health* will be like?	1	2	3	4	5
8.	In 3 months, what do you think your *emotional health* will be like?	1	2	3	4	5

		Very low	**Low**	**No expectations**	**High**	**Very high**
9.	How would you rate your expectations of dialysis?	1	2	3	4	5

Some people have expectations of dialysis, and some people do not. To give us a better idea of what partners think about dialysis before their patient-partner starts on it, could you please write down any thoughts you have on the following:

10. Please write down in what ways you expect dialysis will benefit you or your partner:

11. Please write down in what ways you expect it will **not** benefit you or your partner:

The following questions are about your thoughts and expectations about your partner's dialysis.

		Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
12.	How much have you come to terms with your partner starting dialysis?	1	2	3	4	5
13.	To what extent do you think you will be able to carry on with your daily life when your partner is on dialysis?	1	2	3	4	5
14.	How much do you think you will be bothered by dialysis?	1	2	3	4	5
15.	How bothersome do you expect dialysis to be for your partner?	1	2	3	4	5
16.	To what extent do you think your partner will have the control of dialysis that he/she would like?	1	2	3	4	5

		Very dissatisfied	**Dissatisfied**	**Neither satisfied or dissatisfied**	**Satisfied**	**Very satisfied**
17.	How satisfied are you that dialysis is the best option for your partner at this time?	1	2	3	4	5

		An extreme amount	**Very much**	**A moderate amount**	**A little**	**Not at all**
18.	How bothered would you be if dialysis became a long-term treatment for your partner's kidney disease?	1	2	3	4	5

The following questions are about **how much** you expect dialysis to affect areas of your life or your relationship with your partner.

		Not at all	**Not much**	**Moderately**	**A great deal**	**Completely**
19.	How much do you expect that your partner will involve you in his/her dialysis?	1	2	3	4	5
20.	How much do you think your involvement in your partner's dialysis will match how much you want to be involved?	1	2	3	4	5
21.	How much do you expect dialysis will change your role in the relationship?	1	2	3	4	5
22.	How much do you think you and your partner will act as a team when it comes to handling dialysis?	1	2	3	4	5
23.	How much do you think that you and your partner will be "on the same page" (share similar views) about dialysis?	1	2	3	4	5
24.	How positive do you think you will be about dialysis?	1	2	3	4	5

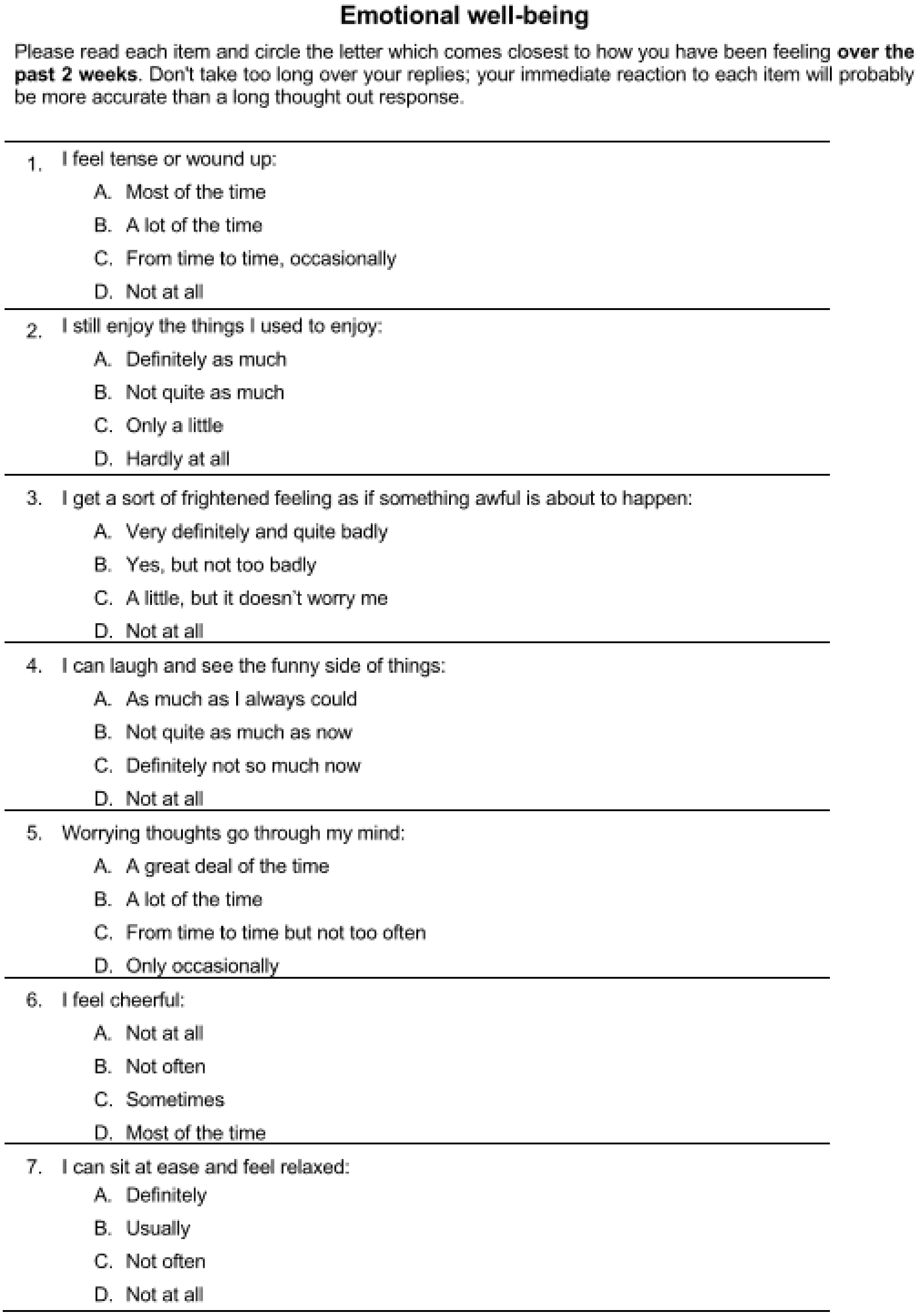
		Not at all	Not much	Moderately	A great deal	Completely
25.	How positive do you think your partner will be about dialysis?	1	2	3	4	5
26.	How well do you think you will be able to express <u>your</u> *feelings* about dialysis to your partner?	1	2	3	4	5
27.	How comfortable do you think <u>you</u> will be discussing *issues* related to dialysis with your partner?	1	2	3	4	5
28.	How comfortable do you think your partner will be to talk about dialysis-related *issues*?	1	2	3	4	5
29.	How willing do you think your partner will be to share his/her *feelings* about dialysis with you?	1	2	3	4	5
30.	How much do you think that your partner will listen to your views on dialysis related topics?	1	2	3	4	5

The following questions about **how often** you think or expect these experiences after starting dialysis.

		Never	Seldom	Quite often	Very often	Always
31.	How often do you think you will you get time for yourself once dialysis starts?	1	2	3	4	5
32.	How often do you think you will feel lonely because of dialysis?	1	2	3	4	5
33.	How often do you think you will feel isolated because of dialysis?	1	2	3	4	5
34.	How often do you think that you and your partner will do activities you enjoy together?	1	2	3	4	5
35.	How often do you expect that you and your partner will be able to find humour in small things or have a laugh?	1	2	3	4	5

The following question asks you to think about **how satisfied** you are with aspects of your life **over the last two weeks**.

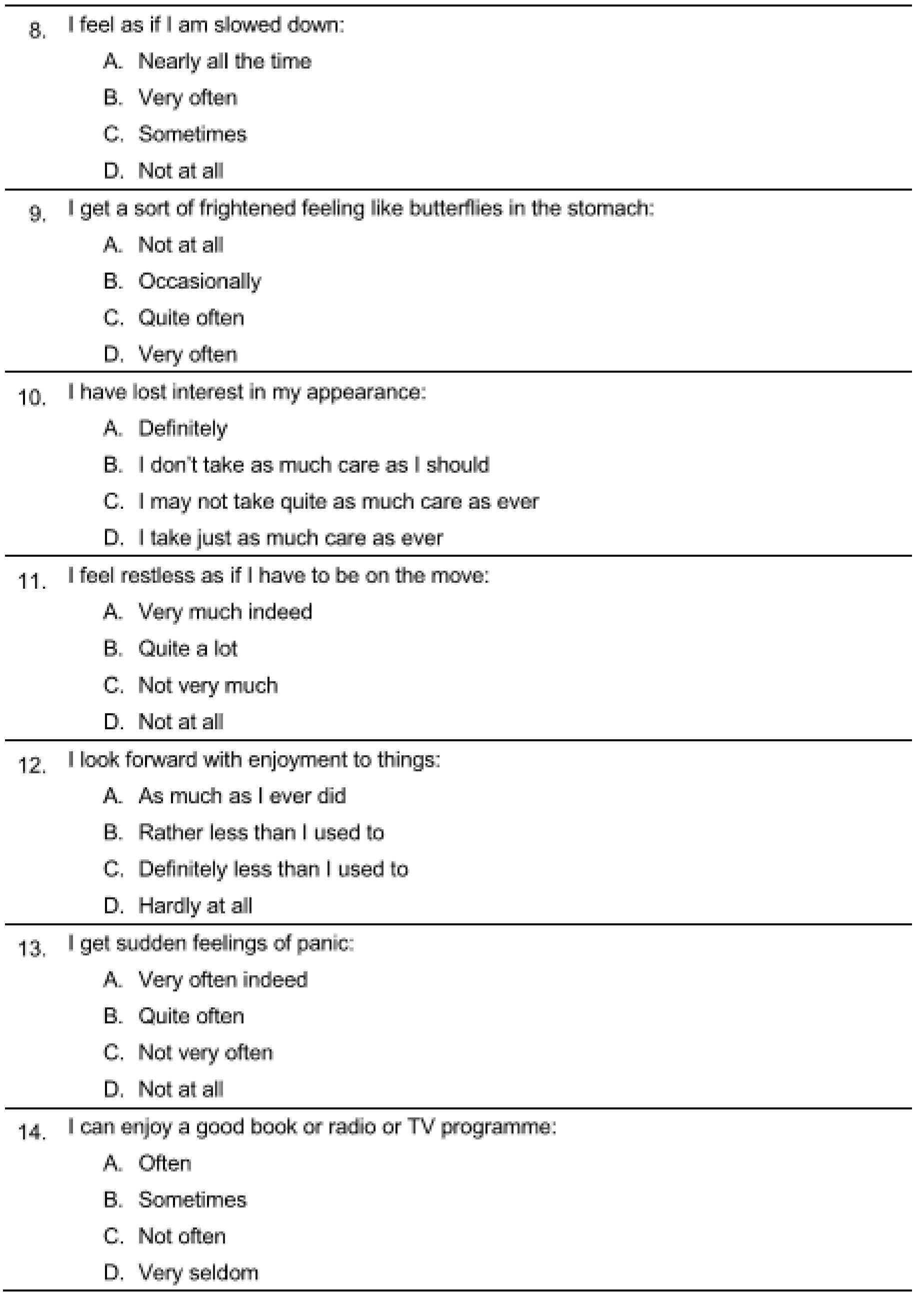
		Very dissatisfied	Dissatisfied	Neither satisfied <u>or</u> dissatisfied	Satisfied	Very satisfied
36.	How satisfied are you with your relationship?	1	2	3	4	5



Emotional well-being

Please read each item and circle the letter which comes closest to how you have been feeling **over the past 2 weeks**. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or wound up:
   - A. Most of the time
   - B. A lot of the time
   - C. From time to time, occasionally
   - D. Not at all
2. I still enjoy the things I used to enjoy:
   - A. Definitely as much
   - B. Not quite as much
   - C. Only a little
   - D. Hardly at all
3. I get a sort of frightened feeling as if something awful is about to happen:
   - A. Very definitely and quite badly
   - B. Yes, but not too badly
   - C. A little, but it doesn't worry me
   - D. Not at all
4. I can laugh and see the funny side of things:
   - A. As much as I always could
   - B. Not quite as much as now
   - C. Definitely not so much now
   - D. Not at all
5. Worrying thoughts go through my mind:
   - A. A great deal of the time
   - B. A lot of the time
   - C. From time to time but not too often
   - D. Only occasionally
6. I feel cheerful:
   - A. Not at all
   - B. Not often
   - C. Sometimes
   - D. Most of the time
7. I can sit at ease and feel relaxed:
   - A. Definitely
   - B. Usually
   - C. Not often
   - D. Not at all



8. I feel as if I am slowed down:
    - A. Nearly all the time
    - B. Very often
    - C. Sometimes
    - D. Not at all
9. I get a sort of frightened feeling like butterflies in the stomach:
    - A. Not at all
    - B. Occasionally
    - C. Quite often
    - D. Very often
10. I have lost interest in my appearance:
    - A. Definitely
    - B. I don't take as much care as I should
    - C. I may not take quite as much care as ever
    - D. I take just as much care as ever
11. I feel restless as if I have to be on the move:
    - A. Very much indeed
    - B. Quite a lot
    - C. Not very much
    - D. Not at all
12. I look forward with enjoyment to things:
    - A. As much as I ever did
    - B. Rather less than I used to
    - C. Definitely less than I used to
    - D. Hardly at all
13. I get sudden feelings of panic:
    - A. Very often indeed
    - B. Quite often
    - C. Not very often
    - D. Not at all
14. I can enjoy a good book or radio or TV programme:
    - A. Often
    - B. Sometimes
    - C. Not often
    - D. Very seldom

Other areas related to your current quality of life

The following questions ask about **how much** you have experienced certain things **in the last two weeks.**

		Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	How much do you feel that pain prevents you from doing what you need to do?	1	2	3	4	5
2	How much do you need medical treatment to function in your daily life?	1	2	3	4	5
3	How much do you enjoy life?	1	2	3	4	5

		Not at all	**A little**	**A moderate amount**	**Very much**	**Extremely**
4	To what extent do you feel life to be meaningful?	1	2	3	4	5
5	How well are you able to concentrate?	1	2	3	4	5
6	How safe do you feel in your daily life?	1	2	3	4	5
7	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things **in the last two weeks**.

		Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
8	Do you have enough energy for everyday life?	1	2	3	4	5
9	Are you able to accept your bodily appearance?	1	2	3	4	5
10	To what extent do you have enough money to meet your needs?	1	2	3	4	5
11	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
12	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

The following questions ask you to say **how good or satisfied** you have felt about various aspects of your life **over the last two weeks**.

		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
13	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
14	How satisfied are you with your sleep?	1	2	3	4	5
15	How satisfied are you with your ability to perform daily living activities?	1	2	3	4	5
16	How satisfied are you with your capacity for work? Note: Work is defined as any major activity including paid work, unpaid work, voluntary or community work, full-time study, care of children and household duties.	1	2	3	4	5
17	How satisfied are you with yourself?	1	2	3	4	5
18	How satisfied are you with your personal relationships?	1	2	3	4	5
19	How satisfied are you with your sex life?	1	2	3	4	5
20	How satisfied are you with the support you get from your friends?	1	2	3	4	5
21	How satisfied are you with the conditions of your living place?	1	2	3	4	5
22	How satisfied are you with your access to health services?	1	2	3	4	5
23	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things **in the last two weeks**.

		Never	**Seldom**	**Quite often**	**Very often**	**Always**
24	How often do you have negative feelings, such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Symptoms

Below is a list of symptoms, which you may or may not have experienced.
Please circle the number to show how you feel each of these symptoms has affected you and how you have been feeling over the **past 2 weeks.**

	Not at all No effect	**Slightly** but not bothered to be rid of it	**Moderately** limits some activity or concentration	**Severely** activities or concentration markedly affected	**Overwhelmingly** unable to think of anything else
Pain	0	1	2	3	4
Shortness of breath	0	1	2	3	4
Weakness or lack of energy	0	1	2	3	4
Nausea (feeling like you are going to be sick)	0	1	2	3	4
Vomiting (being sick)	0	1	2	3	4
Poor appetite	0	1	2	3	4
Constipation	0	1	2	3	4
Mouth problems	0	1	2	3	4
Drowsiness	0	1	2	3	4
Poor mobility	0	1	2	3	4
Difficulty sleeping	0	1	2	3	4
Feeling anxious	0	1	2	3	4
Feeling depressed	0	1	2	3	4

Any other symptoms:					
1.	0	1	2	3	4
2.	0	1	2	3	4
3.	0	1	2	3	4

Which symptom has affected you the most? ____

Which symptom has improved the most? ____

Thank you for answering these questions. Your contribution is greatly appreciated.

Is there anything else you would like to tell us about?
Also, any comments that you think may help us to understand dialysis patients
and their partners would be most appreciated.
Please feel free to use this space for this purpose.

To be completed by the person who gives you the questionnaire pack:

Participant Id: ____________________________ Renal Centre: _____________________________

Date completed: ______________ (dd/mm/yy) Approximate time to complete: __________ (minutes)

How was the questionnaire completed:
_____ Completed without assistance from researcher or investigator
_____ Assisted by researcher or investigator (read aloud)
_____ Other – please provide details:____________________________
Where was the questionnaire completed:
____ At a clinical appointment
____ Before a dialysis session
____ During a dialysis session
____ At home
____ Other: ______________________________________

Appendix W

Quality of life
Starting dialysis

Standard Operating Procedures
Longitudinal Questionnaire Study
Currie Moore, Chief Investigator

IRAS 226 463 | V2 | 24/01/18

MRC Medical Research Council

MANCHESTER 1824
The University of Manchester

Overview

This study is a longitudinal, prospective, observational study which will use questionnaire data to track changes in quality of life in patients and their partner (spouses or significant others). We are interested in assessing how patients and their partners assess their quality of life as they prepare to start dialysis and over the first 90 days (12 weeks). Therefore, the data collection time points for this study are 1) before starting dialysis, 2) 6 weeks after starting dialysis, and 3) 12 weeks after starting dialysis.

Site Codes

Manchester (MFT) Site Code: 1
Salford (SRFT) Side Code: 2
Sheffield (STH) Site Code: 3
York (YTH) Site Code: 4
~~Leeds (LTH) Site Code: 5~~
Bradford (BTH) Site Code: 6
Dorset (DHC) Site Code: 7
Queen Elizabeth Kings Lynn (QEHKL) Site Code: 8
Lancashire Teaching Hospitals (LTHTR): 9
University Hospitals Coventry and Warwickshire (UHCW): 10
Oxford University Hospitals (OUH): 11

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Landline: 01433630464
Office: 0161 275 8300 (last resort!)

Recruitment

This study has a recruitment period of 5 months. Recruitment for all sites will end at the end of April 2018.

Identifying Potential participants

Potential participants will ideally be identified by members of their direct clinical team as they may have a clearer idea of who is nearing the start of dialysis. The inclusion and exclusion criteria for the study are listed below:

Inclusion criteria

Patients will:

- Be in the care of a nephrologist for chronic kidney disease
- Clinical evidence indicates that the patient will start dialysis in the next 2 months *
- Planning to receive a form of out-patient dialysis for the management of chronic kidney disease (including haemodialysis – maintenance at the RDU or satellite unit, those training for home haemodialysis – and peritoneal dialysis)
- Be incident patients or patients who have a transplant which is failing and who now require dialysis
- Have someone that they consider to be a “partner”
- Be 18 years or older

Partners will:

- Be the spouse, partner, boyfriend or girlfriend of a patient who meets the above criteria
- Be 18 years or older

Exclusion criteria

- Unable to read or comprehend English
- Patients with acute kidney injuries and their partners
- Patients who are receiving long-term inpatient dialysis for other health conditions and their partners

* Participants taking part in the study (i.e., completing questionnaires at T1) should have symptoms or clinical indicators that suggest they will need to start dialysis soon. They do not have to have started dialysis before the end of the recruitment period (April 2018), but should ideally start no more than 6 weeks from when they are recruited and no less than 2 days before they start (to allow sufficient time for them to read the information about the study and to complete the first questionnaire, which must be completed 24 hours before they start). Participants must complete the questionnaires at T1 at least 24 hours before starting dialysis.

Clinical indictors that may help you identify potential participants:

- Egfr <10
- Egfr of <15 and significant symptom burden

Record Keeping

Complete records of the number of potential participants identified, screened, refusals, and recruited will need to be kept. Because this study is only eligible to those who comprehend English, we will monitor those who are not eligible due to the language restriction so that we can improve our accessibility to these groups in future research.

Key variables that need to be recorded while identifying potential participants are:

- Total number of patients who start dialysis during the 5 month recruitment time frame
- Number of patients who were not invited to participant due to the language restriction along with:
    - The language they speak
    - Ethnic group (as recorded in the patient's notes)
- Number of potential participants who were identified but who were ineligible because they did not have a partner
- Number of potential participants who were approached to participate and who declined and the reason why if offered:
    - Not interested
    - Not feeling well enough
    - Too busy
    - 1 member of the couple not interested in taking part
    - Other: [Please report it]

Contacting participants

The REC committee that reviewed this study requested that the first in-person approach to patients be made by a member of their clinical care team (i.e., someone that the patient has met or seen before rather some they do not know, like the CI or a clinical research nurse). The clinical care member who approaches the patient about the study should tell the patient briefly about the study (a study about QOL using questionnaires, couples only) and ask if he/she is interested in speaking to the local researcher about it. If so, the clinical care member needs to have the patient sign the 'Consent to Contact Form'. If the patient prefers to speak to the researcher in-person, then they may pass the form onto the researcher and direct the patient to the researcher. If the patient prefers to be contacted by telephone or email, the clinical care member will need to collect the contact details from the patient and then pass these onto the researcher, with the patient's express permission.

I believe that we will have the greatest success in recruiting and maintaining participants in this study by using face-to-face approaches with patients and their partners. Although there is no direct benefit for participants to take part in this study, their participation will provide them with opportunities to speak to members of their care team and researchers during their transition onto dialysis.

If in-person approaches are not effective at the site, Letters of Invitation and the Participant Information Sheet may be mailed to the potential participants. Patients and partners may then make direct contact with the team if they are interested in taking part. This is a less satisfactory way of recruiting participants as we cannot ensure they receive the letters, read them or understand the aims. In this case, a consent to contact form does not need to be completed by the patient/partner as their direct contact is proof of their consent.

Letters that are mailed should be followed up with a phone call or in-person 1 week after the letter is posted. Ideally, the phone call will be made by a member of the clinical care team who is familiar with the patient. If this is not possible, then the local site investigator may contact the patient.

Additional records to be kept:

Participants who are approached in-person, respond directly to mail out, require a follow-up telephone call (who it is made by).

Screening

The two most crucial points in screening potential participants is to establish that they do have a ‘partner’ (someone they consider to be significant in their life and who they have romantic/emotional relationship with) and that this person would be happy to take part.

Participants should be **starting** on dialysis (i.e., not be changing from one modality to another – for example, on PD and now training for HHD). They can however have a failing transplant and be starting on dialysis (given they have not had dialysis in the last 6 months). If they have had in-patient dialysis as part of the pre-operation procedure, they are eligible provided that dialysis occurred less than 6 times during their hospital stay. Please don’t hesitate to contact Currie if you have a case like this as we can simply talk through it.

Both patients and their partners need to comprehend English. At the screening phase, it would also be good to establish whether they would need assistance completing the questionnaire. Assistance that can be provided:

- Large font questionnaire vs regular questionnaire, which is 11 point font
- Administered by the researcher – read aloud due to vision impairments/literacy or arthritis in hands. If you need to read it out, it is helpful to use the Questionnaire Response Scale cards (email Currie if you need them).

Participants may have as much time as they need to decide whether or not they would like to take part (This is a change from the original Protocol – they no longer must have 24 hours to decide whether or not to take part). If potential participants are interested in the study, please have them complete the Consent to Contact Form so that the researcher may have the best details to contact them on. Then establish when you will contact them again about taking consent and completing the first set of questionnaires.

Obtaining Consent

Written consent will be obtained for each individual in the couple (patient and partner) at baseline (T1). All couples should receive the Letter of Invitation and Participant Information Sheet and have a clear idea of the study before providing their consent. The researcher in contact with the participants should ensure that they have had enough time to read the PIS, have a general understanding of the study and its requirements (taking part 3 times, similar questions which are designed specifically for couples at this time period), understand their rights in taking part in research and know who to contact if they have any problems or complaints.

Each participant should get a copy of the consent form to keep for his/her records. You may give them a blank copy or provide them a with photocopy of their signed consent form. Please put a note in the patients' records that they are taking part in the study.

This consent forms are vital to the study. Complete the bottom portion of the form and store it immediately in the secure site file. Because it contains personal information, please ensure it is placed in separate secure location from other study documents (i.e., in a different drawer of the filing cabinet).

Assigning participant identification numbers

The participant ID numbers incorporate 4 variables (site location, couple number, identity in couple, time point in the study) and should follow this format:

Site ID - Couple number – Patient/Carer - Data collection time point
(1-8) (001-100) P or C (1-3)

Example: For MFT (Side Id #1), their first patient participant will be id'd as
1001P1
This patient's partner will be id'd as
1001c1

Id numbers will need to be put on the consent forms (one copy in the site file, one for the participant, and a note in the patient's medical record), the questionnaire pack and the case report form. It is critical that participant ID numbers are on all questionnaire packs so that we can match up responses from each participant

Data Collection

The questionnaires should take on average 20 minutes to complete per participant. Both patients and their partners need to complete the questionnaires during a similar time frame. *This means they need to complete the questionnaire at the same clinical appointment (preferred), or within 3 days of each other.*

Participants must complete the questionnaires independently of each other!
Many of the questions ask about their partner and their relationship. It is natural for them to want to ask the other what they think or they should put; however, it's critical for the validity of the study that that they do not discuss what response to mark!

Equally, it is important that you do not ever provide your own views, even if the participant requests it. If this occurs tell the participant that we want to know what they think.

In total, there are 6 questionnaire packs for this study. There are 3 versions for patients, 1 for each data collection time point – T1, T2, T3. There are 3 similar versions for partners for each time point. It is essential that they are given the correct pack for their group (patient or partner) and time point (T1 – before dialysis; T2 – 6 weeks after starting dialysis; T3 – 12 weeks after starting dialysis). This information is listed on the front of the questionnaire pack (as indicated below):

Quality of life
Starting dialysis

QUESTIONNAIRE
PACK

PARTNER VERSION

Instructions

This questionnaire asks how you feel about **your** quality of life, health and other areas of your life.
Your needs matter even as your partner prepares for dialysis.
By completing this questionnaire, you will help us understand your experience
and how we can better support you both.

Please answer all the questions.
If you are unsure about which response to give to a question, please choose the **ONE** that appears
most appropriate. This can often be your first response.
You should **circle** the number that best fits your response.

Please keep in mind your standards, hopes, pleasures and concerns.
We ask that you think about your life **in the last two weeks**.

Please read each question, assess your feelings,
and **circle** the number on the scale for each question that gives the best answer for you.

Research Team Contact Details:
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MANCHESTER
1824
The University of Manchester

IRAS ID: 226463

Questionnaires Partners T1 V2
Date: 06/10/17

Questionnaires

The questionnaires in this study:

- Quality of life – WHOQOL-BREF (World Health Organization's Quality of Life – 26 questions)
- Psychosocial Factors – Study Specific (questions derived from qualitative and cognitive interviews conducted with couples in the early stages of dialysis; questions ask about expectations, attitude towards dialysis and relationship factors within the couple – 27-34 questions)
- Symptoms – POS-S-Renal or Generic (Palliative Outcome Scale – Symptoms for renal or generic patients – 15 or 19 questions)
- Emotional Distress - HADS (Hospital Anxiety and Depression Score, 14 questions)
- Demographic and personal information

Administering the Questionnaire

- Your approach – before approaching the participant about the study, take a second to stop and take a breath. We want the participant to feel valued in this study.

- Location – the questionnaires do not have to be completed in a dedicated, private room but participants should be away from their partner so that they do not confer over questions. Ideally participant will be in a place that they feel they have enough privacy and quiet to read the questions, think

about them and mark the appropriate response. It is advantageous if during the first questionnaire the researcher is nearby in case the participant has a question. At later time points (T2 and T3), the questions are virtually the same so there should be a reduced need for clarification.
Patients may complete the questionnaires while they are on dialysis, provided that they feel well enough to do so. Generally, the questionnaires should be completed when they feel the best on dialysis.

- Go through the participants' rights and tell them about the study
    - Thank you so much for taking part in this study. This study is about your quality of life and your partner's during a very important time for you both.
    - Participation in this study in voluntary and you may ask to stop taking part or withdraw at any time, and you do not have to give a reason, and your treatment will not be affected.
    - This questionnaire is about you – your quality of life, health and how you feel about things. It is important to us to know what you think.
    - Please be assured that your responses will be confidential – we will not share them with your care team or your partner.
    - It is very important that the answers that you mark are your own and that you circle the answer that best describes your response to the question. Often this is your first impression. [We don't want them to linger unnecessarily long on the questions as this could be tiresome for them and you]
    - If you have a question about a question, please don't hesitate to ask me to clarify what it means. I will try to help but I don't want to sway your response. For this reason I may not answer your question immediately but should be able to do so after you have finished. There may be occasions where you cannot answer e.g. because it will affect what they say at follow-up or because you do not know (and may need to find out and get back to them).
    - Some of the questions are about your partner and what she/he feels or thinks. While we understand you may not know this or may want to check with them for the "right" answer, please put what YOU think is the best answer for them. Don't worry, he/she will do the same for you.
    - Written consent will only be taken at T1 but verbal consent should be taken at each subsequent data collection time point
    - Before you start, have you got any questions?

- Give clear instructions to them about what to do when they complete the questionnaire – are you coming to collect it?

- Provide the questionnaire pack and pen or pencil. Flip through the pack so that they can see all the pages and the space on the back if they want to provide more comments.
    - Okay, well if you are happy with all of this, would you like to begin the questions?
    - It is best if you then move away so that they feel comfortable marking their responses but cannot ask you about every question. It is good if you are close enough if a question should arise.

- Collect the questionnaire and see if they have any questions.

- Check the questionnaire for any missing information – check with the participant then if they accidentally missed a question, left a question blank on purpose, or had a question.

- Thank the participant for taking part. Check whether they are happy to take part again in a few weeks time (about 6 weeks). If so, confirm how they would like to be contacted by you or the researcher. Please put this as a note on the Case Report Form and inform Currie if she is assisting with your follow-ups.

- Apply participant Id to all documents

Note: After the T1 questionnaire, it is likely that patients on MHD will come to dialysis sessions on their own. If you give the partner's questionnaire pack to the patient to take to them:

- Remind the patient that the partner needs to complete it on his/her own
- Put it in an envelope which the partner can use to return it to you (does not have to be posted – the patient can return it the next dialysis session), but partners need to be able to seal the envelope.
- Ring the following day as a courtesy to the partner to let them know you have sent the questionnaire to them.

How to respond to questions about questions:

- General non-directive response:
    - It may help to think about the question thinking about the last 2 weeks.
    - There are no right or wrong answers – just mark the answer that most closely describes how you feel.
    - Is there a response that is similar to your initial reaction to that question?
    - What does the question mean to you?
- Possible questions you might get about the questionnaires:
    - Psychosocial Factors Questionnaire

    - Emotional health – participants asked us to divide health into 2 categories (emotional and physical) so this how they feel and their mental well-being.
    - Expectations – participants may ask ‘Should I have expectations???’ or ‘I don’t have any’. You can say that not all people have expectations about dialysis and it is fine not to. They do not have to answer the question if it is not applicable to them.
    - Free text – expectations – participants may leave this blank if they do not have any thoughts on it but it is a great way of informing us of what they are thinking/thought.
    - Control of dialysis – this is not about deciding which modality but about whether the patient likes control and whether or not they think their dialysis provides them an adequate degree of control.
    - Role in the relationship – your responsibilities, duties and identity in the relationship
    - 4 questions on communicating about feelings/issues – some see these as repetitive, but there are slight nuances between the questions (which have been italicized or underlined).
    - Lonely – this refers to personal loneliness. Some people may feel lonely and many others do not.
    - Isolated – refers more to feeling left out either as a patient group, not understood by colleagues or sequestered because of illness.
    - Satisfaction with the relationship – sometimes participants want to reflect on a time before they had CKD and their relationship then, remind them to think about their relationship in the last 2 weeks.
- WHOQOL-BREF
    - Partners tend to ask – *Is this about my quality of life?* Assure them that we are interested in their experience and quality of life. Ask them to think about themselves and how they’ve felt over the last 2 weeks.
    - Pain question – many patients ask if this is how they feel if they were not on their pain medication. Ask them to think about their daily life over the past 2 weeks. Then ask them to mark how much pain prevented them doing what they need to do, regardless whether they were on pain medication or not.
    - Safe in daily life – this question is asking about their safety in their home and environment
    - Health of physical environment – this is asking about pollution, smog, fresh air

        - Leisure activities – this includes relaxation and travel
        - Perform daily living activities – this is referring to taking care of yourself – bathing, cooking, etc
        - Personal relationships – this refers to the person/people they have the closest relationship with
        - Conditions of your living place – this refers to their satisfaction with their "home"
        - Transport – this refers to transport in general – ability to get where they want to by some form of transport. It is not about their satisfaction with their Audi X5i or Vauxhall Astra
    - HADS/POS-Symptoms/Demographics/Personal Information
        - Please let me know of any questions or issues that arise

Supporting participants

This is a busy and disconcerting time for many of the participants. Although the questions are not intended to cause distress, the topics that they relate to may inadvertently raise questions or concerns they had not previously considered. It is important that we offer them information about where to get support or more information and ensure that taking part is not distressing to them.

Please see the Distress Policy in the next section in this manual for support options available to participants.

Please notify Currie if you feel any of your participants are distressed or require additional support.

Completing the Paperwork

There is a box on the back of the questionnaire that needs to be completed by the local site investigator. Please ensure this is completed so that the research team can monitor these variables across the study.

In addition to the questionnaire, we are also collecting some clinical data on the patients who are participating in the study. Please complete a Case Report Form for each patient within 3 days of their completion of the questionnaire.

The Case Report Form also has an area to report whether the partner completed the questionnaire. If you were not able to collect the partner's questionnaire data and do not think you will be able to contact them about it asap, then contact Currie who will provide assistance, if possible.

Please note that although the data collected in this study is anonymous the raw files contain information that could make the data potentially identifiable. Please ensure that all data files are kept locked in the agreed secure location and are not accessible to people outside of the study.

Transferring the data

The questionnaire data will need to be sent to Currie on a monthly basis. The easiest method of doing this is scanning and sending anonymous versions of the questionnaires. An anonymous version means that any personal or potentially identifiable details have been removed (e.g., T1 – last page not sent but participant ids clearly marked on the questionnaire). If posting anonymous versions of questionnaire data is easier for you, please ensure you either send a copy of the data or keep a copy in your records (this is to prevent data being lost in the mail). At the end of the study, Currie will collect all the data from you(CRFs, Consent Forms, Questionnaires). In the event that Currie requires participants’ personal contact details, these must be inputted into an electronic file and password protected, and then emailed to her.

Distress Policy

If a participant becomes distressed or anxious while completing the questionnaires, the researcher or site investigator will:

1. Ask the participant if they wish to:
   a. have a short break
   b. terminate the session
2. Reiterate that the participant does not have to answer any question(s) they do not want to answer.
3. Have tissues available, and offer if appropriate.
4. Offer the participant the list of resources of places to go for further help.
5. Confirm that the participant is aware of the researcher's contact details on the information sheet.
6. If necessary, the researcher will ask contact one of her supervisors or senior member of the research team immediately (by mobile phone, at any time) for further support

Resources list for Researchers:

Research Team

- Chief Investigator
  - Currie Moore
  - Tel: 07483218960 or Landline 01433630464 or Work: 01612758300
- Principal Investigator
  - Prof. Alison Wearden
  - Tel: 0161 275 2684 or Mobile: 07786517516

Resources list for Patients:

Kidney Disease Specific

National

- British Kidney Patient Association (http://www.britishkidney-pa.co.uk/)
- National Kidney Federation (http://www.kidney.org.uk/)
- Kidney Dialysis Information Centre (http://www.kidneydialysis.org.uk/)

Resources list for Partners:

National

- Carers UK (http://www.carersuk.org/)
- Carers Trust (http://www.carers.org/)
- AgeUK (0800 169 6565; http://www.ageuk.org.uk/home-and-care/advice-for-carers/are-you-a-carer/)

Local

- Your GP

Resources list for both:

Physical

- Your GP practice
- NHS helpline services (phone number: 111)

- NHS website (http://www.nhs.uk/Pages/HomePage.aspx)
- Walk-in centres and A&E (http://www.nhs.uk/NHSEngland/AboutNHSservices/Emergencyandurgentcareservices/pages/Walk-incentresSummary.aspx)
- Local Council

Psychological

- Your GP practice
- NHS helpline services (phone number: 111)
- NHS website (http://www.nhs.uk/Pages/HomePage.aspx)
- Bereavement services (https://www.gov.uk/find-bereavement-services-from-council)
- Drug and alcohol services (0161 882 1000; http://www.mhsc.nhs.uk/services/drug-and-alcohol-services.aspx)
- MIND (0300 123 3393; http://www.mind.org.uk/)
- Samaritans (08457 90 90 90; http://www.samaritans.org/)

Social

- AgeUK (0800 169 6565; http://www.ageuk.org.uk/)
- Relate (0300 100 1234; http://www.relate.org.uk/)
- Bereavement services (https://www.gov.uk/find-bereavement-services-from-council)
- LGBT Foundation (0345 330 3030; https://lgbt.foundation/)
- Local Council
- Community centres

Environmental

- AgeUK (0800 169 6565; http://www.ageuk.org.uk/)
- Citizen's Advice Bureau (http://www.citizensadvice.org.uk/)
- Get Connected (for young people under 25, 0808 808 4994; http://www.getconnected.org.uk)
- Local Council

Resources by sites:

MFT

Renal Care Teams

- Consultant Nephrologist
    - Dr. Sandip Mitra
    - Mobile: 07900242651
- Pre-Dialysis Nursing Team
    - Ms. Susie Travers
    - Tel: 0161 276 4440

- Community Nursing Team
    - Tel: 0161 276 4488
- Haemodialysis Services
    - Tel: 0161 276 6164
- Peritoneal Dialysis Services
    - Tel: 0161 276 4212
- Haemodialysis Training Unit
    - Tel: 0161 291 6273

Renal counselling services and social workers are available. Patients need to be referred to these.

Local

- Northwest Kidney Patient Association (http://www.nwrkpa.co.uk/)
- Kidneys for Life (http://kidneysforlife.org/)
- GMKIN (http://gmkin.org.uk/)
- Manchester Carers (http://www.manchestercarers.org.uk/)

Salford Royal

Renal Care Teams

- Consultant Nephrologist
    - Dr. Rosie Donne
- Pre-Dialysis Nursing Team
    - x
- Community Nursing Team
    - x
- Haemodialysis Services
    - x
- Peritoneal Dialysis Services
    - x
- Haemodialysis Training Unit
    - X

Sheffield Teaching Hospital

Renal Care Teams

- Consultant Nephrologist
    - Dr. Arif Khwaja
- Pre-Dialysis Nursing Team
    - x
- Community Nursing Team
    - x
- Haemodialysis Services
    - x

- Peritoneal Dialysis Services
    - x
- Haemodialysis Training Unit
    - x

York Teaching Hospital

Renal Care Teams

- Consultant Nephrologist
    - Dr. Colin Jones

Contact the Renal Specialist Nurses who can refer to counselling or other services.

Leeds Teaching Hospital

Renal Care Teams

- Consultant Nephrologist
    - Dr. Richard Hoefield

Bradford Teaching Hospital

Renal Care Teams

- Consultant Nephrologist

Dorset County Hospital

Renal Care Teams

- Consultant Nephrologist:

Queen Elizabeth Kings Lynn

Renal Care Teams

- Consultant Nephrologist:
    - Dr. Smita Gunda

Appendix X: Results of multilevel models for changes in QOL

Three level random intercept model of WHOQOL general quality of life between patients and partners

	Coefficients	*95% CI*	*p value*
Fixed effects			
Patients' general QOL			
Baseline (constant)	2.8	2.62 - 2.99	
Patients change to 6 weeks	0.42	0.19 - 0.65	*p* <0.001
Patients change to 12 weeks	0.47	0.24 - 0.71	*p* <0.001
Partners' general QOL relative to patients			
Baseline	0.72	0.51 - 0.93	*p* <0.001
Partners change to 6 weeks	-0.66	-0.98 - -0.34	*p* < 0.001
Partners change to 12 weeks	-0.56	-0.89 - -0.23	*p* < 0.001
Random effects	*Estimate*	*SE*	*95% CI*
Between couple	0.26	0.07	0.15 - 0.44
Between participant	0.13	0.05	0.06 – 0.28

Note. CI=Confidence interval, QOL=quality of life, SE=Standard error, WHOQOL=World Health Organization QOL-BREF version.

Results of the linear combination of parameters analysis in partners' WHOQOL general QOL

	Coefficients	*95% CI*	*p value*
Partners change to 6 weeks	-0.24	-0.47 - -0.01	*p* = 0.04
Partners change to 12 weeks	-0.09	-0.33 – 0.15	*p* = 0.474

Note. CI=Confidence interval, QOL=quality of life, WHOQOL=World Health Organization QOL-BREF version.

Three level random intercept model of WHOQOL physical domain between patients and partners

	Coefficients	*95% CI*	*p value*
Fixed effects			
Patients’ physical domain			
Baseline (constant)	46.02	41.28 – 50.76	
Patients change to 6 weeks	3.44	-0.97 - 7.85	$p = 0.126$
Patients change to 12 weeks	6.56	2.10 - 11.03	$p = 0.004$
Partners’ physical domain relative to patients			
Baseline	21.11	15.74 – 26.47	$p < 0.001$
Partners change to 6 weeks	-5.02	-11.13 – 1.09	$p = 0.107$
Partners change to 12 weeks	-7.58	-13.83 - -1.33	p 0.017
Random effects	*Estimate*	*SE*	*95% CI*
Between couple	165.85	50.73	91.06 – 302.06
Between participant	183.90	40.57	119.34 – 283.37

Note. CI=Confidence interval, SE=Standard error, WHOQOL=World Health Organization QOL-BREF version.

Three level random intercept model of WHOQOL psychological domain between patients and partners

	Coefficients	*95% CI*	*p value*
Fixed effects			
Patients' psychological domain			
Baseline (constant)	61.51	57.30 - 65.72	
Patients change to 6 weeks	-0.66	-5.20 – 3.87	*p* = 0.775
Patients change to 12 weeks	-1.14	-5.83 – 3.55	*p* = 0.633
Partners' psychological domain relative to patients			
Baseline	4.23	-0.70 – 9.17	*p* = 0.093
Partners change to 6 weeks	-1.76	-8.08 – 4.56	*p* = 0.585
Partners change to 12 weeks	-2.64	-9.18 – 3.90	*p* = 0.428
Random effects	*Estimate*	*SE*	*95% CI*
Between couple	116.17	37.41	61.79 – 218.41
Between participant	122.97	31.52	74.40 – 203.25

Note. CI=Confidence interval, SE=Standard error, WHOQOL=World Health Organization QOL-BREF version.

Three level random intercept model of WHOQOL social domain between patients and partners

	Coefficients	*95% CI*	*p value*
Fixed effects			
Patients' social domain			
Baseline (constant)	62.92	58.70 – 67.13	
Patients change to 6 weeks	0.93	-3.70 – 5.57	*p* = 0.693
Patients change to 12 weeks	1.79	-2.96 – 6.54	*p* = 0.459
Partners' social domain relative to patients			
Baseline	1.82	-2.64 – 6.29	*p* = 0.423
Partners change to 6 weeks	-1.74	-8.14- 4.67	*p* = 0.595
Partners change to 12 weeks	-3.29	-9.88 – 3.31	*p* = 0.329
Random effects	*Estimate*	*SE*	*95% CI*
Between couple	161.43	39.98	99.35 – 262.30
Between participant	71.66	23.90	37.27 – 137.78

Note. CI=Confidence interval, SE=Standard error, WHOQOL=World Health Organization QOL-BREF version.

Three level random intercept model of WHOQOL environmental domain between patients and partners

	Coefficients	*95% CI*	*p value*
Fixed effects			
Patients’ environment domain			
Baseline (constant)	67.15	63.55 – 70.75	
Patients change to 6 weeks	-0.56	-3.99 – 2.86	*p* = 0.747
Patients change to 12 weeks	-0.97	-4.48 – 2.53	*p* = 0.587
Partners’ environment domain relative to patients			
Baseline	0.47	-3.17 – 4.10	*p* = 0.802
Partners change to 6 weeks	0.68	-4.05 – 5.41	*p* = 0.778
Partners change to 12 weeks	-1.65	-6.51 – 3.22	*p* = 0.507
Random effects	*Estimate*	*SE*	*95% CI*
Between couple	131.27	30.32	83.48 – 206.42
Between participant	64.90	17.20	38.60 – 109.10

Note. CI=Confidence interval, SE=Standard error, WHOQOL=World Health Organization QOL-BREF version.

Two level random intercept model of WHOQOL general quality of life in patients by comorbidity risk

	Coefficients	*95% CI*	*p value*
Fixed effects			
Low risk patients' general QOL			
Baseline (constant)	3.0	2.67 - 3.33	
Patients change to 6 weeks	0.38	-0.08 – 0.83	*p* = 0.104
Patients change to 12 weeks	0.58	0.11 – 1.04	*p* = 0.016
Medium risk compared to low risk patients			
Baseline	0.06	-0.36 – 0.48	*p* = 0.770
MRP change to 6 weeks	-0.13	-0.69 – 0.43	*p* = 0.656
MRP change to 12 weeks	-0.41	-0.98 – 0.17	*p* = 0.166
High risk compared to low risk patients			
Baseline	-1.0	-1.61 - -0.39	*p* = 0.001
HRP change to 6 weeks	0.89	0.01 – 1.78	*p* = 0.048
HRP change to 12 weeks	0.35	-0.55 – 1.24	*p* = 0.448
Random effects	*Estimate*	*SE*	*95% CI*
Between participant	0.30	0.09	0.17 – 0.53

Note. CI=Confidence interval, HRP=High risk patients, MRP=Medium risk patients, SE=Standard error, QOL=Quality of life, WHOQOL=World Health Organization QOL-BREF version. Comorbidity risk levels were determined following the guidelines set out by Davies et al. (Davies et al., 2002).

Two level random intercept model of WHOQOL general quality of life in patients by gender

	Coefficients	*95% CI*	*p value*
Fixed effects			
Male patients' general QOL			
Baseline (constant)	2.82	2.58 – 3.06	
Patients change to 6 weeks	0.42	0.1 – 0.74	*p* = 0.011
Patients change to 12 weeks	0.29	-0.03 – 0.60	*p* = 0.077
Female patients compared to male patients			
Baseline	-0.05	-0.44 – 0.34	*p* = 0.818
FP change to 6 weeks	0.03	-0.48 – 0.54	*p* = 0.910
FP change to 12 weeks	0.60	0.05 – 1.13	*p* = 0.033
Random effects	*Estimate*	*SE*	*95% CI*
Between participant	0.36	0.1	0.21 – 0.62

Note. CI=Confidence interval, FP=Female patients, QOL=Quality of life, SE=Standard error, WHOQOL=World Health Organization QOL-BREF version.