DEVELOPMENT OF A UNIQUE PERSON-CENTRED SELF-MANAGEMENT BEHAVIOUR SCALE FOR PEOPLE ON HAEMODIALYSIS

Helen Louise Munro Wild

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Index

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AUTHOR’S DECLARATION

This thesis describes and presents the research work I have conducted whilst at the University of Hertfordshire. The data were collected between 2018 and 2022. During this time, I was employed as well as being registered for a PhD. I declare that the work was undertaken by me, including all the patient interviews, focus groups and analysis.

Support in the analysis of the patient interviews and entry and checking of the main survey data, was provided by Megan Smith and Beth Rider. Beth was also involved in supporting the focus groups, along with Dominique Grohmann.

I have written this thesis myself. It has not previously been submitted.

THESIS

It became clear when delivering this research that the perception that not all individuals wish to self-manage should be refuted. Through the introduction of a broader concept of self-management it is recognised that there is a great diversity in the approaches, strategies, and ways one might manage the impact of a life accompanied by illness.

The aim of this thesis is to develop a more holistic measure of self-management to better assess current engagement and support needs using a mixed methods approach and involving a community of experts and people with lived experience.

Helen Munro Wild (2023)

ABSTRACT

Patient engagement in health and managing treatment and life workload is especially important for haemodialysis patients, who experience increased depression and anxiety, reduced QoL associated with treatment, co-morbidities and frailty that is linked with ageing but also illness. Engagement optimises care, quality of life and wellbeing, as well as having potential benefit for patient-staff relationships and communication.

Engagement in self-management is narrowly defined and poorly assessed in the clinical care of people with kidney disease. The aim of this thesis is to understand how self-management is conceptualised and measured in the research literature and to what extent it should be reconceptualised. Then, to broaden and improve on existing measures by developing a more holistic measure of self-management to better assess current engagement and support needs. A mixed methods approach involving a community of experts and people with lived experience will help ensure content validity. The long-term aim is to direct support where it is needed to facilitate engagement in self-management to the extent to which the individual wishes, enabling them to live well.

People with chronic kidney disease who progress to kidney failure, must undertake kidney replacement therapy (KRT) as a matter of survival. Whilst kidney transplantation is the best form of KRT, and linked with better outcomes, often people transition to a means of dialysis (peritoneal or haemodialysis). With this comes a regime of regular treatment and for the in-centre haemodialysis patient, approximately 624 hours a year on dialysis. This requires a person to adapt and manage life alongside illness.

Self-management is a contested concept, and the kidney community have been slow to define and operationalise it in a way meaningful for people with kidney disease. Given the magnitude and frequency of clinical intervention, self-management is often thought about in terms of needling, salt and fluid reduction and home haemodialysis (as the optimum option), with a focus on clinical outcomes and adherence. However, managing a chronic illness and addressing the emotional consequences of the long-term impact, requires an individual to continue living a meaningful life (Whittemore & Dixon, 2008) plan and prioritise daily tasks,

adapt and develop coping strategies (Subramanian et al., 2017) and maintain social support networks whilst continuing to function in a variety of social roles and situations (Liu et al., 2018; Song et al., 2019). This broader concept of self-management is referred to as a tripartite model incorporating the clinical (biological), social and emotional and has its origins in the work by Corbin & Strauss (1985).

In chapters 2 and 3 the gaps in the conceptualisation of self-management in chronic disease and kidney care specifically, are established. Despite being a distinct term, self-management is related and often conflated with other concepts such as self-efficacy, self-care (Richard & Shea, 2011), shared care (Moser et al., 2008), adherence (Evangelista & Shinnick, 2008) or patient activation, a component of SM (Hibbard et al., 2007). Existing measures of self-management developed for people with CKD are critiqued and fall short of the tripartite definition offered in the literature. The chapters that follow describe the development and validation of a novel measure of self-management using best practice principals for scale development (as described in chapter 4). Chapter 5 further explores the patient experience of daily managing, beyond the dialysis chair using narrative from 27 people receiving haemodialysis. In conjunction with the literature review, this empirical data, provided the basis from which themes and candidate items that were developed. In this way, unique to other self-management scales, a more person-centred, holistic approach to defining the concept and developing a measurement, was taken. Social support, emotional managing, communication with healthcare providers, maintaining a meaningful life and the impact of co-morbidity were all themes that guided item development which was iterative and began with the consensus workshop.

Chapter 6 provides an overview of item development before turning to the scale development process in more depth. Here reliability and validity of the scale is explored, enabled through the collection of data from a large survey of haemodialysis patients. Documented methodological rigour and good model statistics as well as strong correlation with two other similar constructs, depression, and self-efficacy, together suggests the **P**atient **R**eported **I**nstrument of **E**ngagement in **S**elf-Management (PRIESM CKD-HD), is a good measure of the concept of self-management. Exploratory factor analysis (EFA) indicated a best-fit three-dimensional model, managing day-to-day, communication and clinical care.

In chapter 7, the use of an overall self-management score and domain scores (daily managing, communication, and clinical care) are explored. Variation in scores is evident between patient sub-groups and this provides further evidence of the validity and reliability of the scale. Statistically significant differences according to key characteristics such as age, income, education and ESKD alongside other long-term conditions were found.

Patient reported outcome measures are widely developed but often not implemented in clinical practice. Understanding how the scale may work in the real world is an important step in scale development, often not undertaken. Chapter 8 describes the exploratory pre-implementation work that was conducted with key stakeholders including patients and members of the multidisciplinary team beyond doctors and nurses. Assessing psychosocial support needs, alongside more clinical needs was broadly supported but barriers as well as facilitators to implementation of the PRIESM CKD-HD (or indeed any patient reported outcome measure), were identified.

Broadening the definition of self-management to behaviours relating to the emotional, physical, psychological, and social burdens of managing may be more important to those on haemodialysis. A move away from the narrow definition of medical management may provide an insight into how gaps in support can be identified and addressed to improve person-valued outcomes such as quality of life and well-being, as well adherence, and associated clinical outcomes. The hope is that the scale can be used to guide conversations and target support. PRIESM CKD-HD is the first measure to have been developed with kidney professionals, those with lived experience, and methodologists using diverse methods to maximise validity and reliability which can help redress the social and emotional balance necessary for engagement in self-management. Chapter 9 gives an overview of how the development of this scale has confronted the complexity and uncertainties around the operationalisation of the term self-management and what the next steps may look like.

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

ACE: Angiotensin converting enzyme (Inhibitors)
ACR: Albumin-to-Creatinine Ratio
AKI: Acute Kidney Injury
ARB: Angiotensin receptor blocker
AVF: Arteriovenous Fistula
AVG: Arteriovenous graft
BHDS: Behaviours in Haemodialysis Scale
CI: Confidence Interval
CHD: Coronary Heart Disease
CDSMP: Chronic Disease Self-Management Prog
CISM: Chronic Illness Self-Management (Scale)
CKD: Chronic Kidney Disease
CKDSCS: Chronic Kidney Disease Self-Care Scale
CKD-SM: Chronic kidney disease self-management (instrument)
CVD: Cardiovascular Disease
CKM: Conservative kidney management
DF (df): Degrees of Freedom
ESKD: End-Stage Kidney Disease
ESRF: End-Stage Renal Failure
EFA: Exploratory Factor Analysis
GIRFT: Getting It Right First Time (programme)
GFR: Glomerular Filtration Rate
HD: Haemodialysis
HRQoL: Health related quality of life
CKD-SMI: Chronic Kidney Disease Self-Management Instrument
HHD: Home Haemodialysis
IA: Inflammatory Arthritis
ICC: Intraclass Correlation
IDWG: Inter-Dialytic Weight Gain
ICHD: In-centre haemodialysis
I-CVI: Item Content Validity Index (rating)
KDIGO: Kidney Disease Improving Global Outcomes
KDBI: Kidney Disease Behaviour Inventory
KRT: Kidney Replacement Therapy
MCAR: Missing Completely At Random
MDT: Multidisciplinary team
MLTC: Multiple Long-Term Conditions
NICE: National Institute for Health and Care Excellence
NHS: National Health Service
ONS: Office for National Statistics
PAM: Patient Activation Measure
PETS: Patient Experience with Treatment & Self-Management
PIH®: Partners In Health (instrument)
PD: Peritoneal Dialysis
PHQ-9: Patient Health Questionnaire (9-item scale)
PKD: Primary Kidney Disease
PKDSMS: Perceived Kidney/Dialysis Self-Management Scale
PRIESM CKD-HD: Patient Reported Instrument of Engagement in Self-Management for kidney patients receiving haemodialysis treatment
QoL: Quality of Life
REC: Research Ethics Committee
RKF: Residual Kidney Function
RMSEA: Root Mean Square Error of Approximation
SEMCD: Self-Efficacy to Manage Chronic Disease Scale
SMAS: Self-Management Ability Scale
SD: Standard Deviation
SDSCA: Summary of diabetes self-care activities
SE: Standard Error
SGLT2: Sodium-glucose transport protein 2
SUPPH: Strategies Used by People to Promote Health
TLI: Tucker Lewis Index
Tx: Kidney transplant

TABLE OF CONTENTS

LIST OF APPENDICES

CHAPTER 1 : CHRONIC KIDNEY DISEASE, PROGRESSION, AND TREATMENT

1.1 INTRODUCTION

This chapter will provide some detail about the physiology and function of the kidneys, followed by an overview of chronic kidney disease (CKD), progression to renal failure, and treatment, as well as causes and risk factors for CKD. The information provided in this thesis relates to adults only. This introduction will set the context for the empirical work that follows which will illustrate that despite the high level of treatment often required by people with end stage kidney disease (ESKD), many non-clinical factors contribute to slowing disease progression, improving patient-centred outcomes, and allowing people to maintain balance, meaning and independence, in their lives.

1.2 THE KIDNEYS

The kidneys are a complex organ, the function of which impacts on many physiological processes and systems within the body (Robson, 2014). Most people have two kidneys, but it is possible to live a healthy, active life with only one functioning kidney. They are located one on each side of the spine, at the back of the abdomen, below the rib cage and are approximately 10-15cms long. The weight varies by sex, with the left usually being slightly heavier in both males and females. For females the average size of the right kidney is 108g and 116g for the left, with an increase of about 20g in each for men (Molina & DiMaio, 2012, 2015).

The main functions of the kidneys are to remove waste products from the body, maintain electrolyte homeostasis and regulate blood pressure. They receive 20-25% cardio output, about 1.0 to 1.1 litres per minute (Kaufman et al., 2023) The two kidneys together filter 200 litres of fluid every 24 hours, returning necessary substances to the blood via a complex tubular network and removing waste that then becomes urine, which averages about 1.5 litres per day (ibid). Creatinine is a product of creatine phosphate released from muscle and protein metabolism, expelled within urine, and used to estimate kidney function.

A nephron is the functional unit of the kidney, and each nephron is a long tubule or extremely fine tube. Bowman’s capsule is a part of the nephron that forms a cup-like sack surrounding the glomerular capillary network, creating the Bowman’s space. Together these things comprise the glomerulus that represents the initial location of the renal filtration of blood, of which there are an estimated 900,000 in each adult kidney (Falkson & Bordoni, 2023).

Filtration of liquids and solutes of the blood occurs in the glomerular capillaries. The filtration process is based on size and electrical charge and the filtrate that enters the Bowman's space is without protein and cell content. These are not filtered in the glomerulus, but instead remain in the blood stream when the filtration process is working correctly.

In a study conducted by (Fenton et al., 2018), adult males under the age of 35 years had a glomerular filtration rate (GFR) of 92mL/min/1.73m^2, compared with 88.1mL/min/1.73m^2 in females. The data came from prospective living kidney donors and is comparable with other estimates of average kidney function.

1.2.1 Chronic kidney disease (CKD) to end stage kidney disease (ESKD)

CKD is defined as the presence of kidney damage or decreased kidney function that persists for 3 months or more (Levey et al., 2020). It is often progressive, clinically silent and asymptomatic in the early stages meaning many people are unaware they have it. Diagnosis of CKD can be difficult but is usually determined by the presence of retained waste products in blood and protein in the urine.

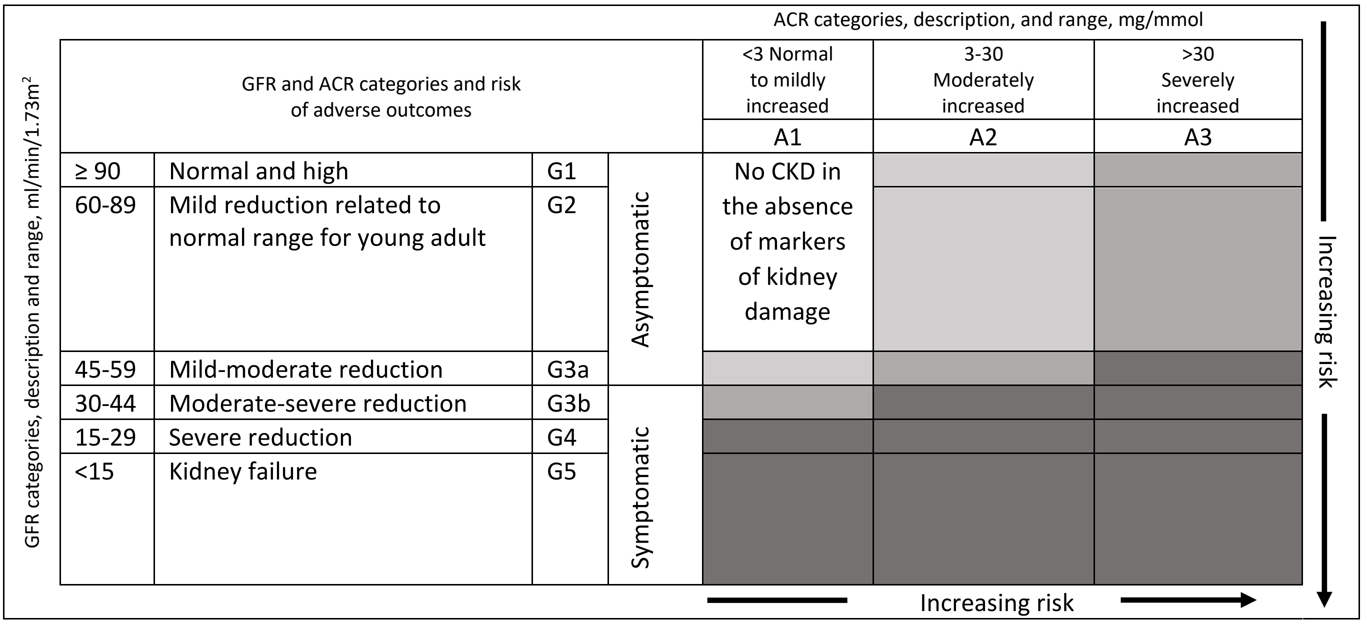
Nephrotic syndrome is defined as the presence of proteinuria (>3.5 g/24 hours). The aetiology of the syndrome cannot be determined by the presence of elevated protein in the urine alone, however it is regarded as a prominent marker of kidney damage (Eknoyan et al., 2003), although it is a relatively rare way for kidney disease to become evident (Hull & Goldsmith, 2008). Urinary albumin-to-creatinine ratio (ACR) is the preferred method to detect elevated protein loss. Data from the Health Survey for England (combined data for 2003-2016) shows prevalence of albuminuria in the general population increases with age from an average of around 9% to >20% in ≥75-year age group (Hounkpatin et al., 2020).

Another measure of kidney function is glomerular filtration rate (GFR). In clinical practice this is usually estimated from the serum creatinine level (eGFR). The precision of the estimate varies according to the measure of eGFR used, and is dependent on several characteristics including age, sex, and body size. For example, creatinine levels decrease with age and routine screening of a primary care sample suggest almost one fifth (18.2%) of people ≥60 years have some stage of CKD (Hirst et al., 2020). This broadly aligns with findings from the Health Survey for England which found 17.9% of 65–74-year-olds with stage 3-5 CKD (Hounkpatin et al., 2020). Hill et al. (2016) suggest this rises to 27.9% any-stage CKD in patients aged 70 to 80 years. Whilst deterioration of kidney function is part of the ageing process, only a very small proportion of all people with CKD will die from end stage kidney disease (ESKD), the effect of kidney disease is not limited to its impact on the kidney itself. Reduced kidney function affects many organ systems but notably the cardiovascular system. Indeed, impaired kidney function is an independent risk factor for cardiovascular disease (CVD). Globally, it's estimated that 7% of the total CVD burden can be attributed to impaired kidney function (Bikbov et al., 2020).

Broadly, GFR is the best overall measure of kidney function but defining abnormality indicated by low eGRF based on serum creatinine measurement, together with elevated ACR according to defined thresholds, results in more accurate classification of CKD stage. It is likely to mean a higher proportion of undiagnosed disease being detected, as well as reducing the risk of false positives sometimes associated with the use of eGFR alone (Hirst et al., 2020; KDIGO 2012 Clinical Practice Guideline). The classification of CKD based on eGFR and albumin: creatinine ratios (ACR) thresholds as defined by NICE and KDIGO guidelines and referred to by Evans et al. (2022) and Hirst et al. (2020), is shown in Figure 1.1.

An eGFR of 60 ml/min/1.73m2 or above is indicative of not having CKD in the absence of other markers. An eGFR less than 60 ml/min/1.73m2 on at least two occasions defines CKD (Forbes & Gallagher, 2020). Stages G3b to 5, indicate progressive disease and an increasing prevalence of symptoms and complications of the disease. An eGFR below 15ml/min; is described as kidney failure (Hirst et al., 2020) but the use of ACR thresholds is useful in determining increasing risk prior to reaching this eGFR threshold.

Figure 1.1: Classification of chronic kidney disease (CKD) using glomerular filtration rate (GFR) and albumin: creatinine ratio (ACR).



ACR categories, description, and range, mg/mmol

GFR categories, description and range, ml/min/1.73m^2

GFR and ACR categories and risk of adverse outcomes				<3 Normal to mildly increased	3-30 Moderately increased	>30 Severely increased
				A1	A2	A3
≥ 90	Normal and high	G1	Asymptomatic	No CKD in the absence of markers of kidney damage	░	▒
60-89	Mild reduction related to normal range for young adult	G2			░	▒
45-59	Mild-moderate reduction	G3a		░	▒	▓
30-44	Moderate-severe reduction	G3b	Symptomatic	▒	▓	▓
15-29	Severe reduction	G4		▓	▓	▓
<15	Kidney failure	G5		▓	▓	▓

Kidney replacement therapy (KRT) in the form of haemodialysis (HD) or peritoneal dialysis (PD), or pre-emptive kidney transplant (Tx) is usually necessary when the patient has declined to an eGFR of between 7 to 8 mL/min/1.73 m^2. In 2018, mean eGFR at the start of KRT was 7.4mL/min/1.73^2, this has decreased to 7.0mL/min/1.73^2 in 2021 (UK Renal Registry, 2023).

It should be noted that estimates of eGFR using creatinine are less reliable in certain circumstances and recently published NICE guidance (Chronic Kidney Disease: Assessment and Management NG203, 2021) highlights that the use of eGFR has not been validated in some Black, Asian and other minority ethnic groups. However, evidence on specific eGFR equations or ethnicity adjustments are not from UK studies, so currently no recommendations specific to adjustments and ethnicity are available (ibid).

There is some discussion about the optimal time to start KRT (Ku et al., 2019; Rosansky, 2014; Tattersall et al., 2011; Cooper et al, 2010). It is recommended (KDIGO 2012) that dialysis be initiated in stage 5 CKD (eGFR ≤ 15mL/min/1.73 m^2) when significant symptoms occur (e.g., nausea, loss of appetite, fatigue, breathlessness, and pruritus); or when hydration status or blood pressure become difficult to control; or nutritional status deteriorates, or cognitive impairment develop. Urgent initiation is required when there are severe acid-base or electrolyte abnormalities, severe fluid overload, and severe complications such as pericardial effusion. Whilst earlier initiation to dialysis specifically (median eGFR 16.8 mL/min/1.73 m^2) has been associated with modest reductions in mortality and cardiovascular events, it is unlikely that this outweighs the longer time spent on dialysis (Fu et al., 2021). Ku et al. (2019) predicted time in CKD stage 5 defined as eGFR of 15 mL/min/1.73 m^2 to eGFR of 5 mL/min/1.73 m^2 as median 17.7 months, which was longer than the actual median time of 9.6 months from eGFR 15 mL/min/1.73 m^2 to KRT. The largest differences were found in relation to systolic blood pressure, proteinuria and serum albumin The authors concluded time may provide a novel perspective with which to determine initiation of KRT.

The likelihood of symptoms increases throughout stage 4 and 5 and some, such as lack of energy and fatigue, can persist even after dialysis initiation. Symptoms of fluid retention (swelling of legs and abdomen, breathlessness due to fluid in the lungs) are common, as are those related to anaemia such as headaches, fatigue, and palpitations. Paraesthesia, restless legs, discolouration of skin, bone pain and the need for nocturnal urination are other symptoms. Psychological symptoms are also apparent; depression, anxiety and distress and can be viewed as significant co-morbidities.

1.2.2 Progression to kidney failure

There are broadly two types of kidney failure. Acute kidney injury (AKI) usually occurs in the context of severe underlying illness involving dehydration, haemorrhage, or sepsis, in which the kidney(s) can be considered in terms of an 'innocent bystander'. Hence it is usually of sudden onset and is potentially reversible. In contrast, end-stage kidney failure due to CKD is irreversible and progression usually gradual. Opportunities for people with progressive CKD to receive education around treatment choices and illness trajectory are key. There is evidence that patient focussed education materials can be helpful in guiding optimal RRT decision making and whilst there have been few RCTs looking at the effectiveness of pre-dialysis education, data from observational studies suggest that pre-dialysis education can improve treatment decisions (Cassidy et al., 2018) particularly in relation to peritoneal dialysis which is associated with better quality of life (Devoe et al., 2016; Korevaar et al., 2003; M. R. Lynch & Shah, 2021; Walker et al., 2016). Combes et al. (2017) recommend that pre-dialysis education may be better viewed and delivered as an ongoing renal replacement therapy education which allows continued review of patient's' treatment choices. The use of decision aids can also be helpful in reducing any bias in the information presented around treatment choice (Bekker et al., 2023). In a smaller proportion of people, irreversible kidney failure can occur precipitously and the transition onto dialysis, without any opportunity for preparation, can be particularly traumatic. A small proportion of these may be due to non-recoverable AKI. Whether progression is sudden or gradual, it can have a major impact on treatment decisions, the patient experience of KRT initiation, and adjustment to the major change in circumstances and future possibilities.

CKD is generally asymptomatic until stage 4, so the opportunities to manage disease progression may not occur before then. Once identified, the main aims of clinical management are to slow deterioration of kidney function, reduce cardiovascular risk and address any complications related to CKD (such as renal anaemia, CKD mineral bone density, metabolic acidosis). Preserving residual kidney function is associated with better patient outcomes including survival and quality of life (QoL) (Mathew et al., 2018). Clinical management including monitoring of kidney function, anaemia, volume status, mineral and electrolytes, and treatment for risk factors such as high blood pressure, is key in preserving residual kidney function (RKF).

Factors associated with the decline of RKF include high blood pressure, the degree of proteinuria obesity, protein and sodium intake, diabetes (glucose control), hydration status and primary kidney disease (PKD) (Kjaergaard et al., 2011). Drugs including Angiotensin converting enzyme (ACE) inhibitors and Angiotensin receptor blockers (ARBs) have been shown to control blood pressure, reduce proteinuria and slow progression to CKD. Lv et al. (2013) conducted a meta-analysis which suggested protection against progression to renal failure from blood pressure lowering is particularly pronounced among those with proteinuria. Recently sodium-glucose transport protein 2 (SGLT2) inhibitors have emerged as effective agents in reducing progression in those with low or medium risk of CKD progression (Caruso & Giorgino, 2022), further evidence is needed for populations at higher risk. Patients also have a key role to play and following a low-salt diet, avoidance of excessive protein intake, and ensuring adequate hydration are all key aspects of managing the disease and slowing progression (Clark et al., 2016; Metzger et al., 2018; Shi et al., 2022). CKD progression is strongly associated with poor outcomes and has a significant economic burden (Evans et al., 2022). Haemodialysis specifically is associated with poorer QoL and higher levels of depression (R. Chan et al., 2009; Khan et al., 2019).

1.3 TREATMENT OF END STAGE KIDNEY DISEASE

There are 52 adult renal centres in England that offer KRT, including 20 transplant centres. Excluding transplant, haemodialysis is the most common therapy, and the process imitates the filtering function of a working kidney. There are two modalities (types) of dialysis; peritoneal (PD) and haemodialysis (HD). Mortality is very high among patients on HD, especially in the three months after initiation. Across high income countries, approximately one quarter of patients will die in the first year (Himmelfarb et al., 2020). For PD, the long-term risk of mortality is broadly similar to that for HD. In the last 20 years mortality risks have reduced (ibid), although still unacceptably high and usually due to cardiovascular events and infection.

1.3.1 Transplantation

Renal transplantation is the best modality of KRT and is linked with better QoL and better survival (Hart et al., 2017). Knowledge of human leukocyte antigen (HLA) typing and matching, recipient preparation, donor matching, and postoperative care have improved considerably since the first transplant in 1954. However, there are factors which may affect the decision to offer transplantation for a given patient such as age, high BMI, and suitability for long-term immunosuppression post-transplant. Data for 2021 show 3,525 patients were actively awaiting transplant, similar to 2019. However, total kidney transplants fell by 33% between 2019-2020 (n=3,509) and 2020-2021 (n=2353), likely affected by Covid-19. The prevalence of transplantation of those active or suspended on the list was approximately 20% in 2020. Several European studies indicate that inequalities such as socioeconomic status, older age and health literacy may exist in terms of access to the waitlist for transplantation (Vanholder et al., 2021; Wu & Oniscu, 2021; Zhang et al., 2018).

1.3.2 Haemodialysis

Approximately 93% of patients receiving in-centre haemodialysis, do so 3 times per week, with 1.5% more often. The duration is usually between 3-5 hours, with between 66-70% of patients spending usually 4 hours per session (UK Renal Registry, 2023). Haemodialysis can be conducted as in-centre or satellite clinic care, or at home.

An arteriovenous fistula (AVF) is the most common type of access used, alternatively an AV graft. A central venous catheter is another option, either as a tunnelled or non-tunnelled line. The latter is often used for short term access for acute situations and is more prone to mechanical complications, lower blood flow rates and infection (Sohail et al., 2021). A fistula is surgically created by joining a suitable artery to a subcutaneous vein. After maturation this allows access for the dialysis needles, to allow blood to exit from the bloodstream to the dialyser and then return to the patient. Within the dialyzer impurities pass by diffusion and convection from the blood to the dialysis fluid. Common complications include clotting of the fistula and infection. Careful infection control is mandatory. Pain associated with needling is common and is now viewed as an important measure within a broader tool to measure patient experience at the service level (Hawkins et al., 2022).

In recent years there has been growing recognition of home haemodialysis as the optimum option in terms of treatment with better QoL. Similarly, over the last 10 years an increase in participation in shared-care (where patients take a more active role in their in-centre care) is evident (Wilkie & Barnes, 2019).

As part of the NHS renal Services Transformation and Getting it Right First Time (GIRFT) programmes, increase in the provision of home therapies is being prioritised, with a focus on making this opportunity more equitable. A target prevalence rate of 20% of patients dialysing at home across all renal centres is in place (Lipkin & McKane, 2021). The proportion of home haemodialysis is not yet approaching this and data from the renal registry shows centre variation in England ranges from 0.4 to 8.4% of people on home haemodialysis. To date, 16 units have met or exceeded this minimum (data includes both HHD and PD), and incident home dialysis patients are mainly on PD (ibid). Some studies have demonstrated a survival benefit with home dialysis, but results are conflicting, in terms of outcomes and cost benefits (Jacquet & Trinh, 2019; Kerr, 2012; Roberts et al., 2022; Vinson et al., 2019) and home haemodialysis patients tend to be systematically different in that they are generally younger, less comorbid and more eligible for a kidney transplant (Woods et al., 1996). As a guide, a recent treatment comparison in terms of annual costs is shown in Table 1.1: Average annual cost per patient by treatment type and these costings are comparable with those reported by (Roberts et al., 2022) and included annual satellite unit costs (£19,990). Aside from additional expenditure for centres and patients, other factors such as current workforce shortages may stall current efforts to increase home dialysis rates. Despite this, most staff would opt for home therapy themselves (Hutchison & Courthold, 2011).

1.3.3 Peritoneal dialysis

A peritoneal catheter is used to remove waste products from the blood via the patient's abdomen, in an alternative method to haemodialysis. This form of dialysis is generally a home-based therapy and can be provided as assisted peritoneal dialysis (asPD) with the help of a device or person for very elderly or frail patients or those with social, cognitive or physical barriers (Giuliani et al., 2022) who may struggle with PD without support. Like home haemodialysis, PD requires a high level of self-care and therefore patients opting for this modality tend to be younger and less comorbid. PD provides more autonomy and freedom and generally means avoiding frequent and lengthy hospital trips. Pain associated with regular "needling" is also avoided, and generally QoL may be better (Chuasuwan et al., 2020), although catheter infection leading to peritonitis is a concern. As Shrestha (2018) suggests, there are advantages to PD and perhaps this modality should be advocated for use in all patients, particularly as the initial modality.

Table 1.1: Average annual cost per patient by treatment type

Type	Description	Cost
In-centre haemodialysis	Three sessions per week	£24,726
Home haemodialysis	Three to four sessions per week	£25,116
Home peritoneal dialysis	Six sessions per week	£21,216

Source: Improving dialysis care outcomes, House of Commons debate pack (2022)

1.3.4 Conservative kidney management (CKM)

Some elderly patients may have a smaller benefit from KRT, making conservative treatment more appropriate. Using this approach, an alternative plan to meet care needs which address symptom management and psychological support, as well as support for family is taken, rather than undergoing KRT. Patients who have chosen CKM, tend to live for a shorter time than those on dialysis, this effect is likely to be confounded by age and co-morbidities. Data from a systematic review suggest CKM may have advantages for the sub-sample of patients being offered or accepting this approach, in terms of QoL, symptom burden, hospitalisation and place of death (Engelbrecht et al., 2021).

1.4 INCIDENCE AND PREVALENCE OF CHRONIC KIDNEY DISEASE

Data collected by the UK Renal Registry comprises patients who have been referred to a kidney centre for care, and therefore represents a sub population of CKD patients, and many people, particularly in the early stages (undiagnosed or managed in primary care), are not represented in the data.

At the end of 2018, 66,612 people were receiving kidney replacement therapy, increasing to 69,497 in 2021 (UK Renal Registry, 2023), median age 59 years which varies by modality, with youngest median age in transplant patients (51 years). Approximately 8,175 (11%) had initiated KRT for the first time, an increase of 2.9% since pre-pandemic data collection (2019), and when data presented in the following chapters, was collected. Approximately one fifth of patients on KRT, start on PD and this proportion has remained relatively stable over time (ibid). Approximately 6% of patients started KRT with a transplant, lower than in previous years due to the ongoing consequences of the pandemic.

Of all people receiving KRT, transplant is most common, with 39,189 patients (56.4%) living with a functioning graft in 2021. There is considerable centre variation within England in the proportion of transplanted patents, ranging from 18.2% to 72.6%. Haemodialysis, comprising both home (1,396) and in-centre (25,009), amounts to 38%, followed by the remaining 3,903 (5.6%) on PD, the proportion varying between centres from 1.8% to 12.7%. Diabetes type-2 accounts for 31.3% of patients starting KRT (ibid).

Late presentation/referral is defined as a patient first seen by kidney services within 90 days of starting KRT for ESKD and is associated with poorer health outcomes, Chan et al (2007), suggest the risk of death doubles and poorer experience of care and treatment. Late presentation was 18.2% in 2021 which is an increase from approximately 16% in 2019 and 2020 and is associated with being younger (Patrice et al., 2019). People of lower socioeconomic status (Bello et al., 2008), and people with co-morbidities are also more likely to present late (Olaitan et al., 2019). Other than patient characteristics, the absence of a CKD code in the general practice record has also been found to be an important modifiable risk factor (ibid) and indicates the role secondary prevention has in slowing disease progression and improving patient outcomes and experience. The causes of late presentation are complex and are likely due to a mix of patient and service-related factors.

1.4.1 Ethnicity and socio-economic status

Data on ethnicity in incident and prevalent adult KRT patients is suggestive of an over-representation of Asian and black people in the KRT populations (Mathur et al., 2018; Roderick et al., 1996) and can be seen in Table 1.2 which compares data from the renal registry with Census data. Differences are less pronounced when looking at the data for Wales which is likely to reflect, in part, the greater proportion of white people in the general population, and a smaller sample size (approximately 3.1 million).

People from South Asian and Black backgrounds are three to five times more likely to start dialysis than people from Caucasian backgrounds (Roderick et al., 1996) and are therefore over-represented within the group accessing dialysis services (Roderick et al., 2009). There is also variation in access to transplants in terms of ethnicity, with patients from Asian and black communities less likely to receive a kidney transplant (Lipkin & McKane, 2021). People from lower socioeconomic groups are more likely to have CKD and progress quicker to latter stages of disease, evidence presented in the kidney health inequalities report published by Kidney Research UK (Caskey & Dreyer, 2018). Once renal failure occurs, they have poorer survival on dialysis and are less likely to be treated with PD (ibid). There is also recent evidence that more deprived patients on HD have higher hospitalisation rates which may reflect greater adverse effects on dialysis in this group (Rosenberg et al., 2023). Lower health literacy, linked with lower socioeconomic status, is also associated with reduced access to a transplant (Taylor et al., 2019). Uptake of home haemodialysis is approximately two-fold higher among white patients than those classified 'non-White" (28% compared with 13%) (Tabinor et al., 2017) and the protocol for the InterCEPt study which will explore variation in home haemodialysis in relation to factors such as socioeconomic status as well as ethnicity, has been published (Tshimologo et al., 2022).

Table 1.2: Comparison of ethnicity data for adult KRT patients by incidence and prevalence.

	Renal Registry data 2023				**Census 2021**	
	Incident adult KRT patients		Prevalence adult KRT patients		Adult population Data	
Broad ethnic group	England (%)	Wales (%)	England (%)	Wales (%)	E&W (%)	Wales (%)
White	72.1	96.1	71.9	94.0	81.7	90.6
Asian	15	2.6	15.1	3.9	9.3	2.9
Black	9.2	1.3	9.5	0.8	4	0.9
Mixed	-	-	-	-	2.9	1.6
Other	3.7	0	3.5	1.3	2.6	0.9

Source 1: Renal Registry 25th Annual Report, 2023 data to 31/12/2021
Source 2: Census 2021, Office for National Statistics (ONS)

1.5 CKD AND OTHER CHRONIC DISEASES

CKD is one of several long-term conditions which require a person to adjust to the demands of treatment and life with the condition. Other chronic diseases include cardiovascular disease, dementia, and diabetes, and in the UK, prevalence is estimated at 3-4% (Bhatnagar et al., 2016), 4% (NHS Digital, 2021; Office for Health Improvement & Disparities, 2021) and 7% (NHS Digital, National Diabetes Audit 2021), respectively. Inequalities exist with higher rates in Black and South Asian groups, this is most pronounced in type-2 diabetes (Pham et al., 2019) but also evident in cardiovascular conditions (Hull et al., 2014). Inequalities in mortality are also evident for cardiovascular disease and diabetes in people from low-income household (Public Health England, 2021).

CKD by comparison, has much higher prevalence, with an estimated 15% of people aged ≥35 years having any-stage kidney disease (Health Survey for England, 2017). Using estimates from a primary care population, Hirst et al. (2020) suggested these rates increase to 18.2% for those aged ≥60 years. It is estimated that more than 1.8 million people in England have diagnosed CKD, with perhaps an additional 1 million more people with undiagnosed disease (Kerr, 2012). General population surveys suggest that doctor-diagnosed CKD prevalence is much lower than estimated CKD prevalence in the general population.

CKD is independently associated with increased risk for cardiovascular disease (the most common comorbid condition in dialysis patients) and all-cause mortality (Gansevoort et al., 2013). Decrease in renal function following the development of cardiovascular disease is a strong predictor of mortality in patients, while cardiovascular disease is the main factor in the death of many dialysis patients (Lekawanvijit & Krum, 2014). Type 2 diabetes has emerged as the most important risk factor for CKD in the developed world (Hill et al., 2016) and is present in 30-50% of CKD patients (Alicic et al., 2017; Webster et al., 2017). It remains the most identified primary kidney disease (PKD), linked to faster decline in kidney function; Asian, African and Caribbean populations with diabetes show the most rapid decline in kidney function (Mathur et al., 2018).

Rates of CKD also show disparity by ethnicity. African and Caribbean populations have a high incidence of end stage kidney disease (ESKD) (Mathur et al., 2018) and there is a disproportionate burden of dialysis and mortality linked to diabetes and kidney complications (Wilkinson et al., 2019). The average life expectancy on dialysis is estimated to be between 5 to 10 years (NHS England, 2018). There is some evidence of a lower mortality rate amongst black patients on dialysis compared with white patients (Cole et al., 2014), however the reasons behind this apparent survival paradox (against a background of increased risk) and variation by co-morbidities, are not fully understood (Wilkinson et al., 2019).

1.6 THE IMPACT OF CO-MORBIDITIES AND MULTIPLE LONG-TERM CONDITIONS

A recent study in Scotland (n= 1, 274, 374) found that 98.2% of adults with CKD had at least one comorbidity (MacRae et al., 2021). Complex morbidity is defined as 3 or more conditions affecting 3 different organ systems. Having multiple long-term conditions (MLTC) is defined as 2 or more chronic conditions and occurred in approximately 87% of people with CKD, about half having 4 or more conditions (ibid)). Data from the Health Foundation suggests people with CKD have on average, 3.3 additional conditions (Stafford et al., 2018) and highlights the complexity faced by these patients in terms of treatment and symptom burden.

Which conditions are causing which symptoms is sometimes hard to know. Within the context of treating CKD, other illnesses are often thought of in terms of co-morbidities. Co-morbidity puts the index condition at the centre when approaching treatment. This may not always be appropriate and is not always the route to best care in terms of person-centred goals and this is discussed further in later chapters.

1.7 CONCLUDING REMARKS

The purpose of the kidneys is to maintain balance and homeostasis which provides a useful analogy for the person who, amid living with chronic kidney disease, and then end stage kidney disease, tries to maintain balance and a stable equilibrium between two interdependent elements: life and treatment.

Although the use of dialysis increases survival rate in patients with ESKD (Murtagh et al., 2007), there are many adverse impacts from dialysis. Research on the patient experience suggests individuals on haemodialysis often encounter a change in self-identity and a more constrained life leading to limitations in activities, and that the specific challenges of CKD and HD can have a strong psychosocial impact. Specifically, increased depression and anxiety, reduced QoL associated with treatment, co-morbidities and frailty that is linked with ageing but also illness, are all common factors for people receiving haemodialysis. The importance of the timing of dialysis initiation and shared decision making (Morton et al., 2010), and developing relationships with health professionals (Reid et al., 2016) along with the struggle of daily life experiences (Angioletti et al., 2018) have all been highlighted in qualitative research with patients.

Many patients spend more than 16 hours per week receiving treatment, however much more of a patient’s time is spent away from the clinical setting, balancing life with dialysis and managing other co-morbidities. The lived experience of managing CKD is complex and multifaceted (Havas et al., 2017b). It’s essential that wellness continues to be managed and monitored by the person labelled in other contexts as patient and not only judged according to biochemical values within optimal ranges. “While patients value longevity, reducing symptom burden and achieving maximal functional and social rehabilitation are prioritized more highly” (Himmelfarb et al., 2020).

CKD like other long-term conditions is a marker for inequality, and differential outcomes between patient groups are evident. Transplant is usually linked to a better quality of life, whilst haemodialysis is linked to higher rates of depression, lower quality of life and poorer survival rates. Many people with chronic kidney disease will experience more than one form of KRT during their illness.

Whilst dialysis may be the most time-intense and arduous for the patient, engagement in health behaviours such as fluid restriction, dietary changes and managing psychological health, as well as maintaining purpose, resilience, and joy to buffer against loss of hope, have all been associated with positive health outcomes. The importance of early engagement by patients in their health and wellbeing, is a critical part of secondary prevention. “To improve dialysis patient outcomes, it will be necessary to improve the health status of patients before they enter a dialysis program” (Eknoyan et al., 2003), not just physically but in terms of psychological health and social support.

The following chapter will go on to examine the psychosocial aspects of living with illness and managing the impact of treatment in a way that can be described as self-management. The role the patient can play in optimising their care via fluid, diet, and perhaps treatment related self-care, but also beyond the physical to the psychosocial factors that improve quality of life and can be linked to health outcomes.

A note from the outset; I will use the words person and patient interchangeably. Whilst the use of the term person-centred broadens and extends the perspective to consider a whole-life context (Håkansson Eklund et al., 2019), which is the approach this work takes, people are patients in the sense that they are all receiving treatment for CKD.

CHAPTER 2 : THE CONCEPT OF SELF-MANAGEMENT – DEFINITION, MEASUREMENT, EFFECT.

2.1 INTRODUCTION

The role of self-management is critical in chronic disease and can be the key to patient empowerment, improved outcomes, and increased wellbeing. This chapter will provide an overview of the complexities of the definition and operationalisation of the term within chronic disease generally, and ESKD specifically.

Van De Velde et al. (2019) attribute a "demographic and epidemiological evolution" to the increasing interest in self-management. Changes in patterns of health and disease have led to a global reduction in infectious diseases such as malaria or tuberculosis due largely to antibiotics and vaccinations (Horton, 2010). The increase in the prevalence of chronic disorders (currently most evident in 'the west'), within the context of an ageing population means the consequences of ill health have shifted. Lifestyle and dietary changes, medical technology advancements, and better infectious diseases management has meant a shift from morbidity and mortality due to famine and pandemic to the "age of degenerative man-made diseases" (Omran, 2005) in which chronic, long-term conditions are now the leading causes. The consequence is that we live longer but perhaps with more disability, reduction in quality of life and an acceptance of managing rather than curing. A British male born in 2016 will live approximately 69.1 years in good health; a female 71 years (Newton, 2017) however, average life expectancy at age 65 years remains approximately 83.5 for males and 86 years for females (Office for National Statistics, 2021b). Despite a decrease from ≥90 years reported less than a decade ago, life expectancy remains high for the current older population (Office for National Statistics, 2019) but approximately 15 years of life will be spent in poor health.

Health is "the ability to adapt and self-manage in the face of social, physical, and emotional challenges (Huber et al., 2011). This definition moves beyond WHO definition of health (2006) as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' and aligns with the definitions of self-management which will follow.

This chapter will provide an overview of the theory and operationalisation of the concept of self-management, both generally and in relation to other long-term conditions. The importance of self-management for haemodialysis patients will be outlined, and chapter 3 will then consider the kidney disease research literature specifically in terms of how self-management is conceptualised and measured.

Despite being a distinct term, self-management is related and often conflated with other concepts such as self-efficacy, self-care (Richard & Shea, 2011), shared care (Moser et al., 2008), adherence (Evangelista & Shinnick, 2008) or patient activation, a component of self-management (Hibbard et al., 2007). Definitions for each of these terms are in Table 2.1, however the nature of relationships is unclear. The definitions and concepts may overlap and differ, but there may not be a causal relationship between them. The uniqueness of self-management is characterised as neither representing an internal state or intention and extending beyond tasks relating only to treatment, to incorporate the impact of illness and treatment. The nuances and sometimes misuse of these other terms will be covered in this chapter.

Table 2.1: Definition of key terms.

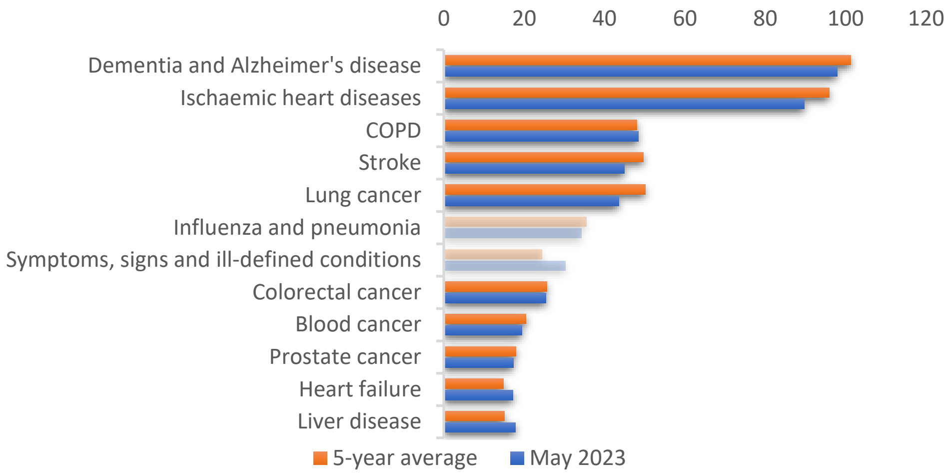
Term	Definition	References	Relationship with SM
Self-management	Sub-set of self-care focussed on managing the impact of disease in terms of symptoms, treatment, physical, psychological, social consequences and lifestyle changes.	Barlow et al., 2002; Wilkinson & Whitehead, 2009	
Self-efficacy	"Beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments."	Bandura (1977) p. 3.	A mechanism through which SM can be achieved (Peters et al, 2019).
Self-care	Specific behaviours that individuals initiate and perform on their own behalf, with the intention of achieving, maintaining, or promoting optimal health and well-being. More recent definitions suggest informal caregivers may have a more central role.	Denyes et al., 2001; Richard & Shea, 2011; Vellone et al., 2013.	SM falls within the wider domain of self-care or vice versa (Richard & Shea, 2011).
Shared care	A system of relational processes that includes providers-family-patient. May be emotional, practical, or informational support that enables individuals to be involved in their own treatment to the extent they wish.	Fotheringham et al., 2017; 2021 Sebern & Woda, 2012.	Shared care better supports and empowers individuals to self-manage more broadly, beyond engagement with treatment (Wilkie & Barnes, 2019).
Adherence	The ability to follow a healthcare professional's recommendations on treatment regimens, regarding timing, doses, frequency, and periods of drugs-consumed but also diet and lifestyle.	Deaton (2000).	Adherence is a sub-component of SM usually with a focus on clinical outcomes and treatment costs (Howren & Gonzalez, 2016).
Patient activation	Level of motivation, knowledge, skills, and confidence to make effective decisions to manage their health.	Wagner (1998) cited in Lightfoot et al., (2022); Hibbard et al., 2004; 2007.	Activation represents a narrow aspect of SM (Lawless et al., 2021) and may be a precedent to self-management.

2.1.1 Long-term conditions (LTCs) and implications of self-management

Long-term (also referred to as life-long) conditions or chronic diseases refer to illnesses for which there is no cure, they include diabetes, arthritis, chronic obstructive pulmonary disease (COPD) and chronic kidney disease (CKD). Dementia and Alzheimer's disease was reported as the leading cause of death in England and comprises 10.9% of all deaths (ONS mortality data, May 2023). Excess deaths reported for the same time, were highest for symptoms, signs, and ill-defined conditions (which includes "old age" and "frailty"). The age-standardised mortality rate (ASMR) was significantly higher in this most recent time point since the beginning of 2001. Excess deaths are calculated using a five-year average as a comparison (Caul, 2022) and give a sense of how much higher the death rate is compared to what might be expected (it has been adjusted for COVID by excluding 2020 in the five-year average). This is relevant because despite the adjustment, it could be that the pandemic and consequences on health services may still be having a lasting effect (OECD and European Union, 2022).

The 10 most common underlying causes of death registered in May 2023, compared with the five-year average for May (2017 to 2019, 2021 and 2022), for England are shown in Figure 2.1 (bars for LTCs with non-infectious aetiology in bold). However, the factors that cause illness can be very different. When combining death and disability for the same time period, low back pain ranks second, and depressive disorders 7th for England, with an increase in depressive disorders of over 12% in 2019 compared with a decade earlier (www.healthdata.org/united-kingdom-england).

Figure 2.1: Age standardised mortality rate (per 100,000 individuals per year), deaths registered in the year-to-date (January to May 2023) compared with the five-year average, England.



It’s estimated that 15 million adults, which equates to about 28% of adults in the UK (Park, 2020) have at least one long-term condition (Department of Health and Social Care, 2012). Research in primary care (314 practices) in Scotland suggests a slightly higher proportion; about 42% with almost a quarter (23%) experiencing multimorbidity (Barnett et al., 2012).

As described in chapter 1, multimorbidity refers to the presence of two or more LTCs in any individual and increases with age. With such a high burden of LTCs, and multimorbidity being relatively high in older age groups; predicted to increase to over 50% in those aged 65-74 years by 2035 (Kingston et al., 2018), the need for engagement in self-management is even greater. People with long-term conditions now account for about 50% of all GP appointments, 64% of all outpatient appointments and over 70% of all inpatient bed days (Aiden, 2018), these data pre-date COVID and are likely to be even more relevant in post-pandemic Britain. Multimorbidity (alongside increased polypharmacy) is linked to higher mortality and poor health outcomes as well as progressive loss of resilience, and impaired homeostasis (Aggarwal et al., 2020). The ability to manage multiple long-term conditions effectively, preserving balance and quality of life is imperative.

The next section will explore the concept of self-management and review the evidence that improving or increasing engagement in self-management will have an impact on outcomes that patients value beyond clinical outcomes.

2.1.2 Clarifying the concept of self-management

Engagement in self-management can occur irrespective of condition or current health status to slow illness progression, control symptoms and maximise ‘wellness’ (Grady & Gough, 2014).

The underlying theories of self-management have developed from the bio-medical models of health centred around clinical outcomes and treatment adherence (Kralik & Koch, 2001). Bandura and Cervone (1977, 1986, 1989) the original proponents of social cognitive theory, linked beliefs with behaviour change; perceptions of self, outcome expectations and other factors such motivation, with self-efficacy. Self-efficacy will be discussed further in a following section; however, it’s broadly defined as an individual’s beliefs in their capacity to act in a way that enables specific goals to be reached (ibid).

Engel in 1981, conceptualised the biopsychosocial model, an alternative to the focus in healthcare on biochemical processes. In his biopsychosocial model, a systems-linked approach considered the individual experience, the two-person interaction with the doctor, nurse, family member etc, the family, the community which includes healthcare and work, and other factors such as age, sex, education, and socioeconomic status as levels within a system in which a person experiences health and illness. This conceptualisation lacked application, and it was Corbin & Strauss (1988; 1985) who described self-management in relation to chronic disease as medical management, adopting new behaviours and emotion management.

Not until the next millennium was a self-management concept pioneered within a self-management programme. Lorig et al (2001) highlighted the variation in conceptualisation of self-management and identified five core behaviours; problem solving, decision making, accessing resource, forming patient-provider relationships, and taking action, which sit within the biopsychosocial model. The Chronic Disease Self-Management Programme (CDSMP) was launched as the Expert Patient Programme in the

UK which brought self-management to UK health policy (Department of Health, 2001; Kennedy et al., 2007; Lorig et al., 2001; Wilson & Mayor, 2006) Evidence from this programme is presented later in this chapter, but the premise goes beyond looking at compliance with instructions from healthcare providers, to education and equipping people with the skills to manage their own condition. Linked to this is personalised care planning which concerns the access to and provision of information, with the emphasis on involvement and choice, as well as self-management (Coulter et al., 2015; Department of Health., 2010).

In 2003, Lorig went on to note the person-centred nature of self-management, meaning goals and actions may better fit with patient priorities than those of providers. Interestingly, according to Fletcher et al (2019) this ethos stands in juxtaposition with the act of embedding self-management in policy which perhaps served to align it even further with the medical model which places emphasis on "experts" in authority advocating compliance and alignment with more clinical outcomes. Wilson et al (2007) also questioned whether patients were truly empowered.

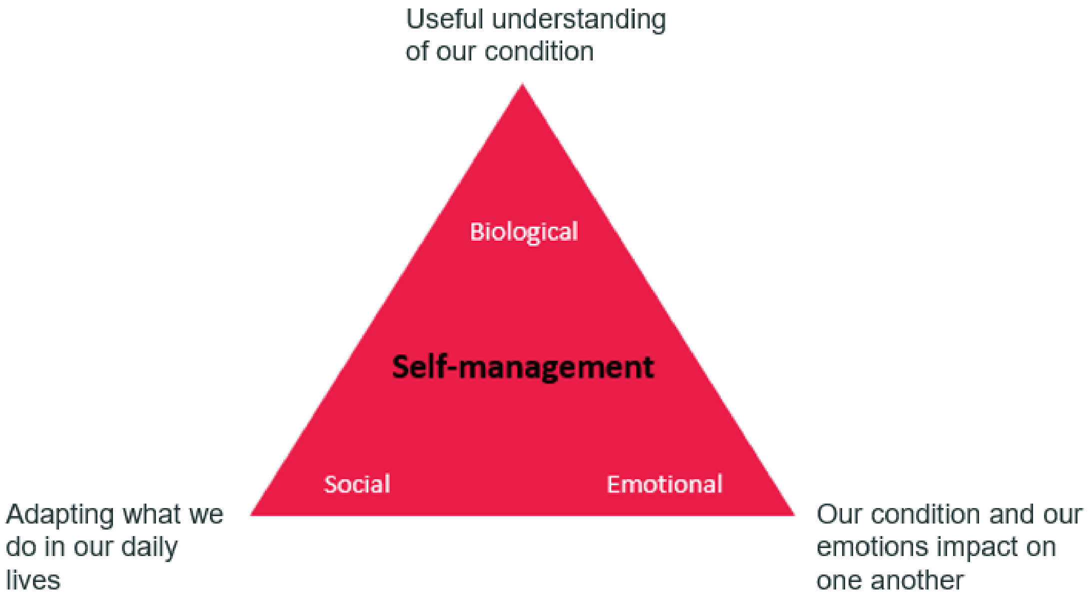
This has been counterbalanced somewhat since with contributions from the Health Foundation who have linked self-management with decision making, with a collaborative patient-provider relationship at its centre (Ahmad & Health Foundation, 2014). Drawing on definitions by Corbin & Strauss (1985), and Lorig & Holman (2003), the following is a starting point in terms of defining self-management:

"Tasks undertaken by an individual living with a chronic disease and its treatment, that incorporate not only adherence to medically prescribed treatment, but also tasks relating to continued social functioning, and of adapting emotionally to living with the condition and its treatments" (Reston, 2015, p.30).

This definition encapsulates the tripartite model presented by the Health Foundation (Figure 2.2) and aligns with Cicely Saunders's concept of total pain in which she notes there is an over medicalisation of care rather than sufficient attention to the psychological (emotional or mental), social and spiritual aspects of pain (Wood, 2021). The model is also embodied in the Patient Skills Programme, Co-Creating Health (Kosmala-Anderson et al., 2014).

Whilst behaviours within the three domains of self-management may not always be mutually reinforcing, social and emotional aspects of self-management such as maintaining a social circle, seeking information, or preserving emotional wellbeing, may mediate or enable a better quality of life. This can be more important to patients than adherence to treatment regimens and resonates with the idea that behaviours or strategies will seek to manage not just an illness, but life with that illness (Audulv et al., 2012). Even people with multiple long-term conditions have contact with service providers for only a fraction of their lives, and many patient outcomes will be mediated through daily behaviour (Glasgow et al., 2003).

Figure 2.2: The self-management triangle, Health Foundation.



The biopsychosocial model remains essentially a valid approach but has been extended by the biopsychosociotechnical model (Wood, 2012). This model includes the technological determinants of health which in terms of chronic disease, may refer to differential access to care pathways, variation in quality of self-care training and education, and/or inadequate access to transportation to hospital etc. The inclusion of such factors makes the model more relevant to other fields of research and practice such as digital interventions, implementation studies and complex system approaches to research (Card, 2022). But also, highlights the potential impact of broader environmental factors that affect behaviours. Discussion of the relevance of this model will be developed further in chapter 8 (implementation) but mentioned here as it underlines the ongoing shift towards a more practical approach to conceptualisation of health and illness, which recognises the complexity and multifaceted nature of self-management and moves it beyond cognitive strategies and decisions to directly observable behaviours and actions, and the impact of external factors.

Miller et al. (2015, p.159) , incorporate the multiplicity of self-management with change, time and continued effort. “Chronic disease self-management (CDSM) is a fluid, iterative process during which patients incorporate multidimensional strategies that meet their self-identified needs to cope with chronic disease within the context of their daily living. [...) they require the individual to incorporate intrapersonal, interpersonal, and environmental systems to maximize wellness”.

This definition considers self-management an iterative process in which health status as both physical and emotional must be constantly evaluated.

There are many definitions of self-management, but few are both specific and necessarily multifaceted. Exactly what are the observable behaviours and actions? How can they best be measured? And what factors comprising self-management, are antecedents or have a mediating impact?

2.2 ASSOCIATED CONCEPTS

One issue with a lack of consensus relating to definition is that the measure of self-management varies across studies and outcomes measures; activities of daily living, self-efficacy, knowledge of disease, patient activation, and health-related quality of life (HRQoL) have all been used to represent self-management. The term itself is complex to define and often only contextualised within the specific intervention being investigated. The following terms are sometimes conflated with self-management or used as proxy measures.

2.2.1 Self-efficacy

Self-efficacy has already been defined as a person’s confidence in an action. The influence of self-efficacy and its relationship with self-management is not fully understood, and it is not clear whether it is as an attribute of self-management, mediator of change, antecedent or consequence. Despite being included as a measure in many self-management studies, sometimes as a proxy measure, the extent to which improvements in self-efficacy are predictive of actual behaviour change remains uncertain (Ahmad & Health Foundation, 2014). Van De Velde et al. (2019) suggest it is best viewed as antecedent; a useful mechanism for facilitating self-management, but others view it as a mediator, and this is explored in chapter 3 in relation to CKD and haemodialysis.

The main measure of self-efficacy used in research in chronic conditions is The Self-Efficacy to Manage Chronic Disease Scale SEMCD (Lorig et al., 2001; Ritter & Lorig, 2014).

2.2.2 Self-care

Self-care is distinct from self-management, but both can be considered on a continuum. In health, self-care is broadly thought of in terms of normal activity but has come to be associated with treatment tasks in the management of chronic conditions. Richard & Shea (2011) and Matarese et al. (2018) proposed that self-management falls within the broader concept of self-care, and the latter study describes shared responsibility between individuals, carers with at least some healthcare provider input. I would argue that within kidney disease the term is generally used in reference to dialysis care and might be better described as a component of self-management in which monitoring symptoms and the impact of treatment as well as decision making is included. However, within chronic disease research self-care and self-management are often used interchangeably with variability in conceptualisation and operationalisation (Grady & Gough, 2014; Matarese et al., 2018; Richard & Shea, 2011; Van De Velde et al., 2019).

2.2.3 Patient activation

Patient activation is best described as a patient's knowledge, skills, ability, and confidence to manage their own health and care (James, 2013). It is viewed as a precedent to changes in self-management behaviour (Hibbard et al., 2007; 2004) and may provide insight into how to encourage the development of those behaviours. The Patient Activation Measure (PAM) developed by Hibbard and colleagues (ibid) is the most widely used instrument for measuring patient activation. There are four recognised stages of activation that range from stage 1 in which people are not active or even aware of their potential role in their own health, to stage 4 in which people have adopted new behaviours even if they are not consistently maintained.

A measure of patient activation is sometimes used directly as a measure of self-management skills (Aung et al., 2016; Shively et al., 2013; Yadav et al., 2018) and high activation is linked with fewer emergency admissions in those with one or more LTC (Barker et al., 2018).

2.2.4 Adherence

Adherence can be defined as the ability to follow recommendations from healthcare professionals about treatment (Deaton, 2000). Measures of adherence are often used as proxy for self-management (Howren et al., 2016), and indirect measures of adherence specific to the LTC are sometimes explored through biological measurements such as measures of daily blood glucose and overall glycaemic control in diabetes studies (Berg et al., 2016) as a proxy for medication and diet adherence.

The factors associated with why some patients adhere is less researched. Perceived adherence may vary within an individual according to the set of behaviours, for example taking of medication may be diligent whilst diet restrictions may be less rigorously followed. Adherence to self-care activities demands knowledge, motivation and increasing evidence suggests, social support (Gallant, 2003; Shahin et al., 2021; Strom & Egede, 2012)

In conclusion, the terms self-care, adherence, and self-management (possibly also self-efficacy) are often used interchangeably in the literature (Cameron et al., 2018; Evangelista & Shinnick, 2008; Gallant, 2003; Howren et al., 2016; M. Peters et al., 2019). Complexity arises as each of these concepts comprises not one behaviour but many behaviours that may not correlate and are related to many other factors. These difficulties will be explored further in the next section.

2.3 FINDINGS: EVIDENCE FROM SELF-MANAGEMENT SUPPORT INTERVENTIONS

Given the complexities in definition, there are clear methodological issues with measuring self-management and related concepts. Patient education interventions and self-management programmes are often used to describe similar things but vary with the first providing disease specific information and skills and the latter, supports problem solving skills with the purpose of improving health and managing the impact of illness and treatment (Coster & Norman, 2009).

The Health Foundation define self-management support in terms of active partnership, support to build knowledge, skills, confidence, and resilience, and being enabled to sustain efforts to self-manage (De Longh et al., 2015). The importance of self-management support is outlined in the key policy document: (NHS England, 2014). The distinction between support and self-management is that the former is offered by healthcare professionals in the context of care, and the latter is what patients do to a greater or lesser extent, throughout their daily lives (Ahmad & Health Foundation, 2014). There is some evidence of benefit of self-management support, though the effects were modest. Reduced utilisation of healthcare resources has been found in a meta-analysis of studies looking at various LTCs, the effect being strongest in individuals with respiratory and cardiovascular disease (Panagioti et al., 2014)

Two self-management programs for arthritis (ASMP) and diabetes ((Lorig et al., 2009; 1993) are among the earliest and most successful of the Chronic Disease Self-Management Programs (CDSMPs). Delivered as 2.5-hour workshops once a week for 6 weeks within the community, both found improvements in self-efficacy and elements of health status, and among patients with diabetes, improvements were seen in depression and communication with physicians despite no improvement in diabetes control (measured as haemoglobin A1c) (Lorig et al., 2009). This study used a relatively small community-based sample with low A1c at baseline which may be attributed to the lack of effect. In a systematic review of 72 diabetes studies, Norris et al (2000) found improvements in knowledge and glycaemic control, but variation in effect on lipids, physical activity, weight, and blood pressure.

Among patients with arthritis, it was noted that changes to health status were more closely linked to changes in self-efficacy than observable changes in behaviour (Lorig et al., 1993) but that the intervention was effective in improving perception of control and reducing depression, anxiety, and fatigue (Barlow et al., 2000).

Mann et al (2013) found evidence that self-management interventions in those with chronic pain can reduce both the psychosocial and physical burden on affected individuals, while also reducing healthcare use. Similarly, in a systematic review, Jovicic et al (2006) found a reduction in all-cause and heart failure hospital readmissions linked with self-management interventions, however no effect on mortality was found. This aligns with the review by Evangelista & Shinnick (2008) which also explored adherence and self-care in heart failure patients and found that these types of behaviours were consistently associated with reduced hospital admissions (Bennett et al., 1997; Jaarsma et al., 1999; Rich et al., 1993) despite variation in those specific behaviours in each study.

In the study conducted by Jovicic and colleagues (2006) variation in behaviour change was also noted. Despite changes such as adherence to formal medical advice and daily weight monitoring, there was no effect found on functional capability, symptom status or quality of life. In their systematic review of stroke and self–management programmes Lennon et al (2013) found evidence of improvements in knowledge, the physical component of a health-related quality of life (HRQoL – SF-36), and disability and confidence in recovery, however a wider range of outcome measures were used across the 15 studies included in the review, effects for which were not found.

This difficulty surrounding the selection of outcome measures is highlighted in a Cochrane review of self-management intervention studies in chronic disease, mainly asthma and diabetes. Coster & Norman (2009) found a lack of long-lasting effects and lack of clarity about what determines a successful intervention. In addition, they showed that findings within (across a range of clinical outcomes) and between studies do not always show consistency (Lennon et al., 2013; Steinsbekk et al., 2012), even though positive outcomes have been found (Warsi et al., 2004).

Used in conjunction with the CDSMP intervention and across several chronic conditions among 50-to-70-year-olds, Hibbard et al. (2007) found patient activation increased over time in the intervention, but also in the control group. Surprisingly, for several of the 18 behaviours that were measured, the increase in the control group was greater than for the intervention group. Less surprising, was that the study also found an inverse relationship between activation and depression (ibid). Of note, was that all the self-management behaviours measured in this study could largely be described as measures of adherence (e.g., regular exercise, test glucose three times a week, check BP once a week, take medications as recommended). As with the study by Lennon et al. (2013), a later study by Newland et al. (2021) also linked activation and self-management with HRQoL.

In another recent study, Cuevas et al. (2021) conducted a systematic review to explore patient activation as it relates to self-management. Thirty-two articles were identified which included patients with diabetes, cardiac disease, respiratory disease, HIV, arthritis and one each relating to CKD and hypertension. The meta-analysis of the RCTs (n=18) suggested interventions for self-management across chronic conditions were not associated with improvements in outcomes such as regular exercise and monitoring glucose.

The authors conclude that lack of effect may be due to heterogeneity across the studies and likely also variation across the samples in terms of illness. Other research has found similar heterogeneity and uncertainty around the impact of self-management interventions (Jonkman et al., 2016). Perhaps the lack of psychosocial outcome measures and absence of contextual patient data may have meant self-management is insufficiently defined and measured, or that the outcomes are not assessing self-management at all, but adherence. This aligns with the findings by Taylor et al. (2014) who conducted a systematic review of over 1,500 qualitative, quantitative and implementation studies looking at self-management support. The authors concluded that self-management support is a complex intervention and it’s not possible to identify a minimum set of factors that are common to all studies. This may be because in many cases self-management ignores the psychological and social aspects of self-management, but also because each study is likely to measure aspects of care that are likely to be specific to a particular context (e.g., disease, treatment approach etc). Knowledge and beliefs, psychological strategies, strategies to support adherence, practical support around activities of daily living and social support were all identified as core components (ibid). Social support specifically, is widely identified as important to self-management and treatment outcomes but is often not included as a key measure.

Common problems identified across many of the systematic reviews on self-management in chronic disease include small samples, poor descriptions of the intervention and biased selection of outcome measures, as well as overarching poor to moderate quality of individual studies.

Several self-management support tools applied across a number of chronic conditions have shown an impact on self-efficacy, particularly relating to information, group education, telephone coaching and decision support tools. However, the translation to impact on behaviour change or clinical outcomes has broadly been limited or showed no improvement (Ahmad & Health Foundation, 2014). Decision aids as self-management tools seem to have the biggest impact across all three measures: self-efficacy, behaviour change and clinical outcomes (ibid). They may provide a strategy for difficult treatment choices and are more effective than the provision of information in a more conventional format (Bekker et al., 2003).

Greenhalgh (2009) observed that often psychological outcomes such as self-efficacy can be modified in some self-management intervention studies, but adherence and changes in behaviour, less so. Evidence from more recent studies, suggests this is still the case (Cuevas et al., 2021) and that adherence is related to several patient-related factors such as social support and patient activation (Martire & Helgeson, 2017; Paukkonen et al., 2022). Leventhal et al (2016) note the complexity surrounding which factors moderate adherence and how impact of these may change over time, concluding that this complexity has not been sufficiently evaluated.

There may also be some judgement related to perceptions of adherence that make it less suitable for capturing self-management behaviours. As Thirsk & Clark (2014) point out "when patients are judged to have not 'adhered' to a recommended regimen, the implication is that it is the patient's failure to 'self'-manage, rather than the healthcare provider's failure to provide appropriate, effective interventions". Indeed, Schulman-Green et al. (2012) found evidence that healthcare providers can and should support self-management by recognising that engagement by the patient may vary over time in terms of importance and prioritisation and through communication with patients to ensure self-management plans are appropriate.

Findings from studies including mixed populations cannot easily be generalised to specific diseases, and self-management in some disease areas has been more thoroughly researched (e.g., diabetes and arthritis). At the individual level, the presence of multiple LTCs may also partly explain why it is hard to find definitive evidence for the impact of self-management support on health and patient outcomes. There remains a lack of clarity regarding exact mechanisms through which self-management programmes impact participants, especially when components of the intervention are not adequately defined or it's not possible to know which were most influential (Boland et al., 2018; Devan et al., 2018; Schaffler et al., 2018).

The importance of tailoring measures to conditions, sub-populations and circumstances or treatments makes the case for using disease specific measures (Grady & Gough, 2014). The success of self-management interventions is often hard to measure due to problems with conceptualisation, methodological limitations, and choice of outcome measures (Allegrante et al., 2019). Self-management interventions are often multicomponent and complex and may be implemented as part of programs or across sites with varying contextual factors (Jonkman et al., 2016) making evidence of effectiveness of the intervention harder to determine.

2.4 A NOTE ABOUT COVID AND SELF-MANAGEMENT

The pandemic stood in contrast to broader global trends of a reduction in infectious disease. Disruption in the treatment process, reduced access to hospital, delayed diagnosis of chronic disease and cancellation of monitoring appointments, all had implications for health prevention and management of diagnosed and undiagnosed conditions. Despite some advantages, shifts to online healthcare may have presented greater barriers for some, namely, patients with cognitive and hearing disorders, linguistic barriers, and lack of technology. Any existing communication difficulty might have been exacerbated over the phone. Evidence of a decline in percentage growth in prevalence of home haemodialysis (-2.6%) and dialysis broadly (-2.0%) in 2020 was documented in the UKRR 25th annual report.

The ongoing effects on healthcare resources include continued difficulties getting face-to-face GP appointments, long waiting lists, delays in treatment, workforce issues and reported reduction in satisfaction with healthcare for some. COVID has had a negative effect on engagement with self-management among people with type 2 diabetes (Utli & Vural Doğru, 2021) and those with inflammatory arthritis (IA) (Caton et al., 2021). In those with IA, the qualitative analysis suggested some positive effects, particularly around telephone communication in terms of perceived economic benefits, time savings and improved communication regarding patient concerns. However, the pandemic was associated with changes, both negative and positive in diet and exercise (ibid). For example, poor diet is linked with low mood (Frith et al., 2020), and further consideration of factors such as these, alongside the potential impact on important clinical outcomes for some people with chronic conditions is needed.

Daily treatment routines and regular access to healthcare are likely to be essential for most people with multiple long-term conditions. Symptom as well as treatment burden, may be high; the consequences of which can lead to poor adherence (Demain et al., 2015; Heckman et al., 2015) and reduced quality of life of both for the individual and their family and carers (Sav et al., 2015). Living with long-term health conditions requires the management of a broad range of factors that contribute to a person’s health and wellbeing (De Iongh et al., 2015) as well as day-to-day priority setting and decision-making (Bratzke et al., 2015). Research on people with at least one chronic illness living in the Netherlands during the COVID pandemic found that those more vulnerable or with less established or stable self-management behaviours, may have been more likely to need extra support from health services. Social support was associated with improved self-management (Menting et al., 2023).

2.5 SELF-MANAGEMENT AND KIDNEY DISEASE

As described in chapter 1, people receiving haemodialysis experience huge disruptions to their lives because of the treatment as well as multiple symptoms of the condition. Developing knowledge, skills, and behaviours to manage is part of all chronic illness, but CKD is unique in that it is complex and intrusive, particularly when dialysis becomes a necessity (Novak et al., 2013).

The alignment of self-management with the tripartite model is particularly relevant for adults with ESKD for who, "coping with the emotional impact of their care regimen" (Knowles et al., 2016), may be a considerable burden. KRT is lifesaving, but social and emotional support and strategies for managing help minimize symptoms and maintain wellbeing throughout the kidney disease journey. Despite this, Reston (2015) found both conceptualisation and the mechanisms for measuring self-management in haemodialysis populations to be even more clinically focussed compared with other long-term conditions.

The NIHR-funded Self-Made study aimed to explore how best to provide services and support to people living with ESKD to improve their treatment and health through their own actions (Reston, 2015). Specifically, the study evaluated a self-management facilitator role within a renal setting and whether changes to practice could be promoted through that role. A core issue that arose from the work was the definition and conceptualisation of the term self-management within renal medicine.

Despite the acknowledgement of the importance of psychosocial factors in kidney disease, they are usually treated as predictors of adherence rather than in relation to broader concepts of self-management. Mood, social support and illness and treatment perceptions were all found to predict non-adherence in ESKD (Clark et al., 2014). Supportive social contacts and positive psychological factors have also been found to play a role in adherence to fluid restriction (Smith et al., 2010). Autonomy support, sometimes labelled patient empowerment, has also been linked to better phosphate binder adherence (Umeukeje et al., 2018) and other outcomes such as an increase in decision making and a decreased risk for mortality (McCarley, 2009;Drayer et al., 2006). There is some evidence of the importance of social functioning and quality of life in relation to kidney disease, but this is framed more generally, rather than in terms of self-management (Clark et al 2014; Drayer et al., 2006; Moattari et al., 2012; Neri et al., 2011; Plantinga et al., 2010; Spiegel et al., 2008).

In terms of self-management, (Reston, 2015) found a tendency to focus on 'behaviours' limited to the dialysis process, medication, fluid and diet adherence when implementing self-management, or to use psychological correlates like self-efficacy instead. This focus on medical adherence and internal states rather than self-management behaviours relating to the tripartite model, neglects the importance of those behaviours necessary for the maintenance of emotional and social wellbeing.

“Self-management is often oversimplified and poorly operationalised, in both the literature and in clinical practice, to adherence and ‘good/bad’ distinctions that may impede future investigations and interventions.” (ibid).

Broadly, this mirrors what has been summarised thus far in terms of other chronic conditions. Unlike research in some other LTCs, Reston concluded that there is a dearth of information on social and emotional issues in kidney disease.

2.6 A FEW WORDS ABOUT PATIENT ACTIVATION AND KIDNEY DISEASE

Use of PAM was piloted for use in kidney disease through the UK Renal Registry (UKRR) and the measure may provide insight into how likely a patient is to be engaging in elements of self-management, even if it does not tell us anything about the magnitude or precise issues they may be experiencing.

As with other LTCs, low activation is linked with lower adherence to medication and poorer HRQoL. In terms of kidney disease specifically, lower adherence is also associated with receiving in-centre dialysis, and decisional conflict around modality choice (Nair & Cavanaugh, 2020). Although initially no link between patient activation and clinical biomarkers was found (Gair et al., 2019), Wilkinson et al. (2021) have found low activation is associated with greater comorbidity, as well as lower eGFR and lower haemoglobin. This group also suggest only a minority of CKD patients are activated for self-management. Lightfoot et al. (2021) endorse the use of PAM for assessing patient activation in kidney patients and similarly, view activation as a precedent to self-management.

2.7 EVIDENCE FROM SELF-MANAGEMENT INTERVENTIONS IN CKD

Reston (2015) identified 11 self-management interventions in CKD, four aimed to reduce IDWG and others used the results of clinical tests and adherence as proxy measures of self-management. The theory of self-efficacy or the use of self-efficacy outcome measures underpinned 7 studies. He found few interventions look at modifying social support or other psychosocial variables and where they were studied, it was usually as predictors of adherence rather than outcomes or moderators and/or mediators. An update on intervention studies in CKD will be presented in chapter 3.

2.8 IN SUMMARY

A self-management approach to long term conditions is being increasingly advocated and adopted in research (Allegrante et al., 2019; McGowan, 2012) and policy; Realising the value funded by NHS England in 2014 (findings reported by Finnis et al., 2016) and the NHS Long Term Plan (NHS, 2019). Yet perceptions around the interpretation of the concept and the agenda which underpins its use in the clinical setting, means supporting and measuring engagement in self-management is not straight forward (Fletcher et al., 2019). There is still ambiguity regarding the concept and measurement of patient engagement (Van De Velde et al., 2019). It is true to say, that despite the shifts in the literature, dominant definitions operationalised in intervention studies, still focus on clinical outcomes, adherence, and decision-making, rather than addressing the emotional consequences, treatment impact and effort required to continue living a life, rather than living an illness (Whittemore & Dixon, 2008).

The two psychosocial corners of the self-management triangle (Figure 2.3) often remain poorly defined and measured. Any measurement that considers Card's (2022) view of the biopsychosocial (technical) model; that acknowledges the need for a systems approach, the importance of the patient context and a holistic view of health, may be better placed to measure the impact or effectiveness of any self-management intervention.

In a systematic synthesis of theory, Lawless et al (2021) identified 76 theories relating to self-management and self-care, 9 had three or more citations and include social cognitive theory (Bandura & Cervone, 1986), theory of planned behaviour (Ajzen, 1991) and self-care deficit nursing theory (Orem, 2001). The authors acknowledge convergence and overlap across the theories and conclude that self-management should be viewed as a dynamic process of behavioural adaption, utilising social capital to alleviate the impact of disease and treatment to maintain quality of life. This more complex conceptualisation of self-management is likely to require an approach that prioritises partnership, collaboration, and utilises a multidisciplinary team to support engagement in self-management.

Underlying drivers of effective LTC management include a range of social and environmental factors, that aren't always explicitly defined in assessment of self-management (Greenhalgh, 2009; Thirsk & Clark, 2014), and this is particularly relevant for ESKD. Greenhalgh goes on to say that failure to recognise the complexity and importance of the individual context has been a shortcoming in supporting self-management in chronic disease. Any new measure should take the concept beyond favoured clinical outcomes to include the perspectives of people with lived experience and their narrative around what they do to look after themselves.

Constructs such as self-efficacy and self-care focus on the responsibility of the patient without sufficient attention to the impact of social capital, the role of healthcare providers and the confines of the system in which treatment and care is delivered. Whilst components of self-management should all be within the direct control of patients (Jonkman et al., 2016), they will be influenced by the context of life and healthcare delivery.

The following chapter will extend the literature review conducted by Reston (2015) and identify any existing ESKD-specific measures of self-management, as well as identifying any important psychosocial factors that should be considered as components in any new ESKD-specific measure of self-management.

CHAPTER 3 : LITERATURE REVIEW

3.1 BACKGROUND

In chapter one and two, the complexity and time-consuming nature of haemodialysis treatment was explored from a clinical perspective but also with a focus on the disruptive and intrusive effect it can have on a person's life and sense of identity. Mitigating against the psychosocial impacts both of treatment on life and vice versa, is an essential part of self-management. Engagement in managing matters in the dialysis chair and beyond, is a means to maintaining balance and quality of life and the consequences may not always be visible in the clinical setting.

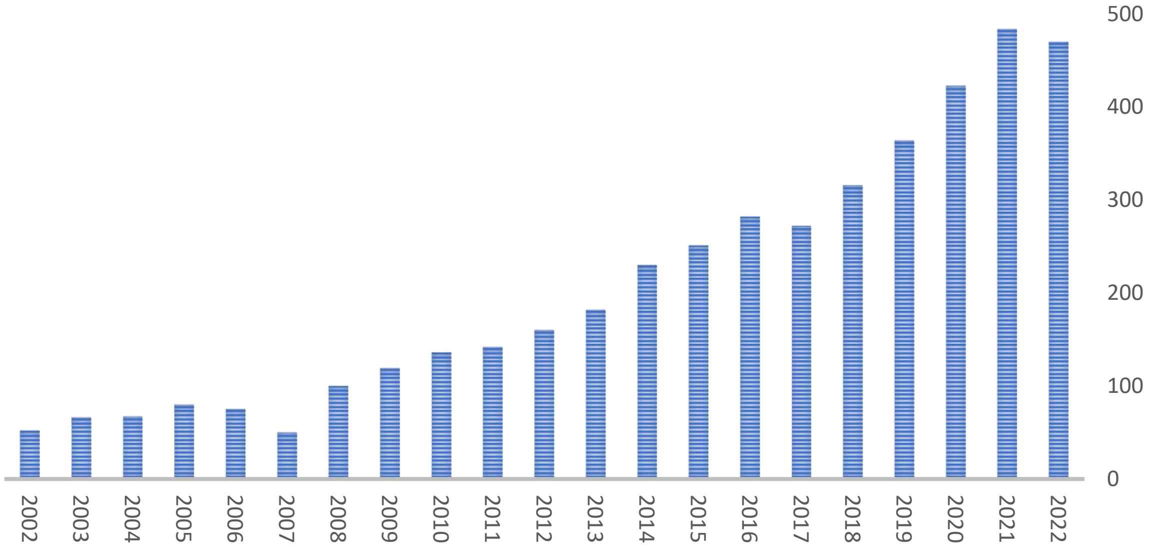
In the last 20 years evidence published on self-management among renal patients has increased, most rapidly in the last decade (Figures 3.1 and 3.22). However, a previous review of the self-management literature in kidney disease found that most studies in this area focus narrowly on clinical measures of adherence and do not address what people do to protect or promote holistic wellbeing (Reston, 2015(Reston, 2015). Specifically, information about social functioning or non-medical behaviour, like seeking support, or social participation, was lacking and yet are known to be important in clinical outcomes. It could therefore be argued that what follows is an overview of studies of adherence more than self-management.

In this chapter, as the first experimental part of the thesis; I will extend and update the literature review conducted by Reston (ibid). In his work, he reviewed the psychological factors related to self-management and concluded that there was a dearth of information on social and emotional issues. He found evidence that self-management is often described in terms of adherence and good/bad patient distinctions in relation to more clinical aspects of managing. For this work, the search strategy was widened to include the term "psychosocial" to explore the concept beyond the confines of adherence and patient compliance. To identify the gaps in understanding and measurement of psychosocial factors that contribute to a more holistic concept of self-management.

This chapter will include a review of the literature which will address the question how is self-management conceptualised and measured in the research literature in terms of the psychological, social as well as clinical?

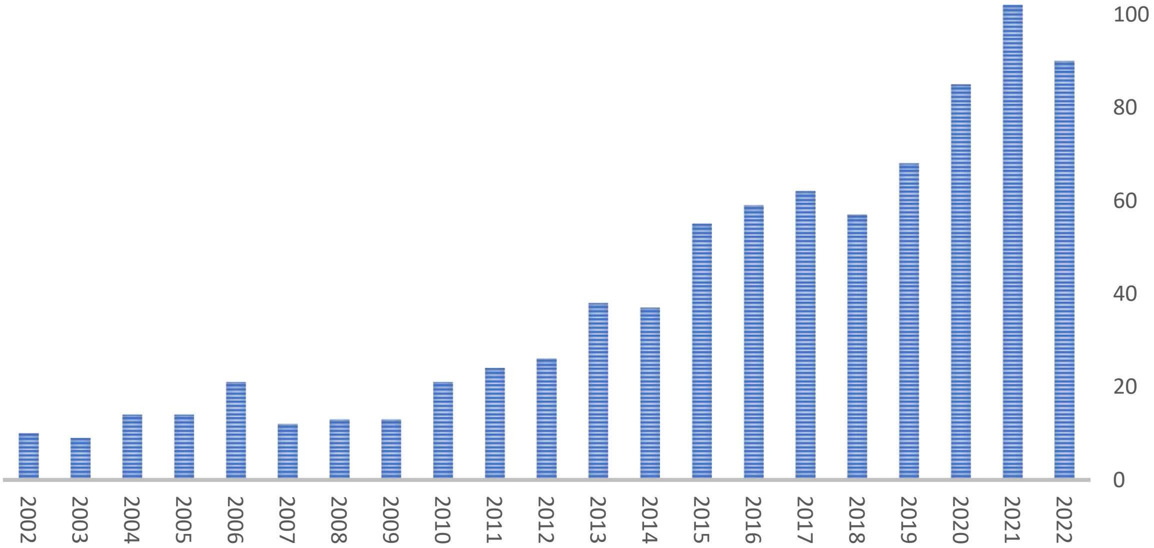
The term psychosocial refers to the cognitive, emotional, social, and behavioural elements of, in this case, self-management, based on the tripartite model introduced in chapter two. Referenced examples follow in the results section.

Figure 3.1: Articles in PubMed in the last 20 years with reference to self-management in kidney disease.



Key search terms “self-management” OR “self-care” AND “dialysis” OR “renal” OR “kidney”

Figure 3.2: Articles in PubMed in the last 20 years with reference to psychosocial and self-management relating to kidney or other chronic disease.



Key search terms “psychosocial” AND/OR “self-management” AND “renal” OR “renal” OR “chronic disease/illness” OR “dialysis”

Lawless et al (2021) conducted a synthesis of theories of self-management which broadly aligns with the idea that it is a dynamic process of behavioural adaption, utilising social capital to alleviate the impact of disease and treatment in order to maintain quality of life. To adequately assess self-management using this broader conceptualisation must mean incorporating wider factors beyond dialysis tasks, adherence and a narrow focus on clinical outcomes. Indeed, factors related to the more human aspects of life and those influencing quality of life are deemed very important by service users, at least as important as clinical outcomes (Bear & Stockie, 2014; Janssen et al., 2015; Reid et al., 2016; Schell et al., 2012). This stands in stark contrast to the focus on biomedical measures of the dialysis process and prioritisation of monthly assessment of urea clearance, anaemia management, phosphate control and interdialytic weight gain, IWG (as proxy measures of adequacy of treatment and patient adherence) and mortality as key outcomes (Himmelfarb et al., 2020). Increasing evidence suggests outcomes commonly used in research and measured and audited within clinical practice, may be of less interest and relevance to patients (Janssen et al., 2015; Wilson et al., 2007).

3.2 METHODS

A systematic scoping review was conducted to identify how the concept of self-management is understood within the renal disease community. Specifically, how it is currently defined and assessed in UK patients on haemodialysis and whether this aligns with the tripartite model. Inclusion of articles that describe the lived experience of living with chronic kidney disease and the impact of treatment was key, to balance the more medical model that has dominated kidney research on self-management to date.

3.2.1 Search Strategy

In conducting the previous literature review, (Reston, 2015) had searched PubMed using the terms “self-management” OR “self-care” AND “ESRD” OR “dialysis” and PsycNet using the terms “self-management” AND “dialysis”. In updating and extending that review, I sought to look at the psychosocial elements of self-management and existing tools or measures for assessing self-management. The two main concepts of interest were “self-management” and “psychosocial”.

The updated systematic search was conducted in PsycNet, Cochrane and PubMed. Search terms were adjusted according to the search engine, for example using PubMed, search fields were restricted to title/abstract due to the high volume of hits using “all fields”.

Note, since the review conducted by Reston, the term end stage renal disease (ESRD) has been replaced by end stage kidney disease (ESKD). The search terms outlined below reflect this change in terminology.

The search terms were:

“Self-management” OR “selfcare” AND “dialysis” Or “renal” OR “kidney”

“Psychosocial” AND/OR “self-management” AND “renal” Or “chronic disease” OR “chronic illness” OR “dialysis”.

The review was conducted between April-June 2018, with an update in November 2018. Note, anything published after January 2019 is not included in this review and did not inform any novel scale development work but may have been used post-development to provide further context.

3.2.2 Selection Criteria

Titles and abstracts were screened using the following criteria.

Inclusion:

- Where self-management or similar term was explored or measured, and the study participants were end stage renal disease patients on haemodialysis, or ESKD focussing on preparing for dialysis >18 years.
- Original research or review paper (including questionnaire development), irrespective of methodology or outcomes, published in a peer review journal.
- Originally in or officially translated into English.
- Where any reference is made to psychosocial aspects of self-management or related concepts for example adherence, self-efficacy, patient activation, decision-making etc.

Exclusions:

- Self-management in other chronic disease areas.
- Participants <18 years.
- Individual case study or opinion piece.
- Not in English.
- Focus is solely on comparing dialysis modalities e.g., outcomes in home haemodialysis versus in-centre haemodialysis, or other aspects of medical management such as drug comparison studies.
- Excluded specific e-health based interventions, where focus is around innovative technology to support elements of self-management.

Generally, articles pertaining to self-management in other chronic diseases were excluded but exceptions were made where viewed as highly relevant e.g., included information specifically about psychosocial elements of self-management or participants included those with CKD. Where psychosocial aspects were referenced specifically, the participant group was broadened to include adult patients at any stage of kidney disease. Articles that discussed associated concepts such as adherence, patient activation and self-efficacy were included where data on outcomes measures relating to these concepts was collected and analysed.

The review was conducted using the web-based reference manager tool Rayyan, which supports knowledge synthesis, particularly where the volume of articles is high. All screening was conducted by the author (lead researcher).

3.3 RESULTS 1: IDENTIFICATION OF PAPERS

Key word searches in electronic databases resulted in the identification of 1,757 articles. It is important to note that the first search (April-June 2018) informed most of the scale development work discussed in chapters 5 and 6, due to the time trajectory of the broader study. A further 80 papers were identified via lateral searching techniques such as ‘cited by’ or ‘similar article’ function in PubMed and using the reference section of key papers. In addition, papers were identified via recommendations made by members of our kidney network. After deduplication, 482 papers were screened using title and abstract which reduced the number of papers for full text review to 191 (Figure 3.3).

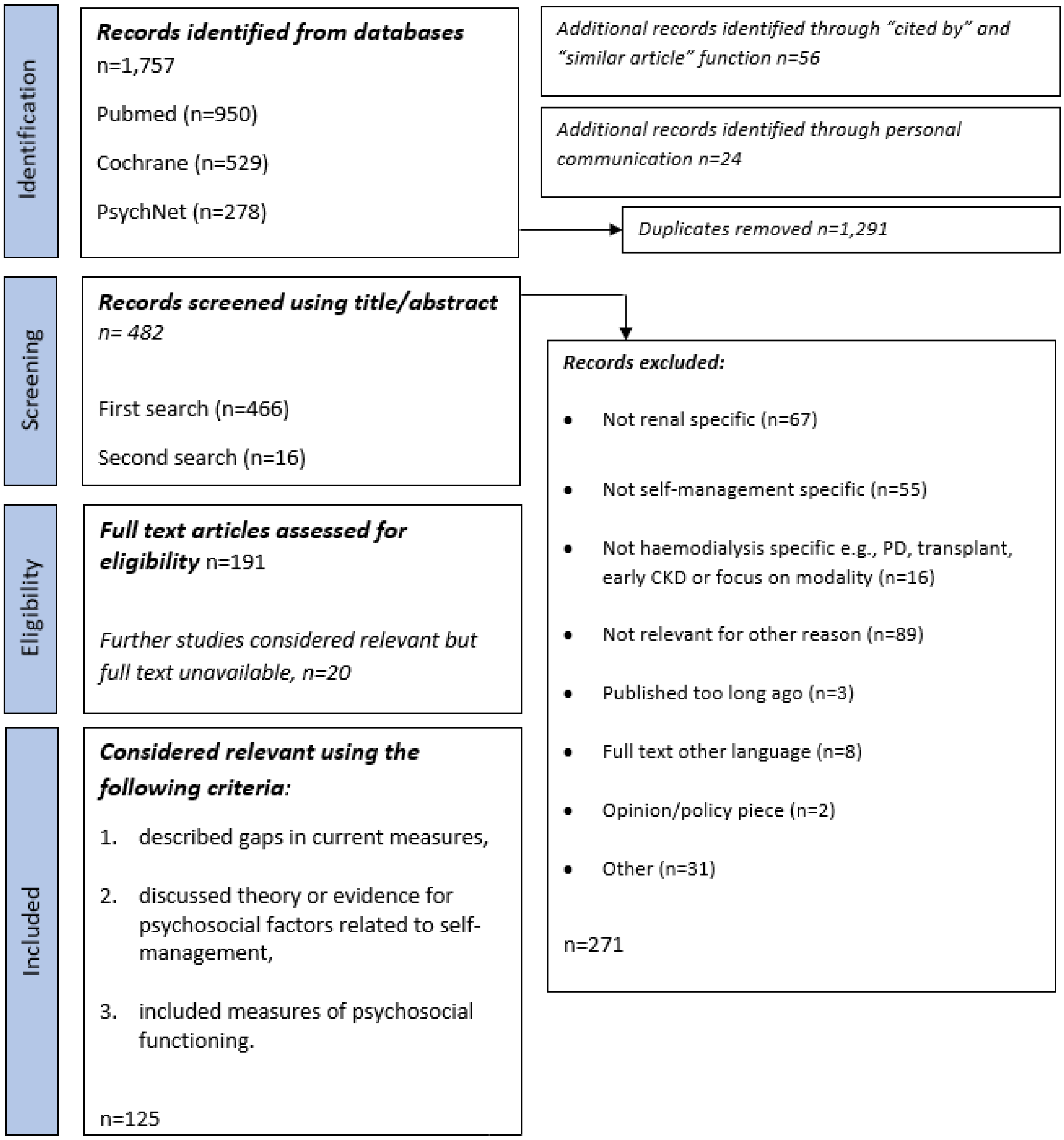
Twenty papers were excluded from the full text review as only the abstract was available.

Of the 191 articles that were assessed via full text review, 125 articles were deemed relevant and underwent data extraction irrespective of study design or quality but referred to one or more of the following:

1. gaps in the conceptualisation or measure of patient engagement in self-management in renal research or care were described or critiqued,
2. referenced theory or evidence associating psychosocial factors as outcomes, moderators, or mediators in self-management,
3. findings related to the effectiveness of self-management interventions, especially where there was an assessment of self-management behaviours/engagement.
4. a measure of self-management had been developed and validated in a CKD population.

Information was extracted on key data including study aims and research question, design, psychosocial and clinical outcomes, and self-management intervention if relevant. However, the following section presents a summary of the connections and overlap between the key and most relevant papers, rather than a broad-based view of the literature.

Figure 3.3: PRISM flow chart



3.4 RESULTS 2: CONTENT ANALYSIS

Psychosocial factors are critical in understanding the impact of disease and treatment and engagement in self-management among people with chronic disease, but specifically those with ESKD on haemodialysis. Eighteen main themes were identified from the literature, that relate to, or describe self-management (Table 3.1) and include themes such as social support, perceptions of control, severity of symptoms, information/knowledge, communication, acceptance of one's illness and coping strategies.

Table 3.1: Overview of the references relating to each core concept with self-management.

Theme	References
Acceptance	Baay et al., 2019; Cousineau et al., 2003; Finderup et al., 2016; Flythe et al., 2015; Hussain et al., 2015; C. C. Lin et al., 2015; Monaro et al., 2014; Morton et al., 2010; Nagpal et al., 2017; Reid et al., 2016; S. J. Taylor et al., 2014; Walker et al., 2017; Wolf & Mori, 2009)(Baay et al., 2019; Cousineau et al., 2003; Finderup et al., 2016; Flythe et al., 2015a; Hussain et al., 2015; C. C. Lin et al., 2015; Monaro et al., 2014; Morton et al., 2010; Nagpal et al., 2017; Reid et al., 2016; S. J. Taylor et al., 2014; Walker et al., 2017; Wolf & Mori, 2009Baay et al., 2019; Cousineau et al., 2003; Finderup et al., 2016; Flythe et al., 2015; Hussain et al., 2015; C. C. Lin et al., 2015; Monaro et al., 2014; Morton et al., 2010; Nagpal et al., 2017; Reid et al., 2016; S. J. Taylor et al., 2014; Walker et al., 2017; Wolf & Mori, 2009)(Baay et al., 2019; Cousineau et al., 2003; Finderup et al., 2016; Flythe et al., 2015a; Hussain et al., 2015; C. C. Lin et al., 2015; Monaro et al., 2014; Morton et al., 2010; Nagpal et al., 2017; Reid et al., 2016; S. J. Taylor et al., 2014; Walker et al., 2017; Wolf & Mori, 2009
Communication	Bear & Stockie, 2014; Berkhout-Byrne et al., 2017; Beto et al., 2016; Bratzke et al., 2015; Checton et al., 2012; Cramm et al., 2015; Curtin, R. B., Sitter, D. C. B., Schatell, D., & Chewning, 2004; Havas et al., 2018; M. Y. Lin et al., 2017; Reid et al., 2016; Schell et al., 2012; Vandenberg et al., 2018
Perceived control	(Clarke et al., 2016; Fan et al., 2016; Gibson et al., 2016; Jansen et al., 2014; Y. Kim & Evangelista, 2010; C. C. Lin et al., 2015; Mehrtak et al., 2017; Subramanian et al., 2017; Wild et al., 2017)
Coping strategies	(Angioletti et al., 2018; Beto et al., 2016; Bratzke et al., 2015; Cameron et al., 2018; Checton et al., 2012; Liu et al., 2018; Nearhos et al., 2013; Speyer et al., 2016; Subramanian et al., 2017)
Hope	(Davison, 2010; Finnegan-John & Thomas, 2013; Goh & Griva, 2018; Griva et al., 2015; Hughes et al., 2009; Ladin et al., 2017; C. C. Lin et al., 2015; McCarley, 2009; Poorgholami et al., 2015
Illness/health perceptions, beliefs and identity	(Cameron et al., 2018; Chilcot, 2012; Chilcot, Joseph Wellsted, David Farrington, 2010; Clarke et al., 2016; Demain et al., 2015; Griva et al., 2010; Hudson et al., 2016; Jayanti et al., 2016; Karamanidou et al., 2008; Khalil & Abdalrahim, 2014; Y. Kim & Evangelista, 2010; Ladin et al., 2017; Leake et al., 1999; Leung, 2003; Monaro et al., 2014; Picariello et al., 2017; Picariello, Moss-Morris, Macdougall, et al., 2018; Reid et al., 2016; S. J. Taylor et al., 2014; Walker et al., 2017; Walsh & Lehane, 2011)
Impact on family	(Cousineau et al., 2003; Gallant, 2003a; Monaro et al., 2014; Pruchno et al., 2009)
Information/knowledge	(Bratzke et al., 2015; Y. C. Chen et al., 2018; Cramm et al., 2015; Curtin, R. B., Sitter, D. C. B., Schatell, D., & Chewning, 2004; I. Davison & Cooke, 2015; Gela & Mengistu, 2018; Ghannadi et al., 2016; Gibson et al., 2016; Glidewell et al., 2013; Havas et al., 2017b; Johnson et al., 2016; H. Li et al., 2014; Oh et al., 2013; Schell et al., 2013; Smith et al., 2010; Vandenberg et al., 2018; S. F. V. Wu et al., 2016)
Lin 2017Managing (daily tasks)	(Angioletti et al., 2018; Beto et al., 2016; Bratzke et al., 2015; Checton et al., 2012; Gallant, 2003a; Horigan et al., 2013; Y.-N. Li et al., 2016; C. C. Lin et al., 2015; Liu et al., 2018; Megari, 2013; Nielsen et al., 2018; Parker et al., 2017; Shahgholian & Yousefi, 2018; S. J. Taylor et al., 2014; Thomas-Hawkins, 2005; Walker et al., 2013)
Meaningful life/quality of life	(Bayoumi et al., 2013; Belayev et al., 2015; Cukor et al., 2014; Demain et al., 2015; Drayer et al., 2006; Ibrahim et al., 2015; Janssen et al., 2015; M. C. Lee et al., 2016; C. C. Lin et al., 2012; M. Y. Lin et al., 2017; McCarley, 2009; Moattari et al., 2012;

	Reid et al., 2016; Saad et al., 2015; S. J. Taylor et al., 2014; Vasilopoulou et al., 2016; Wong et al., 2010; Zyga et al., 2015)
Multi-morbidity	(Bratzke et al., 2015; Coulter et al., 2015; Donald et al., 2018; Ghimire et al., 2015; Griva K. , Nandakumar M., Jo-an H. Ng J. H., Kevin F.Y. Lam K. F. Y., McBain H., 2018; Griva et al., 2015; Y. Kim & Evangelista, 2010; Zyoud et al., 2016)
Social support/capital	(Ahrari et al., 2014; Cameron et al., 2018; Y. C. Chen et al., 2018; Clark, S Farrington, K Chilcot, 2014; Derrett et al., 2017; Gallant, 2003a; Havas et al., 2017b, 2017a; Hudson et al., 2016; Hughes et al., 2009; Ibrahim et al., 2015; Jansen et al., 2014; Karamanidou et al., 2008; Lambert et al., 2017; H. Li et al., 2014; C. C. Lin et al., 2012; Liu et al., 2018; Oh et al., 2013; Oquendo et al., 2017; Parker et al., 2017; Perales-Montilla et al., 2013; Smith et al., 2010; P. M. Wilson et al., 2015)
Support from healthcare team	(N. H. Chen et al., 2018; Duprez et al., 2018; Ghimire et al., 2017; Havas et al., 2018; Oh et al., 2013; Reid et al., 2016; Umeukeje et al., 2016; Welch et al., 2015; Wong et al., 2010)
Symptoms (physical and psychosocial)	**Focus on psychosocial:** (Alosaimi et al., 2016; Chilcot, Almond, et al., 2018; Combes et al., 2015; Cukor et al., 2014; Drayer et al., 2006; Fischer et al., 2013; Gela & Mengistu, 2018; Ghimire et al., 2015; Griva, Neo, et al., 2018; Hudson et al., 2016; Kellerman et al., 2010; M. C. Lee et al., 2016; H. Li et al., 2014; Y. Li et al., 2016; Liu et al., 2018; Pascoe et al., 2017; Picariello, Moss-Morris, Macdougall, et al., 2018; Picariello, Moss-Morris, MacDougall, et al., 2018; Vasilopoulou et al., 2016; Weng et al., 2008) **Focus on physical:** (Flythe et al., 2015) **both psychosocial and physical:** (Belayev et al., 2015; Cox et al., 2017; S. N. Davison, 2010; Knowles et al., 2016; Kusztal et al., 2018; Perales-Montilla et al., 2013)
Treatment decisions	(Berkhout-Byrne et al., 2017; Bratzke et al., 2015; N. H. Chen et al., 2018; Combes et al., 2017; Coulter et al., 2015; Davis & Davison, 2017; I. Davison & Cooke, 2015; S. N. Davison, 2010; Green et al., 2018; Hughes et al., 2009; Hussain et al., 2015; Ladin et al., 2017; Lovell et al., 2017; Morton et al., 2010; Nielsen et al., 2018; Robinski et al., 2016; Rosansky et al., 2017; Schell et al., 2014; Stacey et al., 2017; Walker et al., 2017; Zee et al., 2018)
Work/employment	(Clarke et al., 2016; Farragher et al., 2017; Griva et al., 2010; Janssen et al., 2015; Muehrer et al., 2011)

The number of articles attributed to each theme supports the view that there is growing evidence that psychosocial factors play an important part in describing self-management and explaining engagement. Six themes will be explained in detail here, to illustrate the complexity and interrelatedness of the factors, and how they link with other related factors and concepts such as self-efficacy. These six themes fall within three headings, the last is a composite of three important and overlapping themes. It is not possible to review all themes within this chapter but those selected capture and summarise the most important elements identified in the literature search.

3.4.1 Social support/capital

Social support or access to social capital can be defined as support from family or friends or the wider community and thought about in terms of social roles or the value of positive connection with others. Gallant (2003) and Chen et al. (2018) argue social support and participation are key components of self-management and supportive families are described by Wilson et al (2017) as a source of external resilience for haemodialysis patients. Despite this, its importance is sometimes underplayed by healthcare workers (Ladin et al., 2017).

Social support is associated with acceptance (Monaro et al., 2014; Oquendo et al., 2017; Reid et al., 2016), satisfaction with care (Reid et al., 2016; Robinski et al., 2017), improved medication management (Griva, et al., 2018; Parker et al., 2017), less distress (Hudson et al., 2016), improved quality of life (Ibrahim e al., 2015) as well as slower disease progression/decline in health (Checton et al., 2012; Chen et al., 2018; Derrett et al., 2017) and lower symptom burden (Perales-Montilla et al., 2013).

Depression, as discussed in chapter 1, is a common psychosocial symptom among people receiving haemodialysis and has been found to be negatively correlated with treatment and diet adherence, the effects of which may be mediated by social support (Griva et al., 2019; Oh et al., 2013; Oquendo et al., 2017). Other papers are less clear about the association between social support, depression and various forms of adherence (Ahrari et al., 2014; Clark et al., 2014; Karamanidou et al., 2008; Lambert et al., 2017) but Knowles et al. (2016) suggests social support also mediates the relationship between depression and survival. This combined evidence suggests the link between lower depressive symptoms and higher social support is clear, and others agree(Liu et al., 2018)

Depression is also negatively correlated with self-efficacy (Perales-Montilla et al., 2013). This is a concept related to self-management that refers to the patient’s own concept of their capacity for carrying out actions that will lead to the desired outcomes (Bandura, 1994). Cameron et al. (2018) also hypothesise that social support enables self-efficacy, or alternatively self-efficacy facilitates access to social resources.

In addition, specifically, peer support e.g., talking to other patients can enable a more realistic view of dialysis to be shared and may balance any bias in information shared and discussed by staff (Combes et al., 2017). Indeed, learning from the experience of others may empower patients to use positive coping strategies (Subramanian et al., 2017).

Li et al. (2014) suggest a direct link between social support and engagement in self-management as defined by the HS-SM1 self-management scale (referred to in a later section) and Picariello et al. (2017) suggest more research is needed into social support and its association with fatigue specifically, but also more generally. Havas et al (2017b; 2018) found engaging and sustaining social support and roles is an area that people with CKD require additional support with and is viewed as an important part of the self-management of their condition. Pascoe et al (2017) suggest that psychosocial interventions that include a social support component, tend to reduce anxiety and depressive symptoms in people with CKD.

3.4.2 Symptoms – focus on depression, anxiety and distress

Depression and anxiety are common emotional responses to the challenge of living with chronic kidney disease (Fischer et al., 2013; Palmer et al., 2016; Pascoe et al., 2017; Perales-Montilla et al., 2013; Vasilopoulou et al., 2016) and evidence suggests up to 30% of patients are depressed (Chilcot et al., 2010; Drayer et al., 2006; Palmer et al., 2016; Shirazian et al., 2017). In addition, almost half have experienced distress (Seekles et al., 2020) and at least 50%; fatigue (Picariello et al., 2018). Combined, these aspects of psychosocial wellbeing are likely to have a significant impact on how patients manage their illness, treatment, and life.

Depression rather than chronic pain is an important predictor for all-cause mortality (Kellerman et al., 2010; Kusztal et al., 2018), and is also negatively correlated with quality of life (Belayev et al., 2015; Cukor et al., 2014; Drayer et al., 2006; Li et al., 2016; Vasilopoulou et al., 2016). Higher levels of somatic symptoms are associated with depression (Perales-Montilla et al., 2013; Picariello et al., 2017) and this aligns with findings that lower engagement in self-care activities and self-efficacy (Weng et al., 2008) are also associated with depression.

Distress has been much less researched, and no accepted definition exists beyond its heterogeneity in terms of emotional symptoms and behaviour (Hudson et al., 2016). However, as with depression, there is some evidence that elevated levels of distress are associated with decision making around dialysis withdrawal (Knowles et al., 2016; McDade-Montez et al., 2006), specifically during the transition to end-stage renal failure (Combes et al., 2017). Like depression (Chilcot et al., 2010), it has also been linked with non-adherence (Ghimire et al., 2015; Hudson et al., 2016).

Fatigue also plays an important role in depression and anxiety and engagement in self-management more broadly and is frequently experienced by haemodialysis patients. Self-reported measures of depressive and anxiety symptoms may capture fatigue as a consequence of disease and of dialysis treatment rather than depressive symptoms per se (Pascoe et al., 2017). Emotions and behaviours may perpetuate fatigue even if it is triggered by clinical factors (Picariello et al., 2018) and it can impact the ability to access social capital (Horigan et al., 2013), potentially leading to loneliness, as well as reduced capacity for self-care (Picariello et al., 2017).

Self-management is critical in limiting the impact of fatigue (Horigan et al., 2013; Lee et al., 2007) and is an important part of symptom management more broadly (Novak et al., 2013). Symptom management is perceived as important to address by patients (Davison, 2010), despite the extent and severity often being underestimated and undertreated by healthcare providers (Cox et al., 2017).

The evidence to date, suggests patients' symptoms should be viewed more broadly, to include more than just measures of physical symptom and measures of depression, but also emotions associated with problems such as fatigue, loneliness, pain, and hopelessness (Moattari et al., 2012). There is already some evidence that self-management interventions may reduce depression and distress in patients on haemodialysis (Cukor et al., 2014; Griva, et al., 2018; Hedayati et al., 2016).

3.4.3 Communication, information, and patient-provider relationships

Ongoing information sharing and good communication has been linked to satisfaction with care but more than that, relationships with healthcare providers are important for patient perceptions of support and sense of control (Cramm et al., 2015; Reid et al., 2016). Staff have a role in reducing uncertainty (Schell et al., 2012) and increasing adherence (Oh et al., 2013; Smith et al., 2010). Nurses and the wider multidisciplinary team (MDT), as well as nephrologists, have a critical role in providing information and identifying treatment goals and support needs (Leung, 2003; Wong et al., 2010).

There is also a strong link with treatment decisions (Oquendo et al., 2017; Reid et al., 2016; Schell et al., 2012, 2013, 2014). For example, where nephrologists' opinions are viewed as crucial in making treatment decisions, levels of regret around the decision to start dialysis, tend to be higher (Berkhout-Byrne et al., 2017). Similarly, Ladin et al (2017) suggest that in discussing treatment options nephrologists are often influenced more by personal experience than expressed patient preferences and that patients need more information about choices available, prognosis and goals of care. This underlines the importance of communication skills in ensuring shared decision making, as well as fully exploring treatment choices and how patients can manage both emotional and physical symptoms (Manns et al., 2014). On this last point, Schell et al. (2013) found that untrained providers tend to ignore emotional data and focus on the clinical, however communication that acknowledges emotion and uncertainty in understanding, helps better prepare patients for the future (Schell et al., 2012).

Patient centred care has been flagged as one important aspect of quality (Aiyegbusi et al., 2017; Morton & Sellars, 2019) Clear and reliable information, communication and education are a requirements for better patient engagement and patient centred care (Bear & Stockie, 2014; Bonner et al., 2014; Cramm et al., 2015) and a number of studies link the importance of knowledge and communication (Gela & Mengistu, 2018; Havas et al., 2017a; Vandenberg et al., 2018; Wu et al., 2016) and enhanced patient provider relations (Curtin et al., 2008; Welch et al., 2015), in supporting self-management. The relationship between patient and provider seems key in terms of delivering information and Bratzke et al. (2015) flag the need to explore further how information can be delivered by health care providers to support self-management more effectively. It is worth noting that the way self-management is defined and measured across these studies varies.

Despite the link between information and self-management, provision of disease specific information will not automatically lead to improvements (Bonner et al., 2014) or behaviour change (Michie et al., 2011). Besides patient provider relations, other factors such as the point on the patient journey, heightened distress or high levels of depression, health literacy and the complexity of managing multiple chronic conditions from the patient perspective, will all influence how information is processed, understood, and acted upon.

Enhanced patient provider relationships have been noted by some as a key element of supporting self-management. Welch et al. (2015) and Curtin et al. (2008) found open communication between patients and providers to be linked to self-management via self-efficacy and how skills are taught to patients. Vandenberg et al. (2018) also links patients’ motivation to engage with self-management, with sharing information in a clear and understandable way.

The association between knowledge and self-management and/or self-care has been found in other research (Ghannadi et al., 2016), and some suggest is mediated by self-efficacy (Curtin et al., 2008; Wu et al., 2016), e.g., higher self-efficacy is significantly related to improvements in communication with healthcare providers. Interestingly, Johnson et al. (2016) did not find an increase in knowledge score with disease progression, indicating patients in CKD stage 4 may need ongoing information in order to boost knowledge. This supports the idea that information needs to be regularly repeated to ensure understanding (Berkhout-Byrne et al., 2017; Schell et al., 2012).

3.4.4 Summary

This overview of three key themes from the literature in ESKD suggests a tripartite model of self-management would best fit a more holistic approach to measurement. There is evidence that all the themes listed in Table 3.1 are key components of self-management, despite the complexity and uncertainty around how they relate. Evidence from the literature review points to potential associations between some of the psychosocial factors that define a broader conceptualisation of self-management, including behaviours linked to clinical outcomes such as adherence. For example, social support has an indirect effect on depression and adherence, but also survival. Self-efficacy behaviours have a similar mediating effect between information and knowledge and self-management (defined using the CKDSC scale developed by Wang et al. (2019)).

It should be noted that the term self-management and self-care were used interchangeably in this study (ibid), as are self-efficacy and self-management in other papers (Welch et al., 2015). This highlights the need for clear definitions and standard mechanisms for measurement.

There is evidence that some factors may be directly associated with self-management (as defined within each of the papers). They are social support (Chen et al., 2018; Gallant, 2003; Havas et al., 2017a, 2017b; H. Li et al., 2014), fatigue (Horigan et al., 2013; Lee et al., 2007), depression and distress (Cukor et al., 2014; Griva et al., 2018; Hedayati et al., 2016), knowledge and communication (Gela & Mengistu, 2018; Ghannadi et al., 2016; Havas et al., 2017b; Vandenberg et al., 2018; Wu et al., 2016) and patient provider relations/support (Curtin et al., 2008; Welch et al., 2015). There is also evidence of a link between self-efficacy and self-management (Knowles et al., 2016; Lin et al., 2017; Wild et al., 2018).

There is considerable overlap and lack of clarity within the literature over the mechanisms that might drive some of the associations, and the way in which self-management is defined and quantified shows considerable variation. There are also many other confounding variables such as age, frailty, education, ethnicity, social deprivation, and health literacy that will moderate or mediate effects. This overview serves to provide an initial conceptualisation of the factors that were identified as the most prominent in relation to self-management. It should be noted that the direction of association for some factors (such as fatigue and depression) remains unclear and how these factors vary by other confounding factors such as age, sex and ethnicity is unknown. Understanding the mechanisms for how factors interplay and affect engagement with self-management goes beyond the remit of this thesis.

Much of the research highlights the need for further research in these areas, but for the purposes of this work, psychosocial factors are critical in describing and explaining engagement in self-management, presented here as the ways in which patients maintain life balance and quality of life, and develop behaviours and strategies that mitigate against the impact of symptoms and treatment.

3.5 RESULTS 3A: OTHER SELF-MANAGEMENT MEASURES

Eight self-management measures used with kidney patients were identified in 15 publications at the time the literature review was conducted (Table 3.2). Information on the specific items is missing for 2 measures (Lin et al., 2013; Johnson et al., 2016) and data on the validity and reliability of the scale couldn’t be ascertained for 4 of the 8 measures (Johnson et al., 2016; Y. C. Song & Lin, 2009; Toobert et al., 2000; Walker et al., 2013) as the scale development was unpublished or the full paper unavailable in English (see appendix A for articles that list the items of the scale where available).

The Summary of Diabetes Self-Care Activities (SDSCA) measure was not specific to kidney disease but was adapted to form the Kidney Disease Behaviour Inventory (KDBI).

Two additional scales; self-management ability scale (SMAS) and patient experience with treatment and self-management (PETS) published by Cramm et al. (2012) and Eton et al. (2017) respectively, were not tested or validated with CKD patients but are referenced below due to the high proportion of psychosocial items (SMAS) and the inclusion of CKD patients in the validation sample (PETS) and use in older, morbid populations.

All the self-management scales have significant limitations and are discussed hereafter.

Table 3.2: Published self-management scales for kidney disease.

Measure	Authors	Country	Year	Population	Items/Domains	Limitations
Kidney Disease Behaviour Inventory (KDBI) was developed using the Summary of diabetes self-care activities (SDSCA) measure	Toobert, D.J., Hampson, S.E. & Glasgow, R.E.	USA	2000	SDSCA validated and scale simplified using analysis from 7 studies in type 2 diabetes populations (n~2,000 total). Adapted for kidney patients and used with both HD and non-HD patients.	KDBI 16-item scale (described by Wild et al., 2017) • Specific self-care activities • Adherence relating to diet, medication, attending appointments and dialysis treatment.	High correlation with PKDSMS. Difficult to evaluate as no specific paper found about development of KDBI.
Behaviours on Haemodialysis Scale BHDS	Curtin R.B., Sitter, D.C.B.S., Schatell, D. et al.	USA	2004	In-centre haemodialysis patients across (n=372, 17 centres)	37-item scale across 8 domains • Suggestions to providers • Self-care during haemodialysis • Information seeking • Use of alternative therapies • Selective symptom management • Assertive self-advocacy • Impression management • Shared responsibility in care	Wording, questions with multiple clauses. Recall period 6 months. Only applicable to in-centre haemodialysis. Limited psychosocial elements.
Haemodialysis self-management instrument (HD-SMI)	Song, Y.C. & Lin C.C.	Korea	2009	Developed and tested using a haemodialysis population attending 4 hospital centres (n=196)	Unclear how many items in the final scale. • Problem solving & communication • Fluid and weight control • Diet and HD • Self-advocacy and emotion control	Developed using a Taiwanese haemodialysis population and translated into Korean in a second study.
	also cited by Cha, J. & Kang, J.		2017	Later tested on an additional HD sample (n=215)		Full texts unavailable in English.
Partners In Health (PIH)® instrument	Walker, R., Marshall M.R. & Polaschek, N.	New Zealand	2013	Recruited from two primary care practices serving areas of high socio-economic deprivation included if at 'high risk of CKD progression' (n=52)	13-item scale • Knowledge of health condition/medications/treatment • Medication compliance • Adherence to a healthy lifestyle	Developed as more generic tool to look at treatment burden in patients with multimorbidity. Results of main study not published.

Chronic kidney disease self-management instrument (CKD-SM)	Lin, C.C., Wu C-C., Wu, L-M., et al.	Southern Taiwan	2012b	CKD patients recruited from two medical centres (n=252)	29-items scale • Self-integration • Problem solving • Seeking social support • Adherence	~90% of participants were stage 2 or 3 of chronic kidney disease. Validated in a Taiwanese renal population.
CKD self-management scale (CKD SM)	Johnson, M.L., Zimmerman, L., Welch, J.L. et al.	USA	2016	Sample recruited from 5 primary care, 3 nephrology clinics and 1 dialysis centre in two Midwestern cities in USA (n=85)	15-item scale No information about specific items or domains.	Tested in patients CKD stage 3. Original scale unpublished. Paper does not include scale items. Just mentions 1 item 'I understand my fluid restriction'
Perceived Kidney/Dialysis Self-Management Scale (PKDSMS)	Wild M.G., Wallston K.A., Green JA, et al.	USA	2017	Dialysis (n=146) and non-dialysis CKD patients (n=237). Collected as separate samples	8-item scale • Illness perceptions • Self-identity	Measure of self-efficacy or perceived competency (internal states) rather than SM behaviours.
Chronic kidney disease self-care scale (CKDSC)	Wang, S.L., Chiu, Y-W., Kung, L.F., et al. Originally cited Wang et al., (2016) but full text unavailable	Taiwan	2019	Convenience sample of CKD patients, excluded those on RRT or had received a transplant	16-item scale • Medication adherence • Diet control • Exercise • Smoking behaviour • Blood pressure	Only validated in a Taiwanese population. Assesses patient perceived self-care.

3.5.1 Kidney Disease Behaviour Inventory (KDBI)

The KDBI (Golestaneh et al., 2022; Wild et al., 2017) was developed from a revised self-care diabetes scale (SDSCA) developed by Toobert et al (2000) validated using data from seven different studies. The scale was then used in a renal population (some receiving maintenance haemodialysis and some not) by Wild et al (2018) and described as a novel 16-item self-reported scale measuring self-care activities required for kidney disease management. The KDBI shows a strong preference for behaviours relating to biomarkers and clinical outcomes. The focus in the paper is on how items in the KDBI correlate with another novel scale; Perceived Kidney/Dialysis Self-Management Scale (PKDSMS) and it is unclear how suitable KDBI is for use in a renal population.

3.5.2 Behaviours on Haemodialysis Scale (BHDS)

The self-reported scale developed by Curtin et al. (2004) was named by Reston (2015) as the Behaviours on Haemodialysis Scale (BHDS) as a name had not been provided by the original authors. The BHDS consists of 34 items over 8 domains and of all the renal-specific measures, goes furthest in its inclusion of some psychosocial as well as clinical self-management behaviours. Validated in a sample of in-centre haemodialysis patients, it includes a cluster of questions which relate to defensive or protective self-management strategies which are related to assertive self-advocacy and impression management. It also includes questions about information seeking, communication and social support. When critiquing the BHDS, Reston reported that whilst it was adequately developed, some of the wording of the questions is ambiguous, social and emotional factors are largely absent, it may be less relevant for home haemodialysis patients and the scale has not been widely deployed in other research.

3.5.3 Haemodialysis self-management instrument (HD-SMI)

This measure was developed by Song & Lin (2009) using a Taiwanese population receiving haemodialysis treatment, for the purpose of measuring self-management behaviours (n=196). Four factors were identified using factor analysis: partnership, self-care, problem-solving skills, and emotion management. Another paper published by Cha & Kang (2017) translated and tested the scale with a Korean sample. Whilst the scale statistics reported in both abstracts appear adequate, neither full paper is published in English so it's not possible to check the development and validation process, aside from it being likely that the scale is not generalisable to a UK population.

3.5.4 Partners In Health (PIH)® instrument

Walker et al (2013) used the PIH scale with CKD patients with a high risk of CKD progression identified via primary care practices. The revised 12-item scale was originally published by Petkov et al (2010) in patient with chronic conditions to assess their self-management knowledge and behaviours. Domains include knowledge, coping, recognition and management of symptoms and adherence to treatment. Walker et al. (2013) developed the original questions and added a further question relating to family support and used the scale to assess an intervention which introduced an individualised patient management plan to a sample of 52 New Zealand Maori and Pacific peoples. Nothing more is reported about the validation of this adapted scale and the authors refer to another study which remains unpublished.

3.5.5 Chronic kidney disease self-management instrument (CKD-SM) #1

There are two entirely separate scales named CKD-SM, both developed in a sample of early, pre-dialysis (stage 2-3) patients. The first described here and developed by Lin et al. (2013) was developed in a sample (n=252) of Mandarin or Taiwanese-speaking adults with chronic kidney disease. Four factors best describe the 29-item scale; self-integration, problem-solving, seeking social support and adherence to recommended regimen. Data presented on scale statistics are limited and the items may not be directly relevant to people at later stages of CKD and receiving haemodialysis. The scale has recently been used in a sample of non-dialysing patients in Saudi Arabia (Almutary & Tayyib, 2022) in which they found an association between knowledge and self-management.

3.5.6 Chronic kidney disease self-management scale (CKD-SM) #2

The second CKD-SM is a 15-item 5-point Likert scale designed to measure self-management in patients diagnosed with CKD stage 3. Details of the validation are referred to (Welsh et al., 2013) but remain unpublished. No information about domains or specific items could be ascertained and therefore it is not possible to evaluate this measure.

3.5.7 Perceived Kidney/Dialysis Self-Management Scale (PKDSMS)

Developed from the Perceived Medical-Condition Self-Management Scale (PMCSMS) which was designed to measure perceived competence across a number of chronic diseases, the PKDSMS has been adapted and validated by Wild et al. (2017, 2018). Tested on a sample that included patients on haemodialysis (n=146) and those not dialysing (n=237). Described as a self-management measure it is actually more a measure of self-efficacy (people’s belief in their capacities and their ability to exercise control over their own circumstances) rather than self-management behaviours and the authors show how it correlates against the KDBI (also listed in Table 3.2). Self-efficacy is linked to self-management in that it can underpin motivation and sense of well-being

The PKDSMS focusses on illness perceptions and self-identity, internal states rather than behaviours. Including only 8 questions, it is limited in scope and broadly ignores social and emotional factors. The authors state that by omitting dialysis from each question, for example “I handle myself well with respect to my kidney disease (dialysis)”, all questions remain valid to patients irrespective of dialysis status. This suggests scales developed in the future may have diverse utility if worded correctly.

3.5.8 Chronic kidney disease self-care scale (CKDSC)

The CKDSC was originally developed by Hu (2009) as part of a part of a doctoral dissertation (unpublished) and aims to measure the “action” part of self-management, self-care. Information about the development and validation of the scale is limited has not been reviewed due to difficulties obtaining the full text (Wang SL et al., 2016). In a subsequent study published by the author and colleagues in 2019, it is described as a 16-item, 5-point Likert scale that is both valid and reliable. It was used for the purposes of the study, to examine factors associated with self-care scores such as CKD stage, BMI and education in a Taiwanese sample of CKD patients across all stages but not currently receiving any form of renal replacement therapy (n=449). The scale contains five subscales, including medication adherence, diet control, exercise, smoking behaviours and blood pressure monitoring.

3.5.9 Additional measures

Two additional scales were also identified but are not included in table 3.5 as neither have been developed, or subsequently tested in a kidney population; the self-management ability scale (SMAS) (Cramm et al., 2012) and the Patient Experience with Treatment and Self-Management (PETS) (Eton et al., 2017).

The first is an 18-item scale that has been validated in older people (n=296) shortly after hospitalisation and at risk for cardiovascular disease. It includes six domains: taking initiatives, investment behaviour, variety, multifunctionality, self-efficacy and positive frame of mind. Whilst it does not include patients with CKD, it includes a high proportion of psychosocial items such as social contact and support and interest and hobbies.

PETS is a tool that has been developed as measure of treatment burden in patients with multi-morbidity and consists of 48 items, across 9 content domains. It is reviewed here because the sample included patients with CKD and co-morbidity is an issue for a high proportion of people with CKD. The scale includes measures of social roles and support, and physical and psychological symptoms, but is not directly relevant for people receiving haemodialysis and contains items relating to medical and healthcare expense issues that may only be relevant in countries like the USA, where the scale was developed.

To conclude, only four measures have been validated or used with samples including those receiving haemodialysis and none of the scales have been validated in a UK or European population which makes generalisability of the scale to such populations less certain. The inclusion of psychosocial factors such as those highlighted in the wider literature review, is limited.

3.6 RESULTS 3B: OTHER SELF-MANAGEMENT MEASURES PUBLISHED POST-2019

Since 2019 when the literature review was conducted, a further three measures have been published, two of which have been used with haemodialysis populations. The Strategies Used by People to Promote Health (SUPPH) (Ibelo et al., 2022; Lev & Owen, 1996), CAPABLE (Devia et al., 2022) and Chronic Illness Self-Management (CISM) (Ngai et al., 2020; Uğuz & Uğuz, 2023) were all published after 2019 and so did not inform the scale development outlined in later chapters of this thesis. However, the measures are described below for the purposes of rigour, and their relevance will be discussed again in the concluding chapter.

3.6.1 The SUPPH

The SUPPH is more accurately a measure of “self-care self-efficacy”, rather than self-management, and it focusses on the strategies that people use to promote health. Originally developed by Lev & Owen (1996) and validated in a sample of cancer patients receiving chemotherapy, it was later used in a haemodialysis sample in a study by Ibelo et al (2022). Despite its generality and focus on confidence, it does contain some important psychosocial elements, treatment decisions, meaningful life, anxiety and stress.

3.6.2 CAPABLE self-management scale

The CAPABLE was developed to assess the self-management capacity of patients receiving peritoneal dialysis, using a small sample of peritoneal (PD) patients (Devia et al., 2022). Its focus is on self-care tasks related to treatment. The three domains are sensory, cognitive and motor capacity and the scale does not contain any psychosocial elements.

3.6.3 The chronic illness self-management scale (CISM)

This instrument was developed by Ngai et al (2020) in a young patient sample (12-45 years with chronic illness) and used with an HD population by Uğuz & Uğuz (2023) in Turkey. The 5-point Likert scale consists of 21 items and 4 sub dimensions: self-stigma, coping with stigma, health care efficiency and treatment implementation. Whilst a generalisable scale aimed at a younger population, it does contain items about feeling worried, feeling alienated, seeking emotional support, maintaining communication and taking care of oneself.

3.7 LIMITATIONS

The literature review was intended to scope the gap in self-management and highlight the need for and importance of a more psychosocial focus when considering the definition of self-management and assessing patient engagement. It was conducted as a scoping rather than systematic review, as self-management is referred to in such a large and diverse range of studies. Given the breadth of the factors considered, it is possible that some important papers from other disease areas and within the broader health field were missed. Or that measures assessing other similar or related concepts were overlooked or seminal papers within the themes of self-management were not captured. Some of the most comparable and noteworthy self-management trials in the literature come from diabetes, which is especially relevant given the number of renal patients with this disease (30-50%, the prevalence is higher in black and south Asian patients). The ambition of the overall study meant that scoping review was conducted within tight time and resource constraints which meant that by necessity, the main focus had to be on kidney disease and relevance to haemodialysis treatment. As there is no gold-standard definition of the concept of self-management, studies exploring patient education programmes or behaviour change interventions not described as "self-management" could have been missed. In addition, some papers couldn't be accessed without purchase and so were not assessed for relevance (Browne & Merighi, 2010; Reid et al., 2011).

Adherence, patient activation and self-efficacy are all concepts linked to self-management and are discussed here and in further chapters but were not search terms specifically used in the literature review. Similarly, a theoretical review of related concepts was not within the remit of what was done here. Given the volume of papers retained in the full paper review, it was not possible to assess the quality of each of the studies but rather ascertain in the broadest sense, which elements of self-management appear important and should be considered for future scale development. For this reason, any associations outlined here must be considered with caution and with consideration of the aims of the study.

Despite these limitations, the literature review was conducted in a timely, systematic, and thorough way and the analysis provides a comprehensive basis from which to move forward to the next steps.

3.8 IN CONCLUSION

No measure of self-management currently exists that encompasses factors and behaviours beyond self-care and the dialysis process itself, and those of more medical importance such as adherence. Patients were not involved in development of any of the scales included in table 3.5, and few involved any clinical staff in the early stages of scale development (expert consensus). Engagement such as this is essential for content validity (discussed further in chapters 4 and 6). Terms such as self-care, SM and self-efficacy vary in definition and the terms are often conflated. Specific measures for use with CKD patients on dialysis in the UK that include psychosocial factors are missing from reported research, despite the evidence that factors such as social support, psychological and physical symptoms of illness and treatment, and communication with healthcare providers are relevant to self-management and patient engagement in care and wellbeing. Scales from other countries are likely to translate poorly, and moreover, broadly all underplay the social and emotional self-management behaviours.

This resonates with the broader point made by Janssen et al. (2015) that: "So far, patient preferences have rarely been considered in choosing patient-relevant outcomes for research in the area of CKD stage 5" (p848). However, more recently (and since this literature review was first conducted) there have been notable exceptions (Jaure et al., 2024; Evangelidis et al., 2021; Manera et al., 2021; Farragher et al., 2020).

The evidence suggests increased patient engagement in self-management enhances outcomes important to patients, such as quality of life and reducing symptoms such as depression and tiredness. There is also evidence it may improve some outcomes important to healthcare providers such as adherence. However, it is likely that many patients may need support to optimise engagement with self-management.

By demonstrating the importance of psychosocial factors, the literature review is the springboard from which a new measure can be developed. Without a multidimensional measure of self-management, it may be difficult for patients and healthcare providers to identify support needs around better patient engagement with self-management. The intention is that a more holistic, patient-focussed measure can be developed and validated in a haemodialysis population. The measure can then be used in research but also to identify support needs in clinical practice to enable support to be targeted where it is most required. Underpinning this is the fundamental question of how to identify what support people need to engage fully in self-management and what might be missing?

The literature review provides the theoretical foundation for defining potential domains for the development of a novel self-management scale based on the tripartite model of health. The next step is to use qualitative methods to move from the theoretical to the lived experience.

The development of a self-management scale that incorporates psychosocial behaviours feels in this context, more relevant than ever. To summarise:

Self-management behaviours can be better and more broadly defined to include aspects of medical, emotional and social concepts. There is currently no tool or measurement that allows self-management to be quantified in a way that is more meaningful for patients while remaining relevant to clinical teams.

Having explored the conceptualisation of self-management, there is evidence of the need to reconceptualise the term within a new, more holistic measure. The aim of this thesis from this point, is to describe the development of a novel multidimensional scale to measure self-management behaviours among people receiving haemodialysis. The scale will be based on a definition of self-management in its broadest sense with the intention that this scale can be used in research and clinical practise in the future.

This chapter has explored how self-management is conceptualised and measured in the kidney research literature. The following chapters outline the work that was carried out to address the second aim, to develop a more holistic self-management measure specific for people receiving haemodialysis treatment using a mixed methods approach and involving a community of experts and people with lived experience.

Empirical data from two studies form the basis of this thesis. The work of this thesis is considered exploratory and is likely form the foundation of further work. The construct and the scale itself will evolve together and it is likely that more than one dataset will be required to truly evaluate the scale, in a confirmatory approach.

CHAPTER 4 : GENERAL METHODS

4.1 INTRODUCTION

The work presented in this thesis comprises a series of studies. The need for a novel self-management measurement was ascertained in an initial scoping review (chapter 3), which concluded that there is a need for a measure underpinned by a broader definition of HD-specific self-management, which is relevant to patients. There is no self-management scale relevant to this population that is multifaceted and developed from patient experience and expert consensus using a UK sample. With that established, the second aim was to develop a novel and more holistic HD-specific measure of self-management and evaluate the psychometric properties using a large patient sample. As part of this process, and as an extra step, a further study was conducted to begin to understand how it might be implemented in the clinical setting, the potential barriers and facilitators, and the views of key stakeholders on utility and feasibility.

Figure 4.1: Self-management scale development framework (study one).

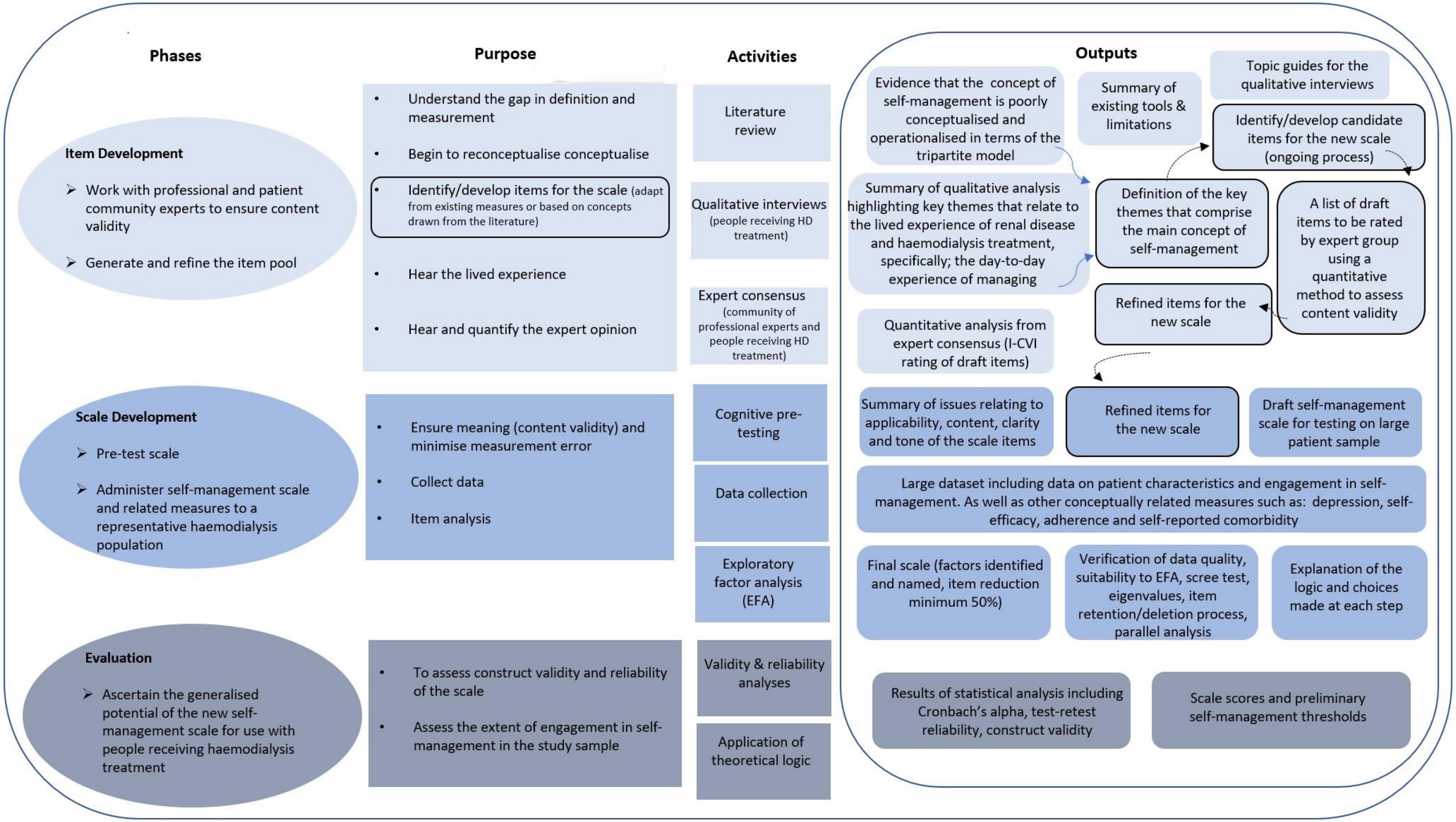
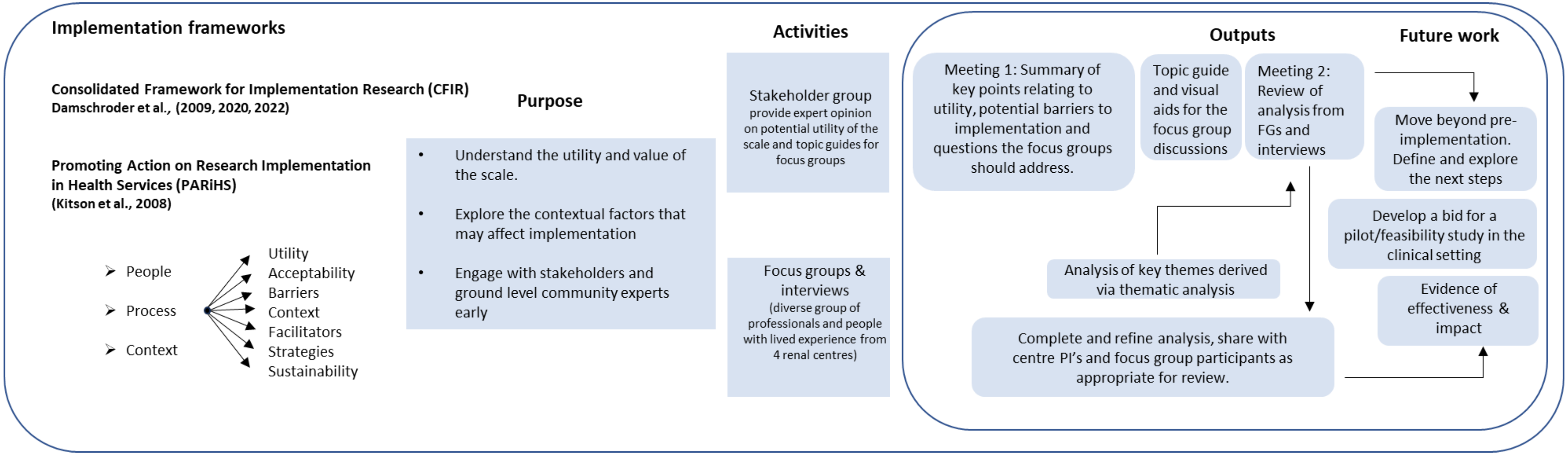


Figure 4.2: Pre-implementation exploratory qualitative analysis (study two).



- Understand the utility and value of the scale.
- Explore the contextual factors that may affect implementation
- Engage with stakeholders and ground level community experts early

Stakeholder group provide expert opinion on potential utility of the scale and topic guides for focus groups

Focus groups & interviews (diverse group of professionals and people with lived experience from 4 renal centres)

Meeting 1: Summary of key points relating to utility, potential barriers to implementation and questions the focus groups should address.

Topic guide and visual aids for the focus group discussions

Meeting 2: Review of analysis from FGs and interviews

Analysis of key themes derived via thematic analysis

Complete and refine analysis, share with centre PI's and focus group participants as appropriate for review.

Move beyond pre-implementation. Define and explore the next steps

Develop a bid for a pilot/feasibility study in the clinical setting

Evidence of effectiveness & impact

4.1.1 Design Overview

The methodological processes will be described in this chapter and are shown in Figure 4.1: item and scale development and evaluation and Figure 4.2: exploration (otherwise described as pre-implementation) of the context-specific factors that might influence implementation processes and outcomes. Ensuring content validity of the scale during development and ascertaining acceptability at the early stages of implementation is important and the key reason for stakeholder involvement (patient and professional) across all elements of the work.

The work was undertaken using an exploratory sequential 3-phase mixed methods approach that involved members of the kidney community, both professionals and those with lived experience (study one). This mixed methods approach, involving those from the target population is recommended (Boateng et al., 2018; Morgado et al., 2017) and is critical to a process of scale development and evaluation that is both systematic and rigorous and is more likely to deliver a robust, multidimensional, generalisable psychometric scale. A further step, often omitted post-scale development, was undertaken using qualitative methods (study two). A pre-implementation exploration of the potential utility of the scale and the setting in relation to implementation (people, processes, context) was conducted with stakeholders. There is no single theory that underpins the entire process, however relevant theories are discussed within the description of each study and the composite phases. The various activities undertaken within each of the phases of the scale development and evaluation study, represent a multiple approach that aims to effectively tackle conceptualisation, contextualisation, and operationalisation issues, as recommended by Younas & Porr (2018). In addition, study two was designed to provide some insight into whether the need to implement the scale is a view shared by staff and patients, whether there is a readiness for change within the specific context of HD care and how future studies to further validate the scale and address feasibility might be designed.

Involvement of patients and professionals in scale development is essential for ensuring content validity (relevance, representativeness, and quality) and should begin at the very start of the scale development process (as noted in chapter 3). It is a prerequisite for validity and should be prioritised during scale development (Zamanzadeh et al., 2015). The approach to scale development for this thesis examines self-management through the lens of lived experience, rather than following others via a disproportionate emphasis on what is considered most important clinically. This issue has been discussed previously in chapters two and three and is a common limitation of other measures of self-management in LTCs and CKD more specifically.

The pre-implementation work, utilised online data collection methods due to the ongoing pandemic and data were analysed in conjunction with implementation science frameworks.

The empirical data collected and analysed within each of the two overarching studies will be addressed in chapters five to eight, along with specific methodological issues not covered in this chapter. The studies are constructed as follows:

Study one – scale development and evaluation

1. The development of a set of concepts and themes related to the lived experience of self-management for people receiving HD.
    a. Literature review – Identify the gaps in the conceptualisation of self-management in kidney care (chapter 3)
    b. Qualitative interviews: the lived experience – Describe a more holistic approach to self-management rooted in the patient experience (chapter 5)
        i. Mapping the themes across the methods
    c. Developing the scale items – expert panel (chapter 6)
    d. Item reduction: consensus via Item-Content Validity Index (I-CVI) rating
2. Scale development
    a. Testing item coherence – cognitive interviews
    b. Survey
    c. Item reduction and extraction of factors
3. Psychometric Evaluation
    a. Tests of validity and reliability
        i. Correlation with other measures
    b. Associations between self-management score and sample characteristics (chapter 7)

Study two - Pre-implementation exploration –

4. Understanding the implementation context, barriers and facilitators to implementation and stakeholder perspectives (chapter 8)
    a. Engaging with stakeholders
    b. Focus group discussions with clinical, multidisciplinary staff and patients.

4.1.2 Common limitations of scale development

A number of papers have been written in recent years, highlighting best practice in scale development. Importantly, they also highlight common methodological issues and pitfalls. These include, underinclusive and/or small item pool and poor conceptualisation of the constructs (Boateng et al., 2018), poor item wording, use of homogenous or unrepresentative validation samples Clark & Watson, 2019), or small samples (Morgado et al., 2017), and an exclusively deductive approach in which content validity is not properly assessed (ibid). To mitigate against this work succumbing to such pitfalls, the work adopted multiple approaches and aligned with recommendations for best practice for psychometric scale development (Boateng et al., 2018; Clark & Watson, 2019; Jebb et al., 2021; Morgado et al., 2017; Younas & Porr, 2018), with an emphasis on content validity. This will be illustrated within this chapter and beyond.

4.2 GENERAL PROCEDURE AND DESIGN ISSUES

4.2.1 Ethics

Both studies received joint research funding from Kidney Care UK (KCUK) and British Renal Society (BRS). The author developed the protocol and led the first study, as well as conducting all the empirical work. The author led the second grant application, developed the protocol, and oversaw the work as chief investigator; facilitating all the stakeholder and focus group meetings, with support and mentorship from the wider team.

The scale development study was approved by East Midlands and Leicester South NHS Research Ethics Committee, REC reference: 17/EM/0451. The work was sponsored by East and North Hertfordshire NHS Trust. The pre-implementation exploration study was approved by Brighton and Sussex NHS Research Ethics Committee, REC reference: 21/PR/0144. Local research and development approval was obtained from each of the participating kidney centres for both studies. Ethics approval letters are provided in appendix B.

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4.2.2 Consent

Participant information sheets (PIS) were provided prior to obtaining written and verbal consent, these were tailored according to role as patient or clinical participant. All participants were given sufficient time to consider their involvement. As part of scale development, patient participants consenting to the survey could also consent to follow-up for the purpose of test re-test (completing the scale a second time at least 4-weeks after initial completion).

4.2.3 The setting

Five kidney centres were involved in the studies: Lister Hospital, University Hospital Birmingham (UHB), the Royal Free Hospital (RFH), Preston Hospital and Kings College Hospital (KCH). Lister and UHB were involved in both studies. Data presented in the following paragraph are taken from the 25th UK Renal Registry Annual Report data to 31/12/2021 (UK Renal Registry, 2023). Data for RFH represent Royal Free, Middlesex and UCL Hospitals, and data for UHB represent Heartlands Hospital and Queen Elizabeth Hospital.

These sites were recruited due to diversity in size, services, and patient population. Both UHB and RFH offer in-house transplantation services. The largest centre is UHB, which since 2018 has provided services to up to 3,312 prevalent patients on KRT and 372 incident patients. RFH is the second largest provider, seeing numbers up to 2,380 and 283 respectively. KCH and Preston see a similar number of patients, with Lister the smallest unit; prevalent patients being up to 1,014 and incident patients 194 (data from table 3.1, UK Renal Registry, 2023). Across the sites and of those on haemodialysis, between 1.1% (Royal Free) and 7% (Preston) are receiving home HD. All centres show a degree of variation in the ethnic background of their patient population. Of in-centre haemodialysis (ICHD) patients, the proportion of Asian patients ranges from 13% at KCH to 31% at UHB. KCH has the highest proportion of black patients; 47.4%, compared to 15.1% at UHB, 9.8 % at Lister, and 1% at Preston. The highest proportion of White patients are seen at Preston (78.8%). The median age of those on in-centre haemodialysis ranged from 62.3 years at Kings to 65.8 years at Preston (data from table 5.2, ibid). This compares to a range of 52.2 years at the Royal Free and 55.3 years at Preston for home HD patients (data from table 7.3, ibid). HHD patients are approximately 10 years younger than ICHD patients.

4.2.4 Participants

4.2.4.1 Patients

All participants recruited in the first study had been receiving HD treatment for at least 3 months either in-centre, at a satellite unit or at home, were able to read and speak English sufficiently well to engage with the interview and/or data collection, were over 18 years old and had capacity to give informed consent. Participants were excluded if deemed by their consultant nephrologist to be too unwell to take part. Inclusion criteria remained the same across all activities and data on participant recruitment and any variation by centre will be reported in the relevant chapter.

For the second study, participants were not required to be current HD recipients or to have ever received HD treatment. All were people with CKD irrespective of current treatment status.

Patients were involved in both the steering groups and expert panels across both studies, and within this context were not considered participants but experts by experience. As such, formal consent was not required (see section 4.2.4.3 below).

4.2.4.2 Professionals

Participants that can be described as professional were clinical or MDT staff working within the kidney services recruited to the second pre-implementation study. They were selected by the kidney centre principal investigator (PI) based on their role within kidney care and interest in patient-centred approaches to self-management or other relevant interests such as self-care, frailty, and supportive care. They included nephrologists, nurses, dieticians, counsellors, psychologists, and senior managers and were recruited to the focus groups in the second study.

4.2.4.3 Others involved for which consent wasn't required

Neither the expert panel in the first study or members of the stakeholder group involved in the second study were consented as study participants, irrespective of whether they were experts by experience or healthcare or allied healthcare professions or other. Aside from the wider research team, only two people were involved in both groups. Data on the stratification by patient or profession are included in the relevant chapters. Most members of the group were identified via the research team's professional network.

4.3 WHAT IS A SCALE?

A scale can be described as a measure of attributes or behaviours relating to a broader concept which uses multiple questions to generate a whole-scale score. Scales are "useful tools to attribute scores in some numerical dimension to phenomena that cannot be measured directly" (Morgado et al., 2017).

A 7-point Likert scale was chosen as it is a common format for measurement of psychosocial constructs and related behaviours, lends itself to self-reporting (Jebb et al., 2021) and gives some indication of the magnitude or severity of a need or issue. Using a numbered scale indicates to the respondent that the scale is linear and aligns with parametric methods of analysis. These assumptions are addressed later in this chapter.

4.4 PRELUDE TO THE PHASES AND ACTIVITIES

The rest of this chapter provides a descriptive overview of the main phases and activities, that align with Figure 4.1 and Figure 4.2. This will include further detail about the theories of scale development, evaluation and frameworks that support pre-implementation. Four key things to consider as we move through the description of the methods and onto the empirical data presented in chapters 5 to 8 are:

- Self-management needs to be defined more comprehensively and with the patient perspective in sharp focus.
- Scale development is both a scientific and creative process.
- Qualitative methods contribute to an evidence-based approach and are a critical aspect of scale development.
- Intention to change clinical practice can only work when key stakeholders are engaged and see the potential benefits even before effectiveness is ascertained.

4.5 PHASE ONE: DEVELOPING THE CONCEPT AND GENERATING THE SCALE ITEMS.

The concept of self-management has been discussed and defined in chapters 2 and 3. The initial working definition is reiterated here:

Self-management is the term given to the tasks undertaken by an individual living with a chronic disease and its treatment. Self-management tasks incorporate not only adherence to medically prescribed treatment, but also tasks relating to continued social functioning, and tasks of adapting emotionally to living with the condition and its treatments (Reston, 2015).

The overview of the literature review in chapter three suggests this should be broadened. Current thinking is well summarised in the following two definitions.

Self-management support should take a multi-disciplinary approach that enables integration of the illness into a person's life context by addressing the emotional consequences, treatment impact and effort required to manage. Support should be such that people can continue living a life, rather than living an illness. This needs to acknowledge the physical, emotional, social, vocational and existential work of chronic illness adjustment (adapted from Whittemore & Dixon, 2008).

Self-management is a dynamic process of behavioural adaption, utilising social capital to alleviate the impact of disease and treatment in order to maintain quality of life (adapted from Lawless et al., 2021).

In summary, any new scale seeking to measure the concept of self-management in chronic disease, should recognise the dynamic nature of treatment and illness experience and the ability of a patient to engage in self-management at any given time. It should be multifaceted, covering elements of the social, emotional, physical, activities of daily living and clinical. Self-management is not the responsibility of any single individual and whilst it should be driven by patient-centred goals, requires support by social networks and health-care providers. Improvements in quality of life may be a more important measure of improved self-management support than clinical measures.

In describing this more holistic definition of self-management, and drawing on further evidence from the lived experience, the next step is to develop relevant themes and scale items for a HD-specific scale. Item development should use both inductive and deductive approaches to analysis e.g., evidence from existing literature and qualitative data from interviews with the population of interest (Morgado et al., 2017). Item review by "experts", in this case, professionals and people with lived experience in the kidney community also aligns with this approach (Clark & Watson, 2019). Commonly used in health research, this design is associated with improved inclusivity and diversity of perspectives, which may strengthen validity of the scales (Song et al., 2011).

4.5.1 Process of item development

The scale items were developed in line with best practice, with the aim of capturing the lived experience (Boateng et al., 2018) to ensure latent constructs; behaviours but also perceptions, are captured by the scale. Themes were developed from the literature review (chapter 3) and then qualitative interviews with patients conducted between September 2018 and January 2019 (chapter 5) were used to generate a parallel source of themes derived from the lived experience. The items were developed from these themes, supported by a workshop with an expert panel of professionals and patients from the kidney community. A subsequent consensus process involving this same panel, was used to narrow down the pool of items. Each component of the overall process provides evidence of the content validity in the final scale and is the crux of the scale development process (Robinson, 2018).

The themes that were inductively generated from the empirical data from the patient interviews, were mapped back to those that had emerged in the literature, with the purpose of generating the scale items in conjunction with an expert panel. Research by Younas & Porr (2018) highlights the importance of using literature reviews to identify existing scales from which individual items can be adapted and modified, rather than generating completely unique items. Therefore, items were adapted from existing measures in other areas of chronic disease where available and suitable for adaption.

Previous work by (Reston, 2015) referred to in chapter 3, identified an unpublished scale he refers to as the Behaviours in Haemodialysis Scale (BHDS), developed by Curtin et al (2004). This was identified as the current best option for measuring self-management in HD patients. As part of this thesis, changes to structural elements and broader issues identified with BHDS by Reston were made and the items considered for inclusion as part of the scale development process. This is discussed in more detail in chapter 6.

Items were also constructed by the author based on concepts drawn from the literature, and themes and sub-themes identified in the patient narrative. Items from the best alternative to an existing CKD self-management scale, was also reviewed. All potential items were compiled within themed tabs in an excel spreadsheet and the set shared with the consensus panel was first reviewed and refined over several meetings by the research team. The research team itself had good clinical and methodological representation.

From the outset, it was decided that the items of the scale should focus mainly on behaviours or factors that have a demonstrable impact on self-management behaviours, rather than perceptions or cognitive processes such as beliefs, motivation, and intentions. Behaviours are easier to ascertain when attempting to present the concept as it is understood by people living with the condition and experiencing treatment.

Items generated via these multiple sources of evidence were reviewed, shortlisted and amended through a process of consensus and cognitive pre-testing.

4.6 THE LIVED EXPERIENCE

The literature review highlights the kidney-specific gap in operationalisation of a patient-centred concept of self-management, and the methods are explained in the previous chapter. The next step was to better understand the lived experience of illness and treatment and the broader challenges that individuals face outside the clinical setting. This qualitative work is then used in conjunction with analysis from the literature view to inform item development.

4.6.1 Sampling, and inclusion and exclusion

In developing the scale, the focus for patient recruitment was on people receiving HD as they tend to experience the greatest treatment burden and represent the greatest proportion of those on KRT as outlined in chapter 1.

To maximise the likelihood of a representative sample, similar in characteristics to the wider UK dialysis population, a purposive sampling method was implemented. Heterogeneity in age range, sex, time since diagnosis, number of years on dialysis (vintage) and ethnicity was prioritised. Oversampling of South Asian and Black people reflects the disease and HD burden outlined in chapter 1. Further details on heterogeneity of the sample are given in chapter 5. Patients on HD for less than 3 months or not deemed by the clinical team to be well enough to participate, were not approached for recruitment. Participants had to be 18 years or over, be able to read and speak English sufficiently well to engage with the interview and have the capacity to give consent.

4.6.2 Procedures (recruitment, consent, data collection)

The lived experience was explored with a target sample of 28 people receiving HD treatment, with the intention of using a combination of focus groups and one to one interview. Focus groups allow respondents to explore individual experience in the context of shared experience (Tong et al., 2007) and allow consensus of ideas to develop, whilst interviews allow topics most relevant to an individual to be explored in more depth. Participants could express a preference for interview or focus group, and in this instance, all those approached indicated a preference for interview. For the purposes of pragmatism, specifically to ensure high recruitment levels, it was decided to proceed with interviews only. The potential impact of interview-only data collection is addressed in chapter 5.

Written consent was obtained by the researcher just prior to interview, in addition verbal consent was audio-recorded at the start of the interview. Copies of written consent were shared with participating centres and filed within the patient records.

All interviews were conducted by the author during in-centre or satellite unit dialysis sessions, with two others interviewed in their own home (at their request). Neither were on dialysis at the time. Every consideration was given to maintaining respondent privacy and confidentiality in all locations. Interviews followed a semi-structured format (appendix C) informed by the findings of the literature review. The topic guide interview led an exploration of each patient's day to day experience of living with ESKD and how they manage, specifically, how they cope with illness, symptoms, treatment and life more broadly, and the social, emotional and physical impact they experience and strategies they use to deal with related issues.

Interviews were convened post-consent and audio recorded. Transcription was conducted by two external service providers, and sense-checked for accuracy against the audio where necessary. Some technical or medical terms were incorrectly transcribed. In some of the recordings the sound quality was variable due to noise from the unit and sounds from the dialysis machine. Every effort was made to recover as much of the data as possible by the lead researcher, but where this was not possible "inaudible" was noted on the transcript.

4.6.3 Analysis

Transcripts were entered into NVivo 12 (QSR International Pty Ltd) software and analysed by four members of the research team, including the author. Data were analysed thematically, using a "bottom up" or inductive approach in which the themes are strongly linked to the data themselves. An inductive approach is commonly used in health research and is particularly suited for exploratory analysis. Taking an approach that enabled a coding framework to evolve, complemented the aims of the study.

The approach is not bound by theory and does not need to fit a pre-existing coding frame (Braun & Clarke, 2006). However, coding was contextualised by the findings from the literature review in the sense that all researchers were primed to think about factors related to social and emotional aspects of self-management. This is explored further in the discussion (chapter 9).

Each researcher coded the same six scripts and then inconsistencies and agreements in coding were discussed. While overlap in codes was expected, assumptions and disparities could be reviewed, and broad consensus reached using this approach. A coherent coding frame generated from these six scripts was then broadly applied to the remaining scripts by the lead author. This approach was adopted due to time and resource constraints, but is an accepted method (Coates et al., 2021). The themes and sub-themes remained open to modification and the coding frame was adapted and viewed as iterative when applied to the remaining scripts in a process that was systematic without being rigid (Bryman & Burgess, 1994).

The themes identified from the analysis were mapped back to the literature and clearly defined in terms of the broader concept of self-management. This analysis was used to inform item development and guide the expert consensus process.

4.7 FINDING CONSENSUS: DEVELOPING THE SCALE ITEMS AND REDUCING THE ITEM POOL

A panel of professional and lived experience experts was convened to support the development of scale items and themes, then participate in a consensus process to reduce the item pool. Evaluating the scale items and content in terms of the conceptual definition of self-management via consensus strengthens content validity (Younas & Porr, 2018) and is a standard method (Murphy et al., 1998). The process of consensus adds credibility to the preceding process and presents an opportunity to flag or check for any researcher bias that may have occurred in prior stages, particularly in relation to the qualitative component.

4.7.1 Recruiting the expert panel

Using a convenience sample approached via the research group's professional network, the target recruitment was between 15 and 20 experts, which was achieved. Lynn (1986) recommends a minimum of five, but Rodrigues et al. (2017) suggest the number may be anywhere between 2 and 20, with the general principal that confidence in the ratings will increase as the number of judges increases (Haynes et al., 1995). Maximising the number of panel members also reduces the risk of agreement being inflated by chance factors (Polit & Beck, 2006). In addition, it was hoped that over-recruitment would mitigate against any potential effects of drop out.

The panel included both experts with a professional interest in kidney disease and self-management, and those from the target population (people with ESKD on HD). The quality of any patient-reported measure relies on adequate input during item and scale development from patients as the primary experts (Terwee et al., 2018). Using a combined panel of professionals and patients increases confidence in the content validity of the scale and is recommended (Bastos et al., 2010; Clark & Watson, 1995).

4.7.2 Procedure

The involvement of the expert panel began with a workshop to discuss the concepts and themes generated by the literature review and patient interviews. Important themes were identified, and others deprioritised. The group began to define themes and develop items through discussion. This work guided further item development by the author.

Some months after the initial workshop, consensus of a broader set of candidate items was assessed using item content validity index (I-CVI) rating. This is a method to calculate content validity quantitatively using proportional agreement (Lynn, 1986), and is the most used approach (Polit et al., 2007). This process was conducted via email in two sequential rounds to allow for a more iterative process of item reduction.

Using I-CVI, each panel member was asked to rate each item on a scale of 1 to 4, where 1 is not relevant, and 4 is highly relevant.

Clear instructions about the rating task were provided to the panel, including comprehensive descriptions of each of the themes. Aside from assessing content and relevance to the theme and overriding concept, the panel was asked to assess the wording of each item in terms of simplicity, ambiguity, and tone. Norman & Cairney (2015) stress the importance of avoiding value-laden words, excessive length of statements and nuance. Experts were asked to write additional comments and suggested word changes to the electronic copy of the document.

This process of I-CVI was conducted twice due to the volume of candidate items for the scale. The research group reviewed each iteration and made judgements about further deletion of items due to content overlap, as well as wording modifications.

4.7.3 Analysis

The overall rating was calculated as the number of experts rating 3 or 4 as a function of the total number of experts (Polit & Beck, 2006). Values range from 0 to 1 and I-CVI ≥ .78 was used to determine acceptable validity and inclusion in the self-management scale (Lynn, 1986; Polit et al., 2007). This rating, along with other factors outlined in chapter 6, informed the decision to include or discard items for the draft scale to be used in the survey as part of the scale development process.

4.8 SUMMARY OF PHASE ONE

Throughout this process of concept definition and item development, consideration of content validity and methodological rigour was the central focus. The move from item development to scale development was less definitive and more iterative than sub-headings within this chapter allow. After considerable drafting and redrafting of potential scale items, activities relating to scale construction ensued including some cognitive pre-testing and further redrafting of the items.

4.9 A NOTE ABOUT SCALE FORMAT AND RESPONSE OPTIONS

To allow for sufficient variation in response, a 7-point Likert scale was selected. Internal consistency has been found to be highest for scales with seven or more points (Preston & Colman, 2000). An additional contributory factor was the complexity of the overall concept and the potential ability for those with lived experience to make more granular distinctions. Considerable variation in responses between participants was anticipated, assuming participants would make use of the full scale. This assumption can be checked using the data and is done in chapter 6. There has been some discussion in the literature about whether it is better to include odd or even response options. Some have argued that a middle option can be ambiguous which may increase measurement error (Simms et al., 2019). Use of the middle option may reflect a moderate position on the item, uncertainty for the respondent regarding their position, confusion around the meaning, or when the respondent views their answer as context dependent (Kulas & Stachowski, 2013). All but the first scenario could increase measurement error. However, Simms et al. (2019) conclude “there is no clear and unequivocal psychometric penalty” for using a middle option and can actually lead to a reduction in mis-response to reversed items (Weijters et al., 2009), a matter that is relevant to this scale and will be dealt with in chapter 6. What is clear however, is that a smaller number of response options have a negative impact on the reliability and validity of a measure (Simms et al., 2019).

4.9.1 The ‘not applicable (NA)/don’t know (DK)’ answer choice

Response options were extended so that “NA” or “DK” could be selected as an alternative. When conducting structural analysis of the BHDS scale developed by Curtin et al. (2004), Reston (2015) commented that some questions were not applicable to the participants, and in cases of limited applicability it would make sense to have such an option to avoid missing data, which may occur when participants feel a question is not relevant to them. Similarly, the don’t know option might be selected if the meaning of a question is unclear, or they do not have an opinion. This item included in the novel self-management scale: “I adjust my phosphate binder dose to the size of my meal” may not be applicable to all patients, or at least some patients may believe it isn’t (Umeukeje et al., 2018). In a literature review of survey response scale characteristics, DeCastellarnau (2018) concludes that it’s not clear what impact the use of a “DK” option has on data quality, however Dillman et al (2014) suggest the risk of alienating respondents can occur when the content of an item does not apply to them. Frequency of these responses are summarised and discussed in the analysis.

4.9.2 Response options

A heterogenous sample of response anchors were selected. They were checked for relevance and any ambiguity during cognitive pre-testing (described below).

The response anchors varied according to the statement and as such the scale format can be described as item specific. For example, “I understand how my illness is likely to progress” had the responses “strongly disagree” and “strongly agree” whilst “I feel that I cannot cope with all the things I need to do” had the responses “often” and “never”. The choice to use heterogeneous, item-specific, anchor response labels reflect the breadth and complexity of the underlying self-management construct and the need for non-standardised response anchors (Artino et al., 2011).

In a review of articles published in the Journal of Applied Psychology (JAP) and the Academy of Management Journal (AMJ) between 2005-2009, the most common context label used was agreement; 57% (n=548) of scales (Casper et al., 2020). For the final version of the self-management scale approximately one third; 21/61 items used agreement anchors; the remaining two-thirds varied. Previous work by other authors has shown that agree-disagree scales have been associated with acquiescence bias i.e., the tendency to agree (Billiet & McClendon, 2000). In addition, there is evidence that item-specific responses that link the question with the response i.e. “I am angry about my kidney disease” response as “very angry/not angry at all”, tend to have higher data quality (Saris et al., 2010).

Three items in the scale used this reflection technique. The intensity of the response options also shows variation. Intensity refers to the degree to which an attribute (such as judgement) is expressed by a label (e.g., not at all vs. very), these labels amplify meaning and there is a suggestion that minor variations in the amplifiers used can influence questionnaire response. The item about anger is an example of a strong amplifier, but the importance of the term angry is linked to initiation of dialysis, adherence and involvement in decision making and is evidenced in the literature (Demain et al., 2015; Hudson et al., 2016; Lunyera et al., 2018; Sohn et al., 2018; Taylor et al., 2014).

After item development, 23 different response options were developed to fit the range of items. These reflected frequency of a behaviour (e.g., always to never), degree or extent (e.g., not at all confident to very confident), level of agreement (e.g., strongly disagree to strongly agree), and knowledge of action (e.g., not at all true to completely true). Anchors were provided for the extreme values, i.e., 1 and 7, this format is referred to in the literature as numerical rating scales, rather than a fully anchored rating scale when each number has a word description (Harpe, 2015). This format seems intuitively more in line with interval scale assumption and indicates to responders that the anchors have equal intervals. This goes someway to mitigate against measurement error and is easier to construct (Casper et al., 2020; Weijters et al., 2009).

4.9.3 Positive/negative wording

To counter acquiescence, both positively and negatively worded questions were constructed. Four of the negatively phrased questions were also reverse scored. Negatively worded items are generally used as "cognitive speed bumps" to prevent participants slipping into inaccurate automatic response patterns (Podsakoff et al., 2003, p. 884). They are also useful when a construct is more clearly represented in this way. An example being: "I wasn't as involved in the decision to start dialysis as I would have liked". However, difficulties with using a mix of negatively and positively worded items has been identified in the literature (Kamoen et al., 2013; Salazar, 2015), this is addressed in more detail in chapter 6 and was examined as part of the cognitive pre-testing.

4.10 PHASE TWO: SCALE DEVELOPMENT

The process of scale development includes cognitive pre-testing as a further step in item refinement, then data collection via a large-scale survey.

4.10.1 Cognitive pre-testing

When participants complete a questionnaire or scale while also being asked about the questions or items as they do so, it is known as cognitive pre-testing. The purpose is to evaluate face validity of the scale which refers to the applicability, content, clarity, and tone of the scale items. This helps ensure that the scale remains meaningful for the target user and that the questions are easily understood, not ambiguous or difficult to answer (Younas & Porr, 2018); this minimises measurement error.

4.10.2 Sampling, and inclusion and exclusion

A small group of people (n=11) receiving HD were asked to assess the items via cognitive pre-testing. All were from one of three of the kidney centres recruited to the study (Lister, UHB, RFH). Inclusion and exclusion criteria were the same as for the qualitative interviews.

4.10.3 Procedures (recruitment, consent, data collection)

Participant information sheets were received prior to the interview and written, and verbal consent were provided as described previously. Together, the lead author and participant read through the scale items. Using a combination of think aloud and verbal probing, participants were asked to sense check scale items. Think aloud is a well-suited approach to exploring these aspects of newly developed questionnaires or scales (Willis & Artino, 2013).

A sampling plan ensured that each patient reviewed a set of items rather the entire 66 item scale plus demographic questions. Comments, quotes, and action points relating to each item were recorded (Conrad & Blair; 1996, 2001).

Data from this activity consisted of both the participant's answers to the questions but views on how the questions worked and any required changes to wording or format. Details on the script questions and probes that were used can be found in chapter 6.

4.10.4 Analysis

Data were analysed using an approach adopted by Conrad & Blair (1996) in which issues, response hesitation and specific comments on wording, response categories, content etc were assessed.

As part of this, a preliminary check of floor/ceiling effects was possible, ideally some variability in responses should be evident despite the small sample size. Analysis of the data from the interviews underpinned subsequent rewording and further elimination of items. Cognitive interviews were conducted, coded, and analysed by the author alone.

The final scale comprised 60-items, a 3-fold reduction from the number of candidate items entered into round one of I-CVI. Anticipating a further loss of 50% of items, from 60 items we expected the final scale to consist of between 25 and 30 items.

The final order of questions was determined using a random number generator. The first three questions were positively phrased and selected prior to randomisation. With a ‘positive start’ the idea being to enhance the perceived benefits of responding and reduce any perceived barriers than a more negative question at the start might trigger (Mccoll et al., 2001). The two questions about work were randomised along with the others but kept together for the purposes of consistency and to enable filtering whereby respondents for whom this is non-applicable can easily skip both. The order was checked to ensure there weren’t clusters of negatively phrased items and that the distribution of positive and negative phrasing was relatively balanced to reduce the likelihood of “response set” bias (ibid).

4.11 LARGE-SCALE SURVEY

The psychometric properties of the final draft version of the scale were tested on a large, heterogenous (>350) cross-section of people on HD from the same kidney centres referred to in the participant section. A classical test theory (CTT) is useful in providing a quantitative assessment of scale items. It requires that each item should be distinct from the others yet similar and consistent in reflecting all important respect aspects of the underlying attribute or construct (Cappelleri et al., 2014). Distribution of item responses, evidence of floor and/or ceiling effects, and distribution of total and domain scores were examined in the analysis of the survey data to ascertain distinctness.

Exploratory factor analyses were conducted to assess model fit, reliability and validity of the scale.

Other measures including a questionnaire collecting patient characteristic and clinical data, were sent out in conjunction with the self-management scale.

4.11.1 Sampling, and inclusion and exclusion

Participants were recruited from the kidney services of East and North Hertfordshire Trust (Lister hospital and four satellite clinics based in Harlow, Bedford, St Albans and Luton & Dunstable); the Royal Free Hospital (mainly the Edgware Hospital and three satellite clinics; Barnet, Mary Rankin and Tottenham Hale) and the University Hospital Birmingham (UHB) (including nine satellite clinics; Aston, Great Bridge, Hereford, Kings Norton, Redditch, Smethwick, Sparkhill, Woodgate and Worcester).

4.11.2 Procedures (recruitment, consent, data collection)

The aim was to approach 600 participants for recruitment to maximise response rate which was estimated to be between 60%-70% and translates to a sample size of 360-420. A large sample size in scale development ensures factor stability, allows for sub-group analyses, and minimalizes random sampling error. In addition, kidney centres were encouraged to over sample participants from minority ethnic groups to ensure generalisation of the scale to a diverse HD population.

For scale development, De Vellis (2003) recommends 10 respondents per survey item, however Comrey & Lee (1992) report 300 observations as good and 500 very good. More recent studies suggest a smaller sample size is sufficient for exploratory analysis. Anthoine et al (2014) and Kyriazos & Stalikas (2018) suggest that for exploratory factor analysis (EFA) where there are high communalities and an absence of cross-loading, a smaller sample can be adequate for reliable analysis. Sampling from a heterogenous but relevant population can also reduce the necessity for a very large sample (Tay & Jebb, 2016).

Data was largely self-reported by participants using pen and paper, this method of data collection was chosen in preference to an online survey when considering the participant characteristics, setting and other circumstances (Furr, 2011). Although this latter method can be both time and resource saving, it was felt that elderly and potentially quite frail kidney patients may be less confident with online methods. In addition, data collection was designed such that most participants would be completing the scale on site, whilst on dialysis, without support. There was no resource to provide laptops or tablets for on-line completion. To complete an online survey outside the clinical setting may have led to coverage bias in this population (Rowen et al., 2019).

About one fifth of participants reported needing support with completing the scale, this involvement of others increases the possibility of introducing bias, which may affect the validity of the findings. Participant bias, acquiescent (ACQ) and social desirability (SDR) responding are commonly associated with self-reported Likert scales (Kreitchmann et al., 2019). Respondents may answer in a way they think the researcher approves, with a preference for the positive side of the rating scale (irrespective of item content), or in a way deemed more socially acceptable. Social desirability specifically is a threat to validity (King & Bruner, 2000) and can contribute to a higher association with other constructs (Kreitchmann et al., 2019). To mitigate against this, and improve the interpretation of findings, data was collected using other, conceptually related measures; End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ) (Kim et al., 2010), PHQ9 Depression Questionnaire (developed by Spitzer in 1999 and reported in Kroneke et al., 2001), Self-Efficacy for Managing Chronic Disease Questionnaire (Lorig et al., 2001) and Self-Reported Morbidity Questionnaire (Sridharan et al., 2014). The relevance of each of these concepts to self-management has been outlined in chapter 3.

4.11.3 Analysis

There has been much debate about the appropriateness of analysing Likert scales using parametric or non-parametric methods, dating back to the original measurement framework proposed for Likert scales (Stevens, 1946). To be exact, Likert scales represent ordinal level data, each number is a category ordered in magnitude and it is possible that the intervals between the numbers are not treated equally by the respondent. In this case, analysis should use non-parametric methods. However, this scale is presented with anchors at the end, with a numbered scale between and so our assumption is that the respondent treats the scale as linear. Treating data as parametric has been deemed appropriate in several published articles and papers (Carifio & Perla, 2008; Norman, 2010; Harpe, 2015; Jamieson, 2004). In large samples, differences in sample distributions become less apparent, and parametric approaches to analysis become more robust (Hartley, 2014) and similar conclusions are often drawn from parametric and non-parametric analysis (Harpe, 2015). In later chapters, it is evident that the response profile tends to fit a defined distribution, indicating that the sampling process is linear, providing evidence to support this approach.

4.11.4 Missing data

Missing responses were delt with in the following way:

1. Where scale completion at the respondent level was poor, the data was excluded from analysis.
2. Individual level self-management scale data were excluded completely where the number of missing items on the scale exceeded 5% (4 or more items).

3. For data where 1 to 3 items were missing, the participant-level mean of the observed values was calculated across the observed scale responses and applied to the missing items.

To allow the effect of missing responses in general to be assessed, for example to evaluate the effect of response bias, a sensitivity analysis was undertaken using multiple imputation.

Where the proportion of missing data is high, multiple imputation can be used. Multiple imputation involves using statistical software to create “several different plausible imputed data sets, appropriately combining results obtained from each of them” (Sterne et al., 2009). When considering missing data there is uncertainty as to whether data are missing at random or not completely at random, therefore, analyses on only complete scale responses may be biased (ibid). Little's MCAR test was conducted to explore whether missingness across all 60 items was likely to be random, however multiple imputation was not required because the proportion of missing data was so low (Jakobsen et al., 2017).

For the other validated measures on which data was gathered, missing data were dealt with according to measure specific guidance (where available). Generally, the proportion of missing data was low, the exception was for the PHQ-9 which will be discussed in chapter 6.

4.11.5 Exploratory factor analysis

“Factor analysis can play a crucial role in ensuring the unidimensionality [underlying concept] and discriminant validity [uniqueness] of scales” (Clark et al., 1995). However, a certain amount of subjectivity is required, more than for other statistical processes. All stages of scale development can be described as ‘plenty of science and bit of art’ (Menon & Praharaj, 2019). Whilst conducting the factor analysis, the author referred to previous steps in development of the items to guide decision making.

Construct validity was assessed using exploratory factor analysis (EFA). This allows a scales’ structure to be identified and is effective in “identifying the underlying latent variables or factors of a measure by exploring relationships among observed variables” (Morgado et al., 2017). EFA facilitates item reduction whilst maintaining validity. Sampling adequacy was assessed using Bartlett’s Test of Sphericity (>0.05) and the Kaiser-Meyer-Olkin test (KMO) (≥0.8) values exceeding these thresholds indicate the data are suited to factor analysis.

Item analysis (including mean and standard deviation distributions, inter-item and item-total correlations), scree plots, exploratory factor analysis (EFA), and parallel analysis were all used to assess model fit, dimensionality, reliability, and validity.

Item-total correlations, correlation between factors, strength and specificity of factor loading, communality and internal reliability (coefficient alpha) analysis were used to guide decision making. Model fit was evaluated using standardised root mean square residual (SRMR), root mean square error of approximation (RMSEA), comparative fit index (CFI) and Tucker Lewis Index (TLI). The chi-square statistic was also calculated but is sensitive to sample size (Tong & Bentler, 2013) so considered in conjunction with other measures of model fit, despite the sample size being relatively large (n=363). Satisfactory approximate fit was decided a priori and is stated as three out of the four criteria being met SRMR are ≤.10, and CFI and TLI are ≥.9 (Finch & West, 1997; Hu & Bentler, 2009, as reported in Clark & Watson (2019). Horn's (1965) parallel analysis was implemented using the Monte Carlo PCA for Parallel Analysis to guide factor retention (Dinno, 2009).

An initial cut-off criterion of 0.32 was used for factor loadings in alignment with (Carpenter, 2018). This was increased to <.5 for retention in the final model. Items where there is evidence of cross loading between factors (less than 0.2 units difference), and items with adjusted item-total correlations <0.30 were also considered for omission.

4.12 PHASE THREE: PSYCHOMETRIC EVALUATION

4.12.1 Reliability

Reliability is a measure of score consistency across items (internal consistency) and across time (test re-test reliability). Internal consistency was assessed using Cronbach's alpha for all sub-sales and the final version of the full scale, as recommended by Tavakol & Dennick (2011). An alpha co-efficient of ≥0.80 was considered a priori as an acceptable threshold for reliability (De Vellis, 2003).

Test-retest reliability measures the external consistency of the scale and instrument stability over time. This was assessed by comparing scores obtained at baseline (T1) and at follow up which occurred 4-6 weeks later (T2). Intraclass correlation coefficient (ICC) was applied to baseline data from the first survey and data from the sub-set of respondents consenting to follow-up. Thresholds have been suggested by Portney & Watkins (2015), 0.75 to 0.9 is deemed good and ≥0.9 as acceptable for "clinical measures" (Matheson, 2019). Traditionally standards were more lenient and Cicchetti (1994) defined 0.4 to 0.59 as fair, 0.60 to 0.74 as good, and above 0.75 as excellent.

This is only relevant when the construct is assumed stable. There are points during the kidney care pathway where engagement with self-management may vary, such as when dialysis is initiated, or treatment modality is changed. Study participants were established on HD treatment (>3 months) and a change in circumstances questionnaire was administered at T2 to assess recent and significant changes in personal situation. In this context, it was assumed that engagement in self-management should remain relatively stable.

4.12.2 Validity of the scale

The steps followed in the process of item and scale development were sufficiently rigorous to ensure good content validity. Using a combination of inductive (e.g., patient interviews) and deductive (e.g., literature review) approaches to item development is key in contextualising new and emerging themes within existing theory and evidence. The use of multiple data sources and a combined approach to exploring the data, enabled a move towards a shared and multifaceted measurement of self-management that includes factors relating to psychological, social, emotional and activities of daily living, rather than the focus on treatment and adherence as seen in existing kidney-specific measures.

Further measures of validity were assessed as part of the scale evaluation process. Discriminant and convergent validity are measures of construct validity that go beyond EFA, the "extent to which an instrument assesses a construct of concern and is associated with evidence that measures other constructs in that domain and measures specific real-world criteria" (Raykov & Marcoulides, 2011).

4.12.3 Convergent and discriminant validity

Convergent validity is tested when novel measures are compared with existing measures that assess the same, or similar construct. Establishing correlations with related concepts is important for predicting validity. There are scales with varying degrees of overlap with the self-management scale (convergent to divergent) and it is predicted that theses scales should correlate with self-management to a varying degree. Such correlation will provide additional evidence for construct validity. Existing theory and research (as outlined in chapters 2 and 3) link self-efficacy, depression and adherence to self-management, and data from the scale was correlated with validated measures.

Other clinical and socio demographic data were collected and analysed in univariate analysis with self-management sub-scale as well as composite scores, for example age, sex, ethnicity, relationship status, time on dialysis and other LTC's.

4.12.4 Predictive validity

To establish the scale's predictive validity, a longitudinal study would be required to evaluate whether the interpretation of test scores can predict outcomes of interest over time (Morgado et al., 2017), but this was not possible within the remit of the current work.

4.12.5 Regression analysis

Multiple regression models were used to examine scale scores and their relationship with theoretically important variables. Correlation and bivariate analysis were conducted, prior to a stepwise regression. Sex, age, and ethnicity are potential confounders and were included in baseline models. Chapter 7 describes engagement with self-management in the final sample, and examines whether other associated concepts, person-related characteristics or clinical data, might be related to engagement in self-management.

4.13 SCORING OF THE OUTCOME MEASURES

4.13.1 Introduction

Creating scale summary and domain specific scores allows engagement with self-management to be explored, both as a global measure of the overarching concept, and at a more granular level which will give a more precise understanding of where gaps in support may lie. Domain scores can be used at the individual level to flag any issues, the severity of need and provide a starting for discussion with a patient aboutwhat their support needs may be. The approach to "scoring" self-management and other associated measures is outlined in the following sections.

4.13.2 The Self-Management scale

Raw item scores from the scale were summed to generate a composite self-management score. A composite score is simply an unweighted average of all the items within the scale. Scores for each of the three factors (managing, communication and clinical care) were also generated in the same way using the items in each domain as determined in the exploratory factor analysis. These four discrete scores were then converted back to a standardised 1-7 Likert scale by estimating the average, with higher scores indicating greater engagement with self-management. Note, any negatively worded items retained in the final scale after the exploratory factor analysis, were reverse coded. These self-management scores can be used to determine their association with other variables, and to assess the validity of the scale against other measures with which we might expect a correlation, for example adherence, depression, and self-efficacy.

4.13.3 Assessment of adherence

The End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ) is a 46-item instrument developed by (Kim et al., 2010) to measure adherence to a regular dialysis schedule, medication, diet, and fluid intake. It was chosen because it has been validated specifically for people receiving HD. The only other kidney-specific measure is the Dialysis Diet and Fluid Non-Adherence Questionnaire (DDFQ) developed by Vlaminck et al (2001), which only assesses adherence relating to diet and fluids. A new scale: Adherence to Healthy Behaviours Scale has recently been developed and evaluated for use in people with CKD (Huang et al., 2021), however this was not available when the current study was conducted and was validated on a Southern Taiwanese sample.

Using data from the ESRD-AQ, an adherence behaviour sub-scale score was calculated using questions 14, 17, 18, 26, 31, and 46, in accordance with guidelines (Kim et al., 2010). Data on the attitude/perception sub-scale was also explored using descriptive statistics. Data were categorised into poor (total score <700), moderate (700-999) and good (1,000-1,200) in accordance with Naalweh et al. (2017). Other categorisation methods were also explored (Mukakarangwa et al., 2018).

4.13.4 Assessment of depression

The Patient Health Questionnaire-9 Depression Questionnaire (PHQ-9) was included in the review, and despite the limited research, is commonly used as a screening tool in research and clinical practice (Gregg & Hedayati, 2020; Kroenke et al., 2010). In addition, the PHQ-9 is a short tool that takes approximately 3 minutes to complete, appears to hold good validity in a CKD and ESKD populations (Chilcot et al., 2018; Shirazian et al., 2017), is publicly available (and free) and developed from the PRIME-MD (Primary Care Evaluation of Mental Disorders) procedure (Spitzer et al., 1994) to be self-administered. There is some evidence that sex, age and ethnicity don’t lead to variation in PHQ-9 scores (Huang et al., 2006).

Other valid but longer alternatives for depression screening in people with ESKD include the Quick Inventory of Depressive Symptomatology (QIDS-SR) developed by Rush and colleagues (2003) which contains 16 items, the 21-question Beck Depression Inventory (BDI) which has been validated in an HD population (Chilcot et al., 2008), the Cognitive Depression Index (a 15-question sub-scale of the BDI) and the 14-item Hospital Anxiety Depression Rating Scale (HADS) by Zigmond & Snaith (1983). There is no statistical difference found between the latter three rating scales (Loosman et al., 2010).

The PHQ-9 assesses nine symptoms, which are rated according to whether the symptom has bothered the respondent “not at all”, “several days”, “more than half of the days” or “nearly every day” in the last two weeks.

In this study, PHQ-9 data was explored as both a continuous measure with scores ranging from 0 to 27, and using depression severity thresholds <5, 5-9, 10-15, 16-20 and >20, signifying none, mild, moderate, moderately severe and severe depression respectively. This approach in analysing the PHQ-9 as continuous and categorical has been used by others (Kroenke et al., 2001).

Data were analysed according to a bi-factor model, comprising cut-off points and total score, as well as the two-dimensional factor model to calculate sub-scores on somatic (3-items) and cognitive/affective (6-items) domains (Doi et al., 2018). The somatic items relate to sleep difficulties, fatigue and appetite changes, and examining the data this way allows more detailed assessment of symptoms.

Questionnaires with up to two missing values were scored, any missing values were replaced with the mean score of the completed items as done by Arrieta and colleagues (2017).

4.13.5 Assessment of Self-Efficacy

Despite the association between self-efficacy and improved CKD outcomes, there isn’t a validated disease-specific self-report measure of CKD self-efficacy (Wild et al., 2017); the majority of measures being developed for diabetes patients (Frei et al., 2009).

The only kidney-specific measure found was developed by Lin and colleagues (2012); the Chronic Kidney Disease Self-Efficacy Instrument, however, it has only been validated in a South Taiwanese community with CKD Stage 2 or 3 and is long; 25-items with four subscales (autonomy, self-integration, problem-solving, and seeking social support)

The Self-Efficacy for Managing Chronic Disease Questionnaire (SEMCD6) (Lorig et al., 2001) is the first of only two non-disease specific measures of self-efficacy. It comprises six items on a visual analogue scale, ranging from 1 (not confident at all) to 10 (totally confident) and can be used across multiple health conditions. The measure was chosen because it is both brief, appears to be a valid generic instrument for chronic disease (Ritter & Lorig, 2014), and is widely used.

The PROMIS Self-Efficacy banks for Managing Chronic Conditions have been developed more recently (Gruber-Baldini et al., 2017) and include five self-efficacy domains: managing daily activities, medications and treatments, symptoms, emotions and social interactions. The number of items per domain ranges from 23 to 36, so it is likely that developing short forms would be a priority. Correlations with the SEMCD6 were highest on two domains: managing symptoms and managing interactions. The sample on which the items were validated included people with kidney disease. However, the SEMCD6 measure had higher correlations with fatigue than the PROMIS Self-efficacy banks, which is a symptom highly relevant for those with ESKD (ibid).

4.13.6 Assessment of multi-morbidity

To explore the relationship between self-management and burden of disease, it was necessary to measure multimorbidity of respondents. The most common tool for this in the clinical setting is the Charlson Comorbidity Index (CCI); a weighted index that incorporates both the number and seriousness of comorbid disease prognostic of survival. This index of 19 conditions was developed in a cohort of 559 medical patients (Charlson et al., 1987). This has been adapted for use in people with ESKD (Hemmelgarn et al., 2003). A Charlson score is not routinely recorded across all kidney centres and calculation requires clinician time to interpret ICD codes or access hospital extracts data, creating additional administrative burden, for this reason an alternative self-report measure was used.

The self-reported morbidity questionnaire was chosen because it is an efficient method for assessing comorbidity when medical records are difficult to access or unavailable (Sangha et al., 2003), and has been compared favourably with the use of the Charlson index as described above. Respondents are asked three questions about presence of condition, treatment and limitation in activities. The conditions are heart disease, heart attack, diabetes, cancer, lung disease, liver disease, arthritis and depression. In the version used, the eight conditions included are common co-morbidities associated with ESKD (Sridharan et al., 2014). Bias can be an issue for self-reported measures, but data collected in people receiving HD showed almost perfect agreement with medical records for diabetes, and high agreement for heart disease and cancer. There was some variation for the other conditions (ibid).

Prevalence data were scored binary (yes/no) using the defined categories. Inclusion of free text fields for optional comorbid conditions were included in data collection but not coded for analysis. Other studies have limited analysis to the close ended questions (Sangha et al., 2003). For analysis, an LTC category was generated, and data used to flag respondents as having 0, 1 or ≥2 LTCs.

4.13.7 Clinical data

Time since initiation of dialysis (vintage), interdialytic weight change (IDWG) and plasma phosphate data were collected from clinical records.

Dialysis vintage in years/months was collected from clinical records using time of dialysis initiation to the day of recruitment to the study. IDWG was calculated as a person's pre-dialysis weight minus the post-dialysis weight from the previous HD session. Values were based on the average of three measurements, expressed in absolute terms. Plasma phosphate values were an average of the last three measurements.

4.13.8 Demographic information

Data collection as part of scale development included questions on, age, gender, ethnicity, relationship status, education, household size, employment status, income and treatment travel time (Appendix D). Relationship status and household size were selected as proxies for social support. Employment status was selected as a proxy for workload, but also alongside income as an indicator for deprivation. Education was collected as there is an established link between health literacy and lower educational attainment (Berkman et al., 2011; Kickbusch et al., 2013) and both are linked to self-management (Geboers et al., 2016; Heijmans et al., 2015; van der Gaag et al., 2022). Travel was included as transport issues are often reported for in-centre HD patients. Due to the large numbers of eligible patients from minority ethnic populations represented in the final survey in which the scale was tested, patients were grouped according to broad ethnic group as defined by ONS for the 2011 Census, rather than dichotomously as white and non-white. All categorical variables were dummy coded (i.e. male= 0 vs. female =1, no other long-term conditions (LTC) =0, 1 LTC=1, ≥2 LTC=2. More information can be found on coding in chapters 6 and 7.

4.14 PRE-IMPLEMENTATION EXPLORATION

In the previous section, the process of developing a novel scale was described. As an extension of the development and as part of the early stages of implementation, it is critical to consider how an evidence-based measure might be used in research and clinical practice. Specifically, how the self-management scale might contribute to a person-centred approach to care and help fill a gap in identifying support needs. As part of this, it is essential to begin to explore the feasibility of implementation, the context, and influences on individual (both patients and clinical staff) and organisational behaviours (Eccles & Mittman, 2006). Is there capacity to implement and could the scale be useful?

An explorative study engaging key stakeholders was conducted from April 2021 to January 2023 to explore the perceived utility of the scale and the barriers, facilitators, and potential strategies for implementation in clinical practice. This fits into the first of four stages of implementation (Fixsen et al., 2009).

Specifically, multiple stakeholders and service users were recruited to explore:

- whether the conceptualisation of the term "self-management" as expressed by the tool is valid
- whether the self-management score has utility in the clinical setting;
- whether we should continue to an implementation study (is the tool deemed feasible, and acceptable); and
- what some of the barriers and facilitators to this may look like, and how the implementation context might inform the design and approach to implementation.

4.14.1 Design

This study is located within the first stage of implementation: exploration. The ImpRes Guide suggests that ascertaining need, barriers and facilitators and capacity is important at this stage (King's Improvement Science (KIS) website, 2013). Using qualitative methods (focus groups, and to a lesser extent, interviews) is a valid way of addressing implementation science questions that seek to integrate research findings into healthcare practice, and policy (Hamilton & Finley, 2019; Holtrop et al., 2018; National Cancer Institute, 2020; Nevedal et al., 2021; Peters et al., 2013). Two frameworks informed the study design and data analysis; the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009, 2022) and the Promoting Action on Research Implementation in Health Services (PARIHS) (Kitson et al., 2008). Application of the latter has found evidence, context, and facilitation to be the biggest predictors of successful implementation (Rycroft-Malone et al., 2004). The theory of implementation and relevant frameworks will be discussed further in chapter 8.

4.14.2 Sampling, and inclusion and exclusion

All participants for the small focus groups or interviews were recruited from four kidney centres: Royal Preston Hospital, Kings College Hospital (KCH), London, University Hospital Birmingham (UHB) or Lister Hospital, the latter two of which were involved in the first scale development study. Sampling was stratified, convenient and purposive with the intention of achieving 1:1 ratio of staff and service users, with a total of 6 participants from each centre. Target recruitment was 24 participants with representation from each category: nephrologist, nurse, social workers, dietician, counsellor/psychologist and senior manager, as well as service users. Of those with lived experience, current or previous experience of HD was not a prerequisite for participation.

Potential healthcare or allied health care worker participants were selected based on their role within kidney care, as well as interest in patient-centred approaches to self-management or other relevant interests such as self-care, frailty, and supportive care. Focus groups and interviews took place between July and August 2022.

4.14.3 Procedures (recruitment, consent, data collection)

Participants were recruited by the local PI and provided with a participant information sheet. The lead researcher followed up with those that expressed an interest and written consent was obtained via email by the lead researcher. Pre-read documents were sent 2 days prior to the online focus group, and at least one phone call or email between each participant and the lead researcher occurred prior to the group.

All groups were audio and video recorded with consent, and they were supported by two additional researchers.

4.14.4 Focus groups

Focus groups have become increasingly used in health science research and are a useful mechanism for exploring participants' perspectives, use of language and understanding of concepts (Freeman, 2006; Wilkinson, 1998) . They were the preferred method for this pre-implementation work as the group approach removes the pressure one person may feel to have the answers (Stewart & Shamdasani, 2014). Homogenous groups are potentially easier to facilitate, and for people with a specific condition talking with others who broadly share their experience can make people feel safe to share (Morgan, 2012). Contrasting perspectives and different experiences of a shared area of expertise (e.g., kidney disease), whilst making the conversation more dynamic, may be viewed controversial in terms of the potential perceived imbalance in status.

Mixed groups, including both clinical and allied health staff, and experts by experience, were used to form each focus group (where possible) to maximise the breadth and diversity of opinions within the group. In a study with mental health services users and professionals, Femdal & Solbjør (2018) found that using vignettes (text, images or statements) enabled services users and professionals to talk about power dynamics from their own position, sometimes distancing themselves from practices viewed as less helpful by people with lived experience. The study suggests that contradiction and disagreement without conflict is possible and being able to talk about personal experience in line with vignettes, can be a tool for equality. The use of vignettes at the start of the focus groups was established as part of this study.

4.14.5 Online format

The Covid-19 pandemic was ongoing at the time the study was designed. Given the likelihood that the pandemic would prevent the ability to safely conduct face to face meetings, the study was designed such that all meetings and focus groups would be conducted online using video conferencing software. Guidance on best practice for online data collection was followed (Archibald et al., 2019; Lobe, 2017), along with recommendations for adapting data collection during COVID (Dodds & Hess, 2021). Enhanced technical support was available for those experiencing frailty or whose age may hinder ability to video conference (Moyle et al., 2020). Mixed professional and patient small focus groups were promoted as the preferred scenario, however interviews on Teams or on the phone are valid alternatives (Sturges & Hanrahan, 2004) and were offered where participant preference necessitated. Including some interviews in place of focus groups was a pragmatic decision to ensure heterogeneity in inclusion of people with lived experience and to mitigate bias towards a younger sample (Barbour, 2007).

4.14.6 Reflexivity

As lead researcher, I made my role in the research and my beliefs about the potential role of the scale explicit in the way I presented myself. In line with (Madill et al., 2000) I took a reflexive and critical stance to the entire research process, including analysis and reporting. All focus groups were preceded by a debrief meeting. Further details can be found in chapter 8.

4.14.7 Analysis

All focus groups were audio and video recorded and transcriptions were generated automatically by Zoom, anonymised and checked and corrected for accuracy by at least one of the three researchers. Telephone interviews were recorded and transcribed verbatim by the lead researcher. Transcripts were entered into NVivo 12 (QSR International, Cambridge, MA, 2016) for data coding, management, and analysis.

Reflexive Thematic Analysis as described by (Braun & Clarke, 2006, 2013, 2021a; Byrne, 2022) was used in a six-step approach to analysis, as this iterative, less linear process of coding is well suited to the application of both inductive and deductive methods of coding. This combined approach has support and allows a more comprehensive understanding of the implementation context, particularly barriers (Bonner et al., 2021; Fereday et al., 2006). The Consolidated Framework for Implementation Research (CFIR) was used to guide the deductive coding and is relevant to healthcare settings (Damschroder et al., 2022). An inductive approach allowed exploration of language, beliefs, attitudes and experiences. Using both means ideas can emerge from the empirical data, frameworks and theory from existing literature (Bradley et al., 2007; Sandelowski & Leeman, 2012). This two-pronged approach to understanding enables a rich and multifaceted analysis and allows current knowledge and understanding to be challenged where necessary.

All data were analysed by the lead researcher (HMW) in a process of continued immersion, however at each step of the coding, the process was discussed, and the codebook reviewed by the wider research team. Having conducted all focus groups and interviews, and in reviewing all the transcripts, the author was by this point already familiar with the content. Further familiarisation in step one was conducted as a paper and pen exercise using annotations, comment and direct highlighting of transcript text. The computer software programme NVivo 12 (QSR International, 2016) was used to generate and develop codes and themes in steps 2 to 6. More detail on the approach is outlined in chapter 7.

4.15 SUMMARY COMMENTS

The methodologies described here cover a series of phases and activities across two studies designed to ascertain the need for a novel CKD HD-self management scale, develop and validate such a scale, and start to explore how this evidence-based scale can be used in clinical and research practice. At the heart of this thesis is the idea that self-management happens mostly beyond the clinic door, and not just in the dialysis chair. By taking an iterative, mixed methods approach, content validity is prioritised, and the lived experience is at the forefront of scale development.

The process of scale development and evaluation followed three distinct phases comprising several activities within each, followed by an additional study to explore implementation. The development of an overarching concept, themes and items, scale development, psychometric evaluation and a pre-implementation exploration of barriers and facilitators. Here, the rationale for the methods and relevant theories are explained, in the following chapters the outcome of each stage is reported in detail. Chapter 5 uses empirical data to describe the lived experience, the analysis that underpinned the development of themes and items and preceded the consensus process. Chapter 6 focuses on the development of the scale and results of the large survey. Chapter 7 covers psychometric evaluation of the scale in conjunction with other measures and variables. Chapter 8 explores the pre-implementation context and the perspectives of key stakeholders' evaluation.

CHAPTER 5 : EXPLORING THE LIVED EXPERIENCE

5.1 INTRODUCTION

Introduction

In chapters 2 and 3, I argued that current self-management scales for kidney patients are focused on the clinical setting at the expense of a broader focus beyond the clinic on factors that are important to clinical outcomes. The impact of ESKD and HD can vary between patients and be far-reaching, affecting all areas of life, from activities of daily living to relationships, to mental health. Any measure of self-management should reflect this. In the previous chapter I outlined the methods used to develop a more holistic, patient-focussed measure based on the tripartite model. In this chapter I give space to the patient voice, a crucial element of item and scale development which defines the content validity.

Having established the importance of the patient contribution in conceptualising self-management, but also in operationalising it via a measure, the purpose here is to use face-to-face qualitative interviews with a diverse community population to generate further evidence from a UK sample. The aim of this activity, within phase one of the study was to further explore the patient experience and challenges of daily managing, beyond the dialysis chair and establish person-centred themes. This chapter bridges the gap between the theoretical construct and the lived experience.

Chapter 6 will go on to look at how items for a novel self-management scale were developed using this patient narrative around experience, along with evidence from the literature review.

5.1.1 What is known about the lived experience?

Research in haemodialysis patients often documents the care patients receive from the perspective of the healthcare system, with a focus on clinical outcomes. Although not as established as in some other long-term conditions, the importance of understanding the impact of illness and treatment and the relationship with self-management beyond just the treatment setting, is becoming better recognised in ESKD. The patient voice, however, needs amplification and the experience of self-managing through the patient lens is crucial for developing a better measurement. Despite a growing number of qualitative studies reporting on the patient experience, few published before 2019 could be described as generalisable to a UK HD population or as having a broad focus on day to day managing.

Table 5.1: Qualitative studies (original research) reporting on the patient experience.

Study	Country	Sample	Methodology	Findings
Finnegan-John et al., 2013	UK	ESKD including those on PD and HD n=118, plus carers (n=12).	Thematic analysis	There is considerable psychological burden for people with ESKD including emotional, physical, psychological, social, and existential burdens. ESKD has a significant impact on QoL. Health psychologists can help address this alongside other multidisciplinary approaches that follow a holistic framework.
Glidewell et al., 2013	UK	Haemodialysis patients undertaking some, all, or opting out of shared haemodialysis care (n=15).	Thematic analysis (framework)	Patients identified several benefits related to participating in hospital-based shared care, including less pressure on care givers/family members, an increase in knowledge and a sense of increased empowerment and control. Where patients could participate in shared care together the importance of peer support as an enabling factor was recognised. Barriers included safety concerns, self-management as meaning independent and unsupported and a focus on kidney transplant rather than the need to learn dialysis related skills.
Hagren et al., 2005	Sweden	People on maintenance HD, n=41; age range 29-86 years.	Content analysis	Three main themes were identified; not finding space for living, feelings evoked in the care situation and, attempting to manage restricted life, time and space featured as existential dimensions. The authors suggest a sense of vulnerability and emotional distance from healthcare providers should be recognised by staff who should work to overcome it.
Lin et al., 2015	Taiwan	In-centre haemodialysis patients n=15, age range 30-78 years.	Grounded theory	Characterised psychosocial adaption to a life on haemodialysis. The themes were slipping into, being restricted, losing control and feeling stuck in an endless process. To contextualise, Taiwanese society is described as more pessimistic and that changes in role due to illness may have a greater impact on resilience than in other cultures, particularly among men.
Malik et al., 2022	Pakistan	Adults receiving maintenance HD in outpatient units, n=20, age range 18-75 years.	Phenomenological analysis	Six themes emerged including use of traditional medicine, dissatisfaction with communication with doctors and dialysis decisions, the role of family as both influential and supportive, financial difficulties around treatment and transport, difficulties for women in fulfilling their roles as mothers and wives, and a reluctance to discuss end of life care.

Martin-McDonald, 2003	Australia	People on HD or PD n=10, age range 22-68 years.	Thematic analysis	Five main themes around how people reconstruct their worlds and reformulate themselves via: freedom-restrictions, being normal-being visible, control-acquiesce, hope-despair, and support-abandon. The themes were described as co-dependent on each other and varying with time, circumstances, events, and relationships
McKie et al., 2023	Australia	People receiving haemodialysis. 55 studies included (from the Middle East, North and South America, Europe, Africa, Australasia, East Asia)	Meta-aggregation of qualitative findings	The impact of haemodialysis and illness relates to 11 domains of unmet support needs including practical elements of daily living, information needs, communication with clinician, family related needs, as well as psychological/emotional, physical, social, and spiritual needs. The authors conclude this range of needs are often not being addressed in existing services.
Monaro et al., 2014	Australia	Recently initiated HD patients (n=11), age range 30-84 years and family carers (n=5), age range 52-86 years	Heideggerian phenomenology	The early dialysis period is experienced as 'a lost life' in which feeling overwhelmed by shock and grief was described. This is linked by the author to a lack of mental and physical preparation for dialysis as a long-term strategy. A positive future can be hard to perceive at this point in the journey, both by patients and carers. A greater focus on preparation is needed, in conjunction with engaging families as a source of support.
Moreels et al., 2023	Belgium	In-centre haemodialysis patients living at home, n=20, age range 66-87 years.	Thematic analysis	This study looked at changes in role and functioning of older patients moving from dialysis as a disruption to a means of survival. Further themes focussed on how to support declines in function and role change through modifiable factors such as the social environment, new activity patterns and personally meaningful goals and activities.
Nagpal et al., 2017	USA	Black and Latino adults receiving haemodialysis in medically underserved communities n=36.	Descriptive phenomenology	Five themes were described: an abrupt and unexpected transition to dialysis, denial as an initial response, dialysis as the new normal and to survive one must look forward, change, and impact on family and strength in faith and family. The authors conclude it is important to address psychosocial needs and this is best done using patient-centred models of care.

Sahaf et al., 2017	Iran	Elderly people on haemodialysis n=9, age range 64-85 years.	Interpretative phenomenological analysis	Uncertainty as the main psychological concern. Education and increased knowledge can reduce uncertainty.
Shahgholian & Yousefi, 2018	Iran	Haemodialysis patients n=17, age range 24-83 years.	Descriptive phenomenological analysis	The study derived a concept of good care as being empathy, companionship in everyday needs, social support and concern, and good-quality dialysis. These factors should underpin patient-centred care programs.
Walker et al., 2017	New Zealand	Māori participants that had started dialysis <12 months or were close to initiation n=13, age range 22-72 years.	Thematic analysis	The emerging themes were conceptualised within a framework of whakamā (disempowerment and embarrassment) and whakamana (sense of self-esteem and self-determination). Experience of kidney disease for this groups of Māori people sits within a culture of marginalisation due to late diagnosis, multigeneration fear of dialysis and a lack of cultural considerations during decision making. More should be done to address these issues.
Young et al., 2022	UK	People receiving haemodialysis that had recently experienced a fall, n=25.	Constructivist grounded theory influenced by the socioecological model	The analysis focussed on how participants characterise frailty and the consequences of frailty which were stratified according to the individual, societal and organisational level, an example of each being variable function and psychological ill health, challenges with financial support and burdensome health and social care interactions. Holistic needs assessments, more person-centred health and social care systems and support for families and continued community participation would improve outcomes and experience.

As part of the literature review, ten qualitative studies were found that looked at the lived experience of people on dialysis, but only two involved a UK sample (Finnegan-John & Thomas, 2013; Glidewell et al., 2013) the others were conducted in Iran, Taiwan, Australia, Sweden and two looked at specific populations in New Zealand (Māori communities) and the USA (Black and Latino medically underserved population). Two further studies were found conducted in Spain and Singapore, but the full text was unavailable (Lai et al., 2012; Prieto et al., 2011). All studies reported findings related to the psychosocial experience and impact of kidney disease and treatment, even where the term was not referred to specifically. Table 5.1 includes an additional four studies (including one UK study) that had not been published at the time the self-management scale was being developed.

In another paper by Reid et al (2016), 17 qualitative studies were reviewed with the aim of understanding beliefs and experiences relating to treatment. Whilst only two studies included in the analysis were from the UK (Karamanidou et al., 2008; Mitchell et al., 2009), there was overlap in findings when compared with the other UK paper (Finnegan-John & Thomas, 2013) such as the impact on social interactions and networks, including family. Both mentioned new restrictions on life and Finnegan-John & Thomas (2013) linked diet and fluid changes with social functioning. Codes used by Reid et al (2016) within the "restricted life" theme included the work of maintaining the dialysis regime and time lost. Both papers specifically talked about the importance for patients of regaining control.

Other ESKD qualitative studies have explored the patient experience around particular issues such as treatment decisions and choices (Hussain et al., 2015; Ladin et al., 2017; Morton et al., 2010; Subramanian et al., 2017), the experience of waiting for a transplant (Moran et al., 2011), kidney disease trajectory including end of life (Axelsson et al., 2012; Cervantes et al., 2017; Schell et al., 2013; Tong et al., 2014), adherence (Griva et al., 2013), symptoms including fatigue (Cox et al., 2017; Horigan et al., 2013; Picariello et al., 2018) and peer support (Hughes et al., 2009). All involved patient interviews, except for the Tong et al. (2014), Morton et al (2010) and the Hussain et al (2015) papers which were systematic reviews. The latter two did not include any UK studies. Not all full texts were available.

5.1.2 Recently published

Since this work was conducted, a further four qualitative studies have been published in this area (Malik et al., 2022; McKie et al., 2023; Moreels et al., 2023; Young et al., 2022). The first was a systematic review with a focus on unmet need, the authors point out however that this was not a primary objective in all included studies (McKie et al., 2023), although 6 UK studies were included.

Malik and colleagues (2022) reported on a sample in Pakistan in which the focus was on dialysis and not the wider treatment or illness impact. The latter two were the most relevant to this study. The study by Young et al (2022) was conducted with a UK sample and explored the physical impact of illness, the effect on other LTCs, and challenges to routine and psychological impact. However, this study focussed on a sub-set of frail patients, recently experiencing a fall (within the last 6 months).

As described by Reid et al. (2016), relationships with health professionals were highlighted as key, McKie et al. (2023) defined them as a source of psychological support but also sometimes showing a lack of person-centred care and empathy. Whilst Young et al. (2022) framed the relationship in terms of unmet need, reporting over-dependence and under reporting of issues by patients. Unlike the synthesis by Reid, all four of these more recent papers explored coping strategies adopted by patients, including emotional coping.

5.1.3 What is known specifically in relation to self-management?

Work by Baay et al. (2019) and Schrauben et al. (2022), also published since this work was undertaken used qualitative methods to look specifically at patient behaviours in relation to self-management. Environmental context and resources, knowledge, beliefs about capabilities, beliefs about consequences, and social influences were all identified as domains of relevance for self-management behaviour, and four emergent themes were labelled: *What does this mean for me? Help me help myself, how does this make me feel? and Who am I?* (Baay et al., 2019). These themes highlight the cognitive, emotional, and philosophical nature of living with kidney disease, not just the physical, and emphasise the relevance of a person-centred approach to care in the context of supporting self-management. Again, patient-provider communication, has been identified as an important factor (Schrauben et al., 2022).

Of note, both studies were conducted outside Europe (Canada and USA respectively), and neither sample included people on dialysis. Self-management has also been explored in terms of medication management (Parker et al., 2017; Rifkin et al., 2010). Disruption caused by complex health needs, organisational strategies and social networks, and the need for formal support with managing medication, were the three themes identified.

The study by Glidewell et al (2013) shown in table 5.1 explores the patient experience of self-management in relation to shared dialysis care. Partial or full engagement in shared dialysis care can lead to increased knowledge, a sense of increased empowerment and control and increased communication and support between patients. A need to reduce some barriers to shared care was noted and include concerns about safety, a fear of being more isolated at home, and reduced capacity to process information relating to co-morbidities and time since/impact of diagnosis. The authors concluded that the opportunity to be involved in shared care should be discussed with all patients regardless of age and disability; a view that resonates with wider psychosocial elements of self-management.

5.1.4 In summary

Few UK studies have directly examined the patient experience, beyond the dialysis chair or other specific elements of patient experience, to include everyday practices, routines, and strategies to manage. Crucially, at the time of scale development, only one UK study had done this. Of the kidney self-management measures listed in chapter 3 (Table 3.2), none were developed on a UK sample, and only one reported using qualitative interviews or focus groups with patients in the development process (Song & Lin, 2009).

There are some indications that patient-provider relationships, social support, identity, perceptions of control and coping strategies are part of the lived experience of ESKD and HD and are a feature of self-management or factors associated with it. In this chapter, the experiences of people receiving haemodialysis from three kidney centres in England are explored. Data from the interviews was used to inform development of items for the novel self-management measurement, as well as making a contribution to the development of empirical knowledge.

5.2 DESIGN OVERVIEW

An overview of how the qualitative element of the methodology fits within the scale development process was given in chapter four. In summary, coding of the data from the patient interviews led to the identification of themes. These draft themes were reviewed in conjunction with themes from the literature in an iterative process involving expert consensus. Once the themes were agreed, candidate items that fit within the themes were developed, proceeded by further consensus rating.

In-depth semi-structured interviews were undertaken to explore the lived experience of life with end-stage kidney disease and the impact of haemodialysis treatment. The tasks and perceptions of managing were discussed in the broadest sense with a focus on the specific language used by participants to talk about their kidney journey. Thematic analysis was used to identify themes in the data (Braun & Clarke, 2006) using an inductive approach.

To ensure the quality and transparency in reporting of qualitative studies, the COREQ (Consolidated criteria for reporting qualitative studies) 32-item checklist (Tong et al., 2007) was used as guidance in the design, analyses and writing of this qualitative part of the broader study and is viewed as an important resource (Bristowe et al., 2015).

5.3 METHODS

5.3.1 Setting and participants

Adults on ICHD and HHD were recruited from three kidney centres: Lister Hospital, Stevenage, Royal Free Hospital (RFH), London, and Queen Elizabeth Hospital (now UHB), Birmingham using a purposive sampling method. Interviews were conducted between September 2018 and January 2019. The initial approach was carried out by a consultant nephrologist or kidney research nurse, according to inclusion and exclusion criteria (as outlined in chapter 4). Interested participants were then contacted by the author (lead researcher) to arrange a time and place for interview. To note, we intended to conduct a mix of interviews and focus groups but were unable to recruit to the latter. The barriers were time, space, and convenience. Most patients preferred to use the time on dialysis to participate, and logistically this precluded focus groups. Focus groups were used in the second study (described in chapter 8) and being conducted online, meant patients could participate whilst on dialysis.

Participants provided written and verbal informed consent to the researcher immediately prior to the interviews and confirmed verbally that they felt well enough to proceed. All participants were advised that the interview could be paused or terminated if this changed. None of the participants were interviewed during the first or last 30 minutes of dialysis. COREQ guidelines suggest that saturation should be addressed and has long been recognised as a valid approach in determining sample size in qualitative research (Tong et al., 2007), recently however, Braun & Clarke (2021b) suggest it is more a subjective judgement than an objective declaration preceding analysis. No specific approach to saturation was adopted in this work, but it was evident that little new knowledge was being obtained as the process neared the end, and data collection was conducted over sufficient time to allow analysis to occur concurrently with data collection.

As recruitment was purposive, recruitment logs were used by each site and regularly reviewed with the author to ensure heterogeneity in patient characteristics; age range, sex, time since diagnosis, number of years on dialysis (vintage) and ethnicity. UHB serves a diverse ethnic population, Census data (Office for National Statistics, 2021a) for areas in and around Birmingham show 78% of people living in Sparkhill are Asian, and both Smethwick and Ashton have a high proportion of Black as well as Asian residents (15%; 40% and 16%; 70% respectively). Deprivation is high in these areas, for example 81% of the lower super output areas (LSOAs) in Smethwick are in the 30% most deprived LSOA in England. This ethnic diversity is reflected in the populations these satellite units serve, and patients from these units were recruited for the interviews. Oversampling of these groups, particularly in this area, ensured that the higher prevalence of these patients on kidney replacement therapy (KRT) was represented in the sample.

5.3.2 Data collection

Interviews were conducted according to patient preferences, usually during haemodialysis. The two home haemodialysis patients were interviewed in their own home and not whilst on dialysis. All participants were interviewed alone. One female patient could not complete the interview due to fatigue, and the recording was stopped at approximately 51 minutes.

The topic guide was informed by the literature review (chapters 2 and 3) and piloted with two patients (data included). All questions were open-ended to enable participants to talk about issues pertinent to them but also the research question. This approach allows the participant to tell the story of their illness and empowers them to guide the conversation (Bristowe et al., 2015). A broad question inviting them to talk about themselves was followed by questions about their kidney disease e.g., experience of symptoms, difficult emotions, impact of treatment, day to day managing, activities of daily living and hobbies, types of advice and source, coping strategies, knowledge, roles and relationships, and treatment decisions. Prompts and probes were used to maintain discussion and gain more information (appendix C).

Although the focus of the interviews was a holistic one, exploring living a life, there were questions that could have led to conversations about learning tasks related to one's own dialysis treatment, that align with the concept of shared care. The topic guide included questions about the participant's experience of treatment, how they look after themselves daily and whether there is anything they do or don't do that might be helpful. Each of these questions provided the opportunity to talk about more clinical aspects of managing, particularly for those on home-dialysis or who may have been offered shared care in the in-centre or satellite setting.

To reduce response bias, all interviews were conducted by the author; a female mixed methods research fellow based at the University of Hertfordshire. Whilst unknown to the patients and not involved in patient care, the author acknowledges it is not possible to completely avoid personal biases in the research process. The author had been emersed in the literature during the scoping review, so whilst the approach to coding was inductive, it was done within the context of an a priori understanding of existing literature.

Field notes were not taken to ensure full and uninterrupted engagement with the participant, audio recordings meant the interviews could be reviewed later. Study participants were provided with contact details for the researcher, local chief investigator and local Patient Advice and Liaison Services (PALS). Transcripts were available on request.

Interviews were approximately 60 minutes, audio recordings were made of all interviews and sent to an external service for verbatim transcription. A unique patient identifier was used to ensure patient confidentiality and anonymity, and all transcripts were imported and managed in NVivo 12 (QSR International Pty Ltd). Where there were issues with sound quality (due to the noise from the dialysis machine and more general background noise in the dialysis unit), the author checked the transcript against the original audio recording. The audio recordings for two male patients were of such poor quality, the data could not be transcribed.

5.3.3 Data analysis

Data were analysed thematically using the Braun & Clarke framework (2006, 2013) by three coders. Themes and sub-codes were developed via data driven, inductive thematic coding with a focus on lived experience rather than any specific theory (Rivas, 2018). This approach provided the flexibility sought to identify the behaviours related to managing within the descriptions of the lived experience (Bristowe et al., 2015).

The data were coded in three main steps; familiarisation, development of coding to capture the themes on a small set of scripts, and finalisation of the coding frame, which was then applied to the remaining scripts, a process used in other qualitative kidney studies (Selman et al., 2019).

1. As a first step, the researchers familiarised themselves with the data by reading through the transcripts, noting initial thoughts, and highlighting key sections. Initial codes were then generated from the data.

2. Codes were then collated within identified themes. This was an iterative process. MS, BR and SL independently coded eight interview transcripts and developed an initial set of themes. Consensus/validation was reached by swapping and re-analysing each of the scripts to sense-check

and identify any gaps in the coding frame. Initial themes were discussed with the author and themes were amended and renamed until a consensus was reached.

3. The finalised coding frame developed on the initial eight scripts was then applied to the remaining scripts by the author. Any data in the remaining transcripts that did not fit into the existing frame was noted and discussed with the wider research team before making final amendments.

The themes were refined via a consensus workshop with stakeholders, then the revised draft used in conjunction with the literature review to develop potential items for the novel self-management scale. This process and the associated draft items are presented after the results of the qualitative interviews.

5.4 RESULTS: QUALITATIVE INTERVIEWS

5.4.1 Participants

Twenty-seven people receiving haemodialysis treatment participated. The mean age of the participants was 58 years, range 24 to 89. Participants came from each of the three kidney sites, and the ratio of men to women was approximately 2:1 at each. Approximately 63% of patients in the sample were from minority ethnic groups. All participants had been on dialysis for at least three months, with almost half of the sample having been on dialysis for 2 years or more. There was some local variation in participant characteristics (Table 5.2), with a higher percentage of participants on dialysis ≤ 1 year and more respondents from minority ethnic groups recruited at Lister, and a younger average age at UHB.

Table 5.2: Participant characteristics (qualitative interviews).

Characteristics	Respondents (n=27) No. (%)	Lister (n=11)	(RFH n=6)	(UHB n=10)
Mean age (range), years	58 (24-89)	60 (35-86)	62 (40-74)	54 (24-89)
Age groups				
20-39	5 (18.5)	2 (16.7)	0 (0)	3 (30.0)
40-59	9 (33.3)	2 (16.7)	3 (50.0)	4 (40.0)
60-74	8 (29.6)	4 (36.4)	3 (50.0)	1 (10.0)
≥75	5 (18.5)	3 (27.3)	0 (0)	2 (20.0)
Sex				
Male	18 (66.7)	8 (72.7)	4 (66.7)	6 (60.0)
Female	9 (33.3)	3 (27.3)	2 (33.3)	4 (4)
Ethnicity (broad)				
White British	12 (44.4)	2 (18.2)	3 (50.0)	7 (70.0)
Asian/Asian British	4 (14.8)	2 (18.2)	1 (16.7)	1 (10.0)
Black/African/Caribbean/British	9 (33.3)	6 (54.5)	2 (33.3)	1 (10.0)
Mixed/multiple ethnic groups	1 (3.7)	0 (0)	0 (0)	1 (10.0)
Missing	1 (3.7)	1 (9.1)	0 (0)	0 (0)
Location				
In-hospital	4 (14.8)	4 (36.4)	0 (0)	0 (0)
Satellite	21 (77.8)	6 (54.5)	6 (100)	9 (90.0)
Home	2 (7.4)	1 (9.1)	0 (0)	1 (10.0)
Time on dialysis				
<12 months	10 (37.0)	5 (45.5)	2 (33.3)	3 (30.0)
12-24 months	4 (14.8)	2 (18.2)	0 (0)	2 (20.0)
25-36 months	9 (33.3)	2 (18.2)	3 (50.0)	4 (40.0)
>3 year	4 (14.8)	2 (18.2)	1 (16.7)	1 (10.0)

5.5 RESULTS: THEMATIC ANALYSIS

Fifteen descriptive themes were constructed from the data by the author, and these can be grouped into 4 main elements: perceptions, behaviours, experience, and others (family, peers, health-care providers). What is notable is that most of the themes are not related to clinical care on the chair, the most commonly described themes were coping strategies, daily managing, and communication with and support from the renal team. Illustrative quotes are presented in (Table 5.3).

The purpose of the analysis was to ensure the item development work was underpinned by the patient experience, a key dimension of scale development. For that reason, a full thematic analysis is not presented beyond the example of quotes that support the themes, a starting point for item development.

Table 5.3: Key themes from the qualitative analysis.

Element	Themes	Description	Illustrative quotes
Experience	Dialysis process	The demands of dialysis such as the restrictions around 3-4 day a week schedules, the time lost, complications and the barriers to taking holidays.	"The only difficulty is you can't plan to do anything on the day you've got dialysis, it's a day swallowed up". (Male, White British, 86 years). "Oh gosh, the time is waiting time, waiting to be picked up, now waiting to be collected and taken home, not a particularly good idea I suppose, but that is probably the most inefficient part of the whole of the setup, the transport" (Male, White British, 86 years) "….it's just routine, I hate routine and this is the routine of three times a week. Like this morning I was just coming in and I thought, do you know what? I could just drive to the coast and the hell with it! But you can't do that…" (Male, White British, 74 years) "We used to go across to the channel Islands quite a bit….just short breaks….But now even that's going to be a mission…unless I change my Saturday to Friday, but then that's if they've got the space here. Or organise it when we go away. But it's a lot of palaver just for a weekend away…." (Male, White British, 63 years)
	Symptoms	The experience of both physical and/or emotional symptoms, the burden and severity and how these impacts on self-managing behaviours. Includes the strategies that are used to cope with or prevent symptoms.	"I need something – the pain to go away, so I can do more, but this doesn't happen." (Female. Asian/Asian British, 55 years). "Fatigue, just mind-numbingly, body-aching exhaustion" (Female, White British, 35 years). "When I feel the nausea just like I said I do the tea early in the morning so that's fine. When I feel the tiredness the next morning unfortunately I don't have a strategy for it. I just know it will go away after a few hours and it does, so it's become part of my, you know, my life…" (Male, Black/Black British, 45 years). "think to begin with I didn't handle things very well. I did get really depressed. I didn't want to leave my room, I didn't get washed or dressed, I didn't eat, I didn't do anything. I'd just be in bed all the time, and I think now it's like you try and handle things a bit different, so you don't get yourself into that point" (Female, Mixed race, 24 years).

Other health conditions	The extent to which multimorbidity complicates managing of kidney disease, particularly when multiple care providers are involved, and treatment recommendations/appointments may conflict. How does it impact on day to day priority setting and the capacity to engage with tasks of daily living?	"… The problem being, with the stoma – I have to drink fluids for it to work. And unfortunately, that takes me over, and, if I don't drink enough fluids, it erm constipates me. And to get it back working again, is heavy doses. So, I'm between the Devil and the deep blue sea." (Male, White British, 76 years). "I was on medication for diabetes, blood pressure, glaucoma, this, that and the other. But they never specifically gave me anything for the kidney disease, whether it could have saved it or not I don't know, you know?" (Male, White British, 63 years). "...there was a crash with me inside and it was my aortic valve, which is, well it's not doing its job... when they really got to grips that it is the aortic valve that needs replacing.... they concentrated far more on relevant things. I have my days off [dialysis] on Mondays and Wednesdays and of course then they have those days to call me in for tests, so I've been on the go either here or at hospital" (Male, White British, 86 years).
Kidney transplant	Perceptions of the barriers to being on the transplant list, the experience of waiting, understanding how decisions are made and expectations.	"I was on the transplant list.....for 18 months, but, again, it's just I had cancer, thyroid cancer last year.... That affects me, but not the kidney, as such, and they've obviously taken me off the transplant list now. [...] what happens if you've had cancer, you go off it **[referring to list]** three to five years and that's it. I'm on the list, but I'm not active and I think that term is they used" (Female, White British, 62 years). "I've been trying to get on the transplant list to get another kidney, but they obviously are not keen….they keep putting barriers in the way, and delaying tactics. I assume it's my age…I don't think they're very happy about doing it…So I'm stuck with the dialysis basically…. I mean I had an emergency hip operation and I was fine…I mean I went through the anaesthetic and all this…they're playing the long game…" (Male, White British, 74 years) **[On the prospect of getting a transplant]** "…this is actually my last, last chance, and if I don't do it this time…. then I'm doing this (HD) forever…" (Female, ethnicity not coded, 51 years).

Behaviours	Management of daily tasks	Managing psychological responses to illness as well as practical aspects of managing illness either independently or with support from others, within the context of relationships, goals, values and life as usual.	“I got to wake up 40 minutes before just to start....getting dressed and that, you know, my wife has to help me with my shoes, with my socks because I can’t bend over and do it. I pushed myself as much as I can, I push myself…” (Male, Asian/Asian British 48 years). **[Talking about daughter-in-law]** “...so she does do most of the things anyway, I don't need to do anything... If I stand for about ten/15 minutes my whole back hurts, so in working-wise it's gone down, because I can't do everything by myself. It's like even when I have a shower, if you bend down and my back really hurts”. (Female, Asian/Asian British, 55 years). “Cooking - I don't do much now. I'm a good cook, a very good cook, but not much....[who does the cooking?] No one. If my husband is at home, he does it, but mostly like takeaway or my sister has made something, and she asks us...” (Female, Asian/Asian British, 39 years)
	Knowledge	If, when, and how patients seek information and how they use it. In what context is information sought and for what purpose, may be reassurance or in decision-making about treatment options etc.	“Well due to dialysis, sometimes it’ll crash the body, you know, when you take too much blood or fluids, again I had to do that again myself, - work it out, they didn’t tell me at the time – the nurses” (Male, Asian/Asian British, 48 years) “I think you just have to kind of get on with it, and I've got a future to lead and I'm doing it for my family. So I think the information is there, but I think you personally have to go and find it” (Male, Asian/Asian British, 40 years). **[self-management is]** "…being an expert in your own condition, and knowing as much as you can, and knowing an awful lot more than the medical professionals who only see you once a week. You're living it day to day, and so you have to self-manage to a certain extent" (Female, White British, 35 years). “I do try and learn... as much as I can of self-care, that I'm doing. I've had about five attempts at lining the machine, and in terms of my medication, I take that religiously” (Male, White British, 72 years).

Coping strategies	Emotion and task focussed engagement strategies that are used to manage the illness within the context of everyday life.	“I’m used to now using the smallest cup in the house…In the beginning it’s a challenge, it’s difficult, but after a while I think your body adjusts and you just do it…” (Male, Black/Black British, 45 years). “My big, big recommendation would be to take every form of help that is offered, because you can’t ever have too much help” (Female, White British, 35 years). “I used to pace myself between the day and especially on the Wednesday and Fridays when I’ve had dialysis on Tuesdays and Thursdays. I don’t have to commute, so I just wake up, come downstairs, if I have the energy start work at 9, I don’t have it 10, then I’ll make sure I do my seven and a half hours” (Male, Black/Black British, 45 years). **[Referring to dialysis unit] “**I’ve got this restriction of being here for about 10% of my time but I’m using that effectively, I think, so it’s doing stuff....I use the time....This is a different world and I don’t let it into my home life.” (Male, White British, 72 years).
Meaningful life	Behaviours that help achieve a sense of balance. Maintaining activities that impact on wellbeing and provide a sense of purpose. Examples of how illness has been integrated into daily living a way that enables a person to maintain purpose and meaning.	“…because I’m restricted mobility, I took up electronics again…. I’ve got so many projects things I want to do, but I’m ending up making model aeroplanes for my grandchildren, and stuff like that..” (Male, White British, 74 years). “I played golf up till Christmas, and the combination then of arthritis more [laughs] than anything to do with the kidneys. So my friends are still waiting for me to come back, but I haven’t wanted to. I said to my consultant at Broomfield ‘So I’ll be able to tee off again?’ he said, ‘Yes, with a buggy perhaps’” (Male, White British, 86 years).

Perceptions	Beliefs about risks and consequences	Perceptions about the health risks linked to certain behaviours and adherence. Understanding the impact of behaviour in the long and short term.	"….in the beginning I had stopped and for 2 or 3 months I didn't have... But now I just have, like I would say one quarter of banana and like maybe 3 or 4 times a week, not more than that" (Female, Asian/Asian British 72 years). "I do spoil myself now and again when my potassium's going a little bit low, but I wait until they tell me it's low and then I'll have a few peanuts, but other than that I have to leave them alone, you know? (Male, White British, 63 years). "No. I had a little wine last night - champagne. I tend to think about a litre of water a day, or other liquids like tea. I don't drink coffee, and I don't drink beer. Occasionally, I might have some wine .... it affects me a bit and I don't feel good afterwards" (Male, White British, 72 years). **[Talking about chips and mushrooms]** "I don't think I eat that amount to, you know, worry about, because erm maybe I'll be naughty like two days a week, five days a week I toe the line" (Male, White British, 76 years).
	Illness perceptions	Making sense of illness, its origins, and consequences. Impact of illness perceptions on physical function, adaption & acceptance and the impact of social situations.	**[Talking about employer]** "Even if you're genuinely sick and its nothing to do with your kidney problem, they might go 'oh it's just kidneys again, oh yeah, he's sick again, oh yeah, sick again'. Last year when I was in hospital, I spent two weeks in hospital, I took that as holiday" (Male, Black/Black British, 45 years). "No I can't have a transplant – not that I'm interested – I was on the list but because of the myeloma…I'd rather just finish off my life here, if I have to. I understand that….I could die any time. I've travelled the world in my work, so I don't need to anymore" (Male, White British, 72 years). "…it's a way of life, you have to adapt, so my life now, my priority now is haemo and then life.." (Male, Black/Black British, 45 years). "…and you know you're stuck with it, and it's that or you're in a wooden overcoat, so…..But it does get me down occasionally." (Male, White British, 74 years).

Self-identity	The intersection with illness and self and the degree to which illness is integrated into identity. Relational roles and social identity form core aspects of identity.	“I would say to my parents ‘I’m not doing this again, I’m not going to dialysis, I’m not having the operation. I give up, I’ve had enough. I don’t want to do it again, and I’m sick of being sick’ and I was really really bad…” (Female, Mixed race, 24 years). “…they came around the other day **[referring to grandchildren]**…and the 22 year old went home and said to his Mum, he said…’do you know?....there’s nothing wrong with his brain (referring to patient)…he’s chatting away and he’s got all these ideas…’ and I said to (my wife)..well this is all failing but, thankfully, this is still going…” (patient points to head) (Male, White British, 74 years). “....when I first went to the dialysis centre... I was waiting to be sent in, and I picked up the wrong leaflet and frightened myself to death! I went, oh, my God! And then put it down.....because it didn't really occur to me at that point that people do decide to stop. So, yeah, I quickly put that to the back of my mind, basically, but I'm luckier when you see some of the other people in the dialysis unit, and how poorly they are” (Female, White British, 62 years). “Going out for like shopping with my husband or meeting friends...so now like social life is not there. [...] they live very far so it’s mostly the phone, that’s why sometimes I miss because I like talking to people and meeting them and the age doesn’t matter, whether it’s 3 year old or 80 year old” (Female, Asian/Asian British, 72 years).
Empowerment & control	Approaches to change, coping and enablers of self-management. A sense of control over the illness that is sufficient to allow involvement in the management of it if wanted. An ability to let go or accept things that can’t be controlled.	"I don't have control over the illness, but I do have some control over the management" (Female, White British, 35 years). “…and they do me a printout every month when they do bloods, and so I watch the potassium levels. If we… we eat out quite a lot, so I choose what I want and avoid the things that are wrong” (Male, White British, 86 years). “You’ve just got to change your life, but at 76, you know, what do you change your life to? [laughs]” (Male, White British, 76 years).

	The future	Maintaining hope and anticipation for good things still to come. Anticipation and preparedness for the future, and reflections on a life lived.	"…somewhere in mind is even hope that one day I may come off". (Female, Asian/Asian British, 72 years). "…you get very tired and you can't do the things you did before…I'm getting old…I mean, I'm 75. I can't complain, and I've had a good crack at it." [later goes on to say] [...] just the hope that at some stage you just might get a kidney transplant, and you can start living hopefully a normal life. And they keep saying to me, oh well, because it won't increase your life, and it's no, but it will improve the quality" (Male, White British, 74 years). "...Pre-dialysis I think it's a really bad time in your life because you are not dialysing and there's a hope that maybe your kidney situation will turn around" (Male, Black/Black British, 45 years).
Others	Impact on family	The degree to which family members provide both task-based and emotional support. The impact of this on those caring and the person supported. Examples, enabling self-management, increased family conflict, feelings of being a burden, or where support is perceived as negative and may affect the patient's ability to self-manage.	[In reference to husband] "....it is because of him that everything goes on in the house, the shopping, if my son and daughter has come he will look after them as well and make them tea or cook a bit of rice and all those things, he does a lot. I think without him I wouldn't be anywhere" (Female, Asian/Asian British, 72 years). "It's put a huge strain on the relationship….and we've both had different experiences of the same event. And we've processed it at different times, and we've processed it differently......I think he's looking forward to a time when we will be more of an equal partnership"(Female, White British, 35 years). "My wife had no choice but to go to work" (Male, Asian/Asian British, 40 years). [In reference to wife] "…has become much more of a carer, so she's had to take on stuff that I would normally, like, I don't know, put the bins out or whatever….which is a shame really because I think she gets weary…" (Male, White British, 74 years).
	Healthcare providers	Support offered by clinical staff to promote and support self-management that goes beyond information sharing and medical support of dialysis to wider goal setting, problem-solving support,	In relation to a procedure – "he came and sat down with me, and we both talked to each other, and then he said 'I don't think I can actually do this. I don't think it's going to improve you condition in any way'….but he was there and he was ready to give me the treatment" (Male, Asian/Asian British, 40 years).

	joint decision making and more holistic support. Patient's perception of the quality, availability, and experience of support.	[Decision to go on dialysis] “I remember this one time I was travelling and the nurse said to me…this is going to blow up…you need to start….when I look back I think it was very poor judgement on my part and it was because I was being defensive about it….I just didn’t want to start…” (Male, Black/Black British, 45 years). [in response to being asked if there was more to say] “no, unless you’ve got any influence about me starting home dialysis [you’d be interested?] Yeah, more than interested in that, at my age. I mean I’m quite a fit person for my age, I’m quite alert. [....] Just kind of waiting. Somebody did speak to me right at the beginning, but I haven’t heard anything. [Asked about the benefits] I can keep an eye on my wife”. (Male, White British, 76 years). “And it’s the worrying about it, and if you worry about something the best thing to do is ask the doctor, and they’ll advise you.” (Female, Asian/Asian British, 55 years).

5.5.1 Themes

Dividing the narrative into four main elements (experience, behaviour, perceptions, and others), enabled an understanding of the data that could inform the next steps of item development. Many of the themes that were inductively generated from the data show overlap. For example, quote 1 is illustrative of the importance of good communication with health-care providers (in providing information, dialysis education and reassurance), as well as the role illness perceptions and hope can play in coping.

Quote 1: "...Pre-dialysis I think it's a really bad time in your life because you are not dialysing and there's a hope that maybe your kidney situation will turn around" (Male, Black British, 45 years).

Similarly, quote 2 speaks to an illness identity, psychological symptoms of illness, and a lapse, perhaps, in hope.

Quote 2: "I would say to my parents 'I'm not doing this again, I'm not going to dialysis, I'm not having the operation. I give up, I've had enough. I don't want to do it again, and I'm sick of being sick' and I was really really bad…" (Female, ethnicity unknown, 51 years).

Beyond this broad categorisation of the narrative, and acknowledgement of the overlap, it was pragmatic to retain more themes than usual in qualitative analysis. The findings in Table 5.2 were reviewed via a process of consensus and in conjunction with the literature; to finalise the main themes and conduct item development (this is discussed briefly in chapter 6).

Here is an example of how the data from the patient interview was mapped to the existing literature to be considered within the context of theory and other evidence. Quote 1 suggests effective communication with healthcare staff may be helpful in supporting patients to deal with a "really bad time" and make the difficult decision to begin dialysis. This aligns with other qualitative research that has found timely patient education is essential in treatment making-decisions (McKie et al., 2023) and that initiation of dialysis is often experienced as disruptive event that can result in a persistent emotional struggle or submissiveness (Moreels et al., 2023). Engagement with treatment decisions is an important aspect of self-management, and distress and the emotional impact described by Moreels et al. (2023) is likely to affect the ability to self-manage. Communication and interaction with healthcare staff is linked to both.

This also aligns with broader research. It has been suggested effective communication may enhance patient-centred care and promote greater shared decision making (Schell et al., 2013), as well as reduce distress (Fogarty et al., 1999; Roter et al., 1995). This illustrates how the empirical data from this study can be used in conjunction with published research to begin to flag important themes. As in chapter 3, analysis from the interviews highlights the complexity in conceptualising self-management, but it can be aligned with some more theoretical evidence from the literature of how factors may relate. This example alone suggests items about decision-making, patient-provider communication, information sharing, and the emotional impact of illness and/or treatment should be included in a patient-focussed self-management scale.

Behaviour elements of self-management unrelated to “self-care” in relation to dialysis treatment, are underrepresented in existing measures. Understanding the patient perspective moves thinking away from the medical model and the dialysis chair as the focal point, towards the importance of physical and emotional symptom management, day to day managing, and utilising social support. Managing daily life in different environments is key, within the healthcare systems but also within community and family.

5.6 NEXT STEPS: THEME REFINEMENT AND ITEM DEVELOPMENT

The literature review and empirical data from the patient interviews provided the foundation for drafting potential themes. The transition to a final set of themes and then to item development was iterative and reflective, involving a continuous loop back to the literature and input from an expert panel, followed by some cognitive pre-testing with patients. This is described briefly in the next chapter, as a prelude to the scale development process.

5.7 DISCUSSION

Using qualitative methods to explore real life experience helps ensure validity of the concept(s) being measured in any novel scale. Both Morgado et al. (2017) and Boateng et al. (2018) describe this step as critical to widening perspectives and generating scale items. This chapter provides a high-level summary of the qualitative work that was undertaken to support item development, rather than give a detailed analysis of all fifteen derived themes. However, the analysis does contribute to existing empirical evidence but most importantly, helps to ensure a patient-focussed self-management scale.

A number of themes that were inductively generated from the patient interviews, such as the importance of social support and good communication with healthcare providers, are consistent with other qualitative studies in stage 5 ESKD patients on HD. Accessing, understanding and processing information, and patient empowerment also feature strongly, and we know from the literature review that these are factors linked to self-efficacy (Gao et al., 2022; Wu et al., 2016), which in turn is related to self-management (Knowles et al., 2016; Lee, 2018; Lin et al., 2017; Wild et al., 2018). What is noticeable is that when patients are asked about their experiences and how they manage, they talk very little about what happens in the dialysis chair and much more about what happens beyond the clinic.

The topic guide used in this study in 2018 includes similar topics to those covered by Moreels et al. (2023) in their study exploring the impact of ICHD on the everyday life of older adults in Belgium. Indeed, there was some overlap in the findings in terms of the importance of acceptance and adaption, and involvement in activities that continue to make life meaningful. The focus was on changes in everyday roles and functioning and what the authors label "areas of remediation", which aligns with coping or adaption strategies. Many of these such as support from others, maintaining meaningful activities and developing new activity patterns (routines), are similar to themes within our data, often linked to modifiable factors. However, the focus for Moreels and colleagues was on the impact of ICHD, and how older and more frail adults adapt to their new life. Discussion regarding illness perceptions, the future, emotional symptoms, the impact of comorbidity more broadly, and the role of healthcare providers, was limited.

Other studies report themes that are similar to or overlap with themes found in our work, for example psychological impact and coping responses (Finnegan-John & Thomas, 2013; Young et al., 2022), uncertainty about the future (Sahaf et al., 2017) and concerns about kidney transplant (Moran et al., 2011). The role of education and information in relation to decision making and impact on family were two key themes identified in the synthesis by McKie et al (2023) that were also prominent in our dataset.

The tendency in renal medicine to view self-management through a medical lens is likely to miss what is important to patients and understate the link between psychosocial factors and more tangible clinical factors like diet, fluids, and adherence to advice. This qualitative work suggests that more latent factors such as perceived control, acceptance (sometimes linked to the treatment journey), illness perceptions and distress are likely to be connected to the ability to engage in self-management activities such as self-care, activities of daily living, fulfilling social roles and communication with healthcare staff. Research in other areas of chronic disease suggest the same (Bishop et al., 2008; Goodman et al., 2013; Gregg et al., 2007; Muñoz González et al., 2023; Ye & Shim, 2010).

This work provides the groundwork for a patient informed measure. The item development which evolved from this point will be briefly summarised in the next chapter, which will then move on to look in more depth at scale development with the emphasis on the survey conducted, that enabled collection of data for psychometric analysis of the draft scale.

CHAPTER 6 : DEVELOPING AND EVALUATING A STATISTICALLY ROBUST, HOLISTIC MEASURE OF SELF-MANAGEMENT

6.1 INTRODUCTION

Chapter 5 explored the patient experience of living with ESKD and HD and how it links to engagement in self-management. Many themes aligned with the literature more broadly but also findings from other qualitative research. The findings further illustrate that self-management is complex and layered and taking a person-centred perspective will ensure development of a measure that fits a tripartite model. Already outlined is the issue that current scales tend to rely on a medical model of self-management linked with adherence and compliance.

Moving from the qualitative analysis, this chapter shifts to the process of item development and refinement via quantitative analysis from panel consensus and cognitive interviewing as part of pre-testing. It will then focus in more detail on scale development, specifically administering a draft of the scale as part of a large survey to evaluate the psychometric properties (Figure 4.1: Self-management scale development framework (**study one).**

6.2 ITEM DEVELOPMENT

Theory and evidence from the literature review was linked with the empirical evidence generated by the qualitative interviews to underpin item development. This was not done as a formal process, rather the themes referred to in table 5.3 were used alongside the literature to generate Items for the scale. All candidate items generated by the author were compiled in an excel spreadsheet and reviewed within meetings convened across several weeks with the wider research team. Over 400 items were generated in total, with the least in the acceptance theme (n=7) and the most in the coping and managing themes (n=44). Once the list was refined, on the basis of content and wording, the remaining items were developed and assessed through a quantitative process of expert consensus and cognitive pre-testing.

6.3 ITEM DEVELOPMENT- CONSENSUS PANEL

A consensus panel, made up of individuals with varying expertise, and a common interest in kidney disease, contributed to initial stages of theme and item development, then through a process of expert consensus using item content validity index (I-CVI) rating, reduced and refined the number of scale items. Using this consensus method ensured the content validity was maintained.

The specific stakeholder group activities were to a) support the development of themes; b) begin to develop scale items via a face-to-face workshop; and then c) refine and reduce the number of items for the draft scale through two rounds of item content validity index rating.

6.3.1 Methods

6.3.1.1 Setting

Face-to-face workshop, followed up with two rounds of item assessment via email using Item-Content Validity Index (I-CVI) rating.

6.3.1.2 Panel

The expert panel consisted of nephrologists (3), methodologists (1), specialist nurses (5), health psychologists (1), dieticians (1), a colleague from the UK Renal Registry (1), academics with a special interest (3) and experts by experience (3), all with an interest in psychosocial aspects of self-management and patient experience. In the final scale, a large multidisciplinary sample from a diverse geographical area (London, Sheffield, Lister, Manchester, Coventry and Derby) was involved to ensure a broad perspective.

6.3.1.3 Process

Outlined below are the four elements that comprised the stakeholder workshop which was conducted in October 2018:

1. Presentation and discussion of findings from the literature review and patient interviews by the author.
2. A group activity that prioritised the themes from the analysis in terms of the most relevant to self-management, using anonymised real-time ranking on a 1-10 scale.
3. I-CVI rating of the Behaviours in Haemodialysis Scale (BHDS) evaluated by Reston et al (2015) as the best measure of self-management with a clinical focus.
4. Small group work brainstorming item development. Discussions were facilitated and recorded by members of the university research team.

6.3.1.4 Identifying and prioritizing themes

Twenty-six themes were presented within the workshop, broadly as described in the results of the interviews (15 themes), but with additional themes: communication, self-care, access to support, resilience, barriers, change/transition, employment, cause of kidney disease, holidays, transport, and time. Most of the additional themes were high frequency codes within a main theme, or relevant to several main themes, or had theoretical relevance as defined within the literature. For example, communication is relevant within the patient-provider theme, social support, and coping strategies. These extra 11 themes were derived through discussions among the research group.

Members of the expert panel were asked to anonymously rank the themes for relevance to self-management with 1 (not relevant) and 10 (very relevant), using a web-based audience response tool. A proportion threshold of ≥5 (proportion of scores 5 and above, where 10 is most relevant) was used as a guide to relevance, but no strict cut-offs were used and decisions to retain or omit were conducted in real time discussion during the workshop (Appendix E). Ranking of overall score was also used to guide decisions. Nine of the 26 themes had proportions <.84 and/or low rank; these themes were either eliminated or encapsulated by other themes. For example, dialysis and cause of disease were redefined as acceptance.

6.3.2 I-CVI rating of BHDs

In line with I-CVI methods described in chapter 4, panel members were asked to rate each of the 34 questions in the BHDS. This scale has been identified by (Reston, 2015) as the best current measure of self-management and includes some psychosocial as well as clinical SM behaviours (Appendix A). By introducing this scale as the best alternative early in the process, meant we could think about incorporating some of the items into the new scale at the item development stage.

The I-CVI was calculated as the number of experts providing a score of 3 or 4 divided by the total number of experts. Items that scored above .78 (as described in the methods chapter) were considered in later stages of item development. Of note, most questions in these domains were rated ≥ .78 which may reflect the bias towards self-management limited to clinical tasks, rather than the tripartite model as described in chapter 3.

6.3.2.1 Small group work

In subsequent small group discussion, definitions for themes and potential items for each were discussed. Field notes were taken by each group facilitator and used to continue the item development beyond the workshop. A summary of some of the key discussion points are included in Appendix F, but broadly the group raised questions about the utility and context in which the scale might be used in relation to the patient journey and whether increasing engagement in self-management applies universally e.g., not all people want to self-manage. I will argue in later chapters that this idea needs to be refuted by the introduction of a broad concept of self-management that illustrates that all of us in any context "self-manage", but perhaps in ways not conventionally recognised or valued e.g., via social interaction or taking time to rest. Everybody self-manages in one way or another, rather than some people choose to and others don't.

Using the discussions from the expert panel, the literature review and the qualitative interview data, the author continued item development in conjunction with the wider research group. Items were generated from existing and related tools, or developed by the author using the literature and patient interviews. An example of items considered and/or adapted from existing or related tools are included in Appendix G. Tools included KDQOL13 (Hays et al., 1997), PROMIS (Cella et al., 2007), Brief COPE (Baumstarck et al., 2017; Carver, 1997), Perceived Efficacy in Patient Physician Interactions (PEPPI) (Maly et al., 1998) and Perceived Stress Scale adapted by Cohen et al. (1983). Other scales reviewed in the process include the Self-Management Scale for Diabetes (Lin et al., 2008), the Resilience Scale (Wagnild & Young, 1993), Work and Social Adjustment scale (Mundt et al., 2002), and the Kidney Disease Loss Scale (Chan et al., 2009). This list is not exhaustive and items from the existing self-management scales reviewed in chapter 3 were also considered for inclusion.

6.3.3 Results: Item content validity index rating (I-CVI rounds 1 and 2).

Approximately two months after the consensus workshop, the panel were provided with a definition of the composite themes (appendix H) and were asked to evaluate 155 items allocated to those themes for relevance, clarity, meaningfulness, and completeness. Content validity indices at the item level were calculated, using the >0.78 cut-off. In this first round, I-CVI's ranged from 0.41 to 1.0. Eight items had an I-CVI = 1.0, indicating high consensus regarding relevance. The themes in which the greatest proportion of items were ≥0.78 was "meaningful life" (10/14 items). The results identified 83 (54%) items which were dropped, and of the 72 remaining, 55 were reworded and 14 new questions added.

This process was conducted again 10 weeks later with the same panel members, only one member was unavailable to participate in round 2 of the I-CVI rating. Eighty-nine items were included in round-two, including four items from the BHDS questionnaire (previously rated in the consensus workshop as described above). The four items (How often have you ever: Helped decide where the needles should be placed? Helped decide how much fluid should be taken off? Checked settings on the dialysis machine to make sure they were the same as usual? Adjusted your phosphate binder dose to the size of your meal?) were from domains 2 and 8 (self-care during HD and shared responsibility in care) and addressed a perceived content gap. Some minor amendments to the wording of the questions were made for clarification, in line with recommendations from Reston (2015). I-CVI for all these questions was 0.94 (appendix I).

Across all the items, 71/89 (79.8%) items were rated ≥0.78 and the I-CVI's ranged from 0.59 to 1.0. A further 5 items were removed by the research team where it was felt there was duplication in content and 66 items were used for the cognitive pre-testing. A total of 29 items were dropped and 40 were reworded between the second round of I-CVI (n=89) and the final 60-item draft scale that was tested using a large survey.

Table 6.1 shows the number of items assessed in each round of I-CVI.

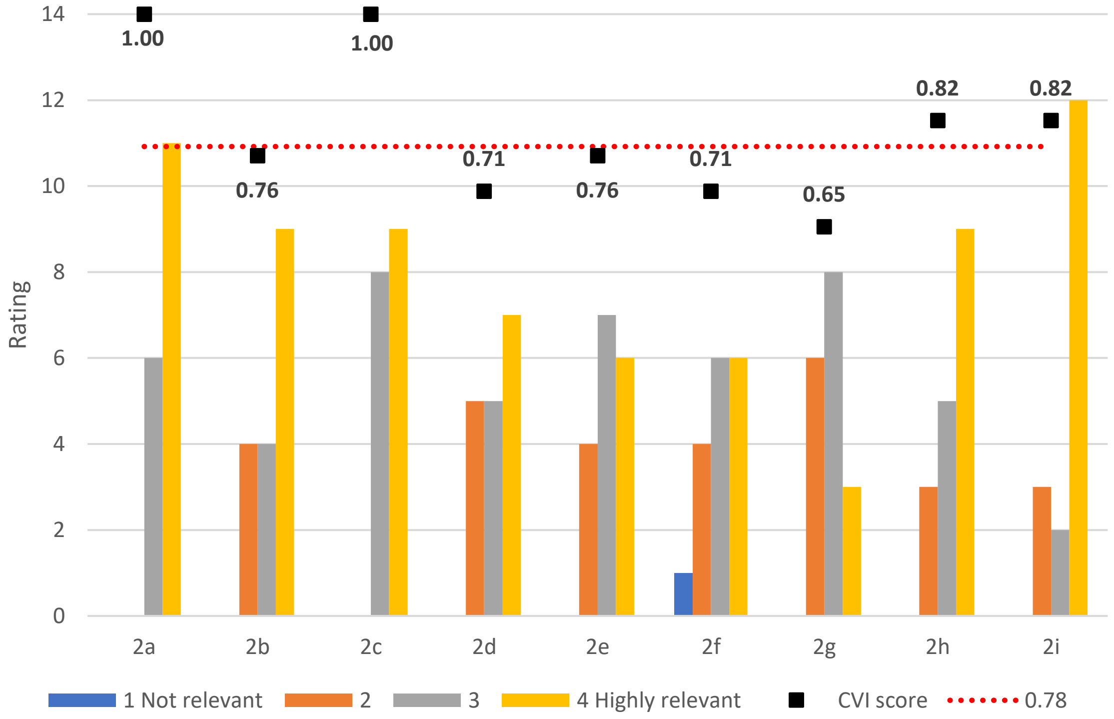
Table 6.1: I-CVI consensus data.

Theme	**I-CVI round 1**		**I-CVI round 2**		**60-item scale**
	Included	Retained	Included	Retained	
Acceptance	10	6	4	4	4
Communication	9	4	5	4	3
Control	8	2	4	3	3
Coping strategies	16	6	8	6	5
General health/multimorbidity	7	2	6	4	5
Hope	8	3	4	2	2
Illness perceptions and identity	12	5	5	3	3
Impact on family	11	6	5	5	5
Information/knowledge	7	4	6	5	3
Managing day to day	14	10	8	5	3
Meaningful life	8	3	4	4	3
Selfcare	0	-	5	5	6
Social support	8	2	3	3	2
Support (MDT)	8	5	7	4	3
Symptoms	9	5	6	6	4
Treatment decisions	13	4	5	5	4
Work	7	5	4	3	2
Total number of items	155	72	89	71	60

Importantly, this table illustrates well how the themes translated into the scale and continued to be represented throughout scale development. At least two questions from each of the themes were retained in the final version of the scale administered to the survey sample, and these are described in the subsequent section.

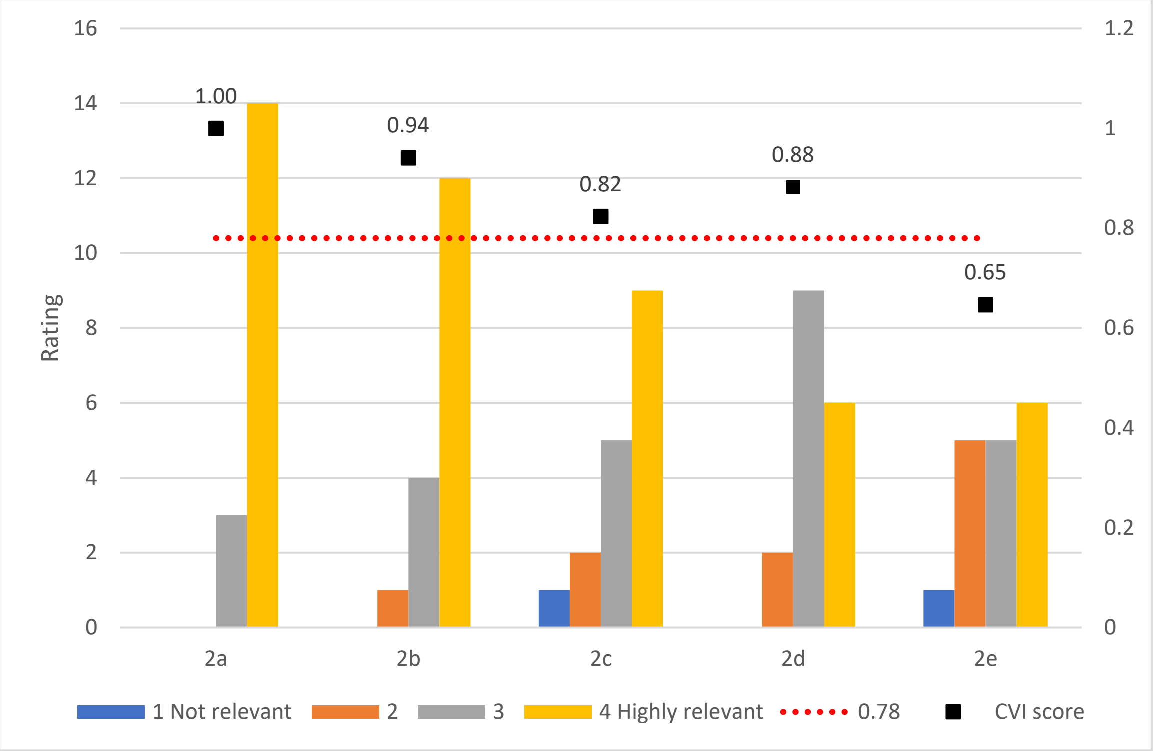
An example of the rating for the communication theme in I-CVI round 1 and 2 are provided in Figure 6.1 and 6.2 (all others are in appendix J). Of the items, 4/9 met the .78 threshold for inclusion in round 1 and 4/5 in round 2. The item about confidence to ask for more information from the doctor was scored universally as 'quite' or 'very' relevant across both I-CVI rounds. Some iterative amendments to the wording were made and this question, along with two others, was retained in the final scale, Table 6.2 provides an example of the development of the items and how the wording of the items changed during each iteration.

Figure 6.1: Mean I-CVI for all items in the communication sub-theme (round 1) and proportion of panel members rating 1-4 for each item (n=18).



Key:
Item 2a - I am confident in my ability to ask a doctor for more information if I don't understand what he/she said.
Item 2b - My doctors talk to me in a way that I find easy to understand.
Item 2c - If I don't understand something, there is always someone in the renal team I can ask.
Item 2d - I have the opportunity to talk to the doctor as often as I feel I need to.
Item 2e - Sometimes I feel like I cannot ask the doctor questions.
Item 2f - I discuss my quality of life with renal staff.
Item 2g - I have comfortable exchanges with my doctor.
Item 2h - In conversations about my care I feel my values, preferences and needs as I express them are respected.
Item 2i - I feel like my doctor treats me as a whole person rather than an illness.

Figure 6.2: Mean I-CVI for all items in the communication sub-theme (round 2) and proportion of panel members rating 1-4 for each item (n=17).



Key:

Item 2a - I feel able to ask a doctor for more information if I don't understand what he or she said.
Item 2b - I am confident I can talk to somebody in the renal team about my care if I need to.
Item 2c - In conversations about my care I feel I'm treated as a whole person rather than someone with an illness.
Item 2d - There have been occasions when I have told staff I wanted something changed about my treatment.
Item 2e - Someone from the renal team regularly checks with me how I'm doing.

Table 6.2: Evolution of wording for items in the communication theme.

Item development	I-CVI round 1	I-CVI round 2	60-item scale
	I am confident in my ability to ask a doctor for more information if I don't understand what he or she said (PEPPI measure)	I feel able to ask a doctor for more information if I don't understand what he or she said	I'm able to ask a doctor for more information if I don't understand what he or she said.
	My doctors talk to me in a way that I find easy to understand.	Dropped	
	If I don't understand something, there is always someone in the renal team I can ask.	I am confident I can talk to somebody in the renal team about my care if I need to.	Wording remained the same
I experience regular and comfortable exchanges of information with my doctor(s)	I have the opportunity to talk to the doctor as often as I feel I need to.	Someone from the renal team regularly checks with me how I'm doing.	Dropped
	Sometimes I feel like I cannot ask the doctor questions.	Dropped	
I have discussed my quality of life with renal staff on at least one occasion	I discuss my quality of life with renal staff	Dropped	
I experience regular and comfortable exchanges of information with my doctor(s)	I have comfortable exchanges of information with my doctor.	Dropped	
Generally, I feel the healthcare staff who provide my care have taken the time to get to know me and my values and preferences.	In conversations about my care, I feel my values, preferences and needs as I express them are respected.	Dropped	
The doctors/nurses treat me like a person rather than just a patient.	I feel like my doctor treats me as a whole person rather than an illness.	In conversations about my care, I feel I'm treated as a whole person rather than someone with an illness.	When I talk to the renal team about my care I'm treated as a whole person rather than someone with an illness.
I would consider switching treatment if it seemed like the right thing to do for me.	No specific question included.	There have been occasions when I have told staff I wanted something changed about my treatment or care (adapted from BHDs).	Dropped

The author worked with the wider research group to make further amendments to the draft scale prior to cognitive pre-testing. This included removing a further 5 items (appendix K) and rewording of 32 items (Appendix L). This version of the scale, along with response categories and instructions, was sent to all expert panel members with thanks for their participation and as a final opportunity to review, comment on wording and sign off.

6.4 ITEM DEVELOPMENT – COGNITIVE PRE-TESTING

As described in the methods (chapter 4), cognitive pre-testing is a recognised step in instrument development and is used for the purposes of identifying any confusion arising from specific scale items and to assess validity evidence based on the assessment process (Peterson et al., 2017). Specific problems with items may include limited applicability, unclear reference, or lack of clarity in an item, and wording or tone (Knafl et al., 2007). Cognitive pre-testing is vital in developing any survey or scale and helps prevent misinterpretation, or a failure to measure what was intended (Tourangeau et al., 2000; Willis, 2005). The process has been described as containing as much art as science (Beatty & Willis, 2007) but is a critical part of content validation. Data collected on item responses are used to look at means and variability of each item e.g., floor and ceiling effects.

6.4.1 Methods

6.4.1.1 Participants

A series of in-person cognitive interviews were conducted with a small sample (n=11) of people receiving haemodialysis, the inclusion criteria is documented in chapter 4. A relatively small sample is sufficient in improving a measure (Willis, 2005) and more recent research suggests 5 to 15 is adequate (Peterson et al., 2017).

6.4.1.2 Procedure

All participants were interviewed at their usual treatment site whilst on dialysis, except one HHD patient who was interviewed at home and not on dialysis at the time of the interview. Interviews lasted approximately 60 minutes, and the last 45 minutes of dialysis were avoided to mitigate against discomfort or tiredness. None of the participants showed any signs of distress, fatigue, or unexpected illness during the interviews. All completed the interviews.

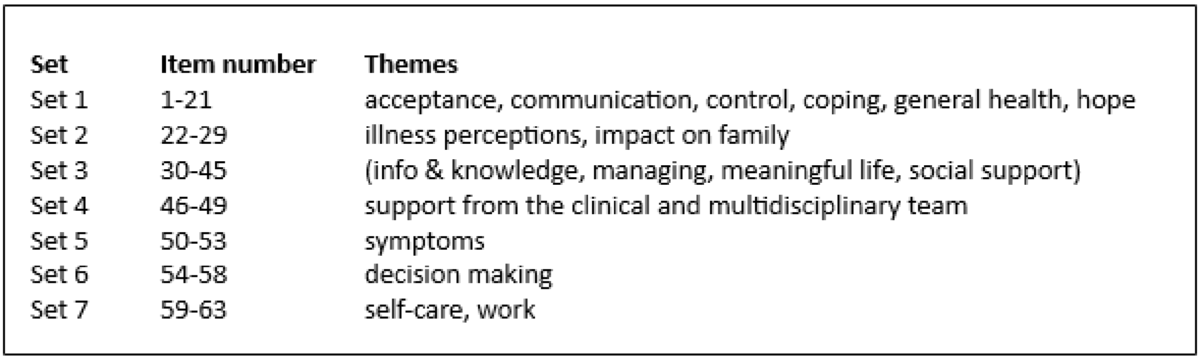
As referred to in the methods chapter, a combined think aloud and verbal probing methodology was used (Willis & Artino, 2013). The author conducted all interviews using pre-set questions and probes (see topic guide in appendix M). Participants were provided with a copy of the scale with written instructions and asked to respond to each item, as well as giving verbal feedback on scale instructions, formatting of items, wording, and response options. Creating the real-world environment and circumstances in which the measurement would be completed, rather than just asking the respondent to read aloud, is recommended (Peterson et al., 2017). Verbal probing was concurrent and occurred immediately after a response to each item was marked on the 7-point scale. The interview was audio-recorded using Audacity software.

6.4.1.3 Sampling plan

Items remained grouped by theme for cognitive pre-testing and a separate paper version of the scale items and separate demographics questionnaire were provided to each participant. To avoid undue respondent burden (Irwin et al., 2010), rather than review the entire scale (66 items), each participant was given all the items in 5 of the 7 sets of items (Figure 6.3).

Comments specific to “types of problems” and “response stages” (primarily, understanding and selection of appropriate response) as described by (Conrad & Blair, 1996; Conrad & Blair, 2001), were recorded using a coding framework (appendix N). Recommendations for item amendment based on the cognitive interviews were reviewed and discussed with the research group.

Figure 6.3: Cognitive pre-testing item sets.



Set	Item number	Themes
Set 1	1-21	acceptance, communication, control, coping, general health, hope
Set 2	22-29	illness perceptions, impact on family
Set 3	30-45	(info & knowledge, managing, meaningful life, social support)
Set 4	46-49	support from the clinical and multidisciplinary team
Set 5	50-53	symptoms
Set 6	54-58	decision making
Set 7	59-63	self-care, work

6.4.2 Results

6.4.2.1 Participants

All interviews were conducted in quick succession over approximately two weeks. There were four with female participants and seven males, with a mean age of 58 years, range 24 to 81 years. Almost half of the sample were from minority ethnic groups and there was variation in time on dialysis (Table 6.3).

Table 6.3: Characteristics of the cognitive pre-testing sample (n=11).

Characteristic, n (%)			
Renal centre		**Ethnicity**	
Lister	4 (36.4)	White	6 (54.5)
Queen Elizabeth	4 (36.4)	Mixed	1 (9.1)
Royal Free	3 (27.2)	Asian	3 (27.3)
Dialysis setting		Black	1 (9.1)
In-centre	2 (18.2)	**Time on dialysis**	
Satellite	8 (72.7)	< 12 months	3 (27.3)
Home	1 (9.1)	1-2 years	4 (36.4)
Sex		2-3 years	1 (9.1)
Male	7 (63.6)	>= 3 years	3 (27.3)
Female	4 (36.4)		
Age			
20-39 years	3 (27.3)		
40-59 years	1 (9.1)		
60-74 years	3 (27.3)		
75-90 years	4 (36.4)		

6.4.2.2 Item refinement

Six items were dropped as a direct result of findings from the cognitive pre-testing process (see Table 6.4). This was either due to respondent comments, floor, or ceiling effects, two or more missing responses or content overlap with other items; usually a combination of at least two factors. People receiving home HD found most of the items relevant to their personal circumstances. All respondents were broadly happy with the tone of the questions and did not find any of them distressing to answer or objectionable in any other way. Aside from the items dropped, the wording of 24 other items was amended; 5 of which had changes to both the general wording of the item and the response options. A further 11 items had only response option changes (appendix O).

Table 6.4: Items dropped after cognitive pre-testing.

Item deleted	Quote	Comment
There is someone in my life whose advice and/or encouragement helps me manage my kidney disease day to day.	“People don’t know enough generally about the disease to give advice. Remove question or take out advice”	Distribution of scores was poor for this item; all respondents selected either 4, 1 or 7. The respondent that selected 4 commented that this was because the number represented a neutral response
I keep a careful watch on what I eat and drink so that I can make changes if necessary.	“I find advice confusing around food and drink. Hard to monitor as the advice is conflicting and so I haven't really changed what I eat and drink……. I'm not sure changing my diet will help me. I'd like to see a dietician but there isn't one available”	There is another question about food and drink, so this question was dropped.
I seek the company of friends, family and/or other patients.	“I would seek company on dialysis but can't”	Patients found this question a bit ambiguous, there may be barriers to seeking company even if one would like to. Two out of seven respondents did not answer this question or selected don’t know.
The renal team support me with setting and achieving my goals.	“It’s just a matter of keeping alive isn’t it?”	All respondents left this question blank or selected non-applicable. There are other questions about the renal team and one other question about more general support. Perhaps inclusion of the renal team means patients may not think about goals beyond clinical care. They feel the question is not relevant to them.

When I need to make a treatment decision, I talk it over with someone I trust.	"If it's a doctor then it's his job to advise me I need this or that. I wouldn't need to talk to someone else, I'd just trust them and do what he/she said" (male, white British patient, QE). "I don't talk to noone, I just talk to myself in my head. I work it out in my own head"	This overlaps with another treatment decision question which is less ambiguous.
I feel confident doing the dialysis myself.	One patient commented "the machine is really doing it" and two felt this question only related to home HD patients.	This view that the question relates only to home HD patients is reflected in the responses; 4/6 responded 1 (not at all confident) and a further respondent checked N/A. There is another question about dialysis in relation to self-care.

6.4.3 Evidence from the scale responses

Evidence of floor or ceiling effects are defined here as ≥50% item responses recorded as 1 or 7. Since the sample size is too small to reliably assess skewness or kurtosis, items were not omitted based on a floor or ceiling effect alone, but these data were examined as part of cognitive pre-testing. More than 50% of respondents marked one or seven for 41/66 items assessed. In addition, one or more participants didn't provide a response for 13/66 items, despite don't know (DK) and not applicable (NA) being included as possible response options.

Missing data was most problematic for 'I feel more isolated that I did before I started dialysis' and 'The renal team support me with setting and achieving my goals'. The latter question was dropped as none of the participants marked a response. But the former was retained as the research team felt this to be an important question and one that may be answered in the context of self-reporting (without the researcher present). To note, this part of the study was conducted pre-COVID.

For the purposes of transparency, data captured at this stage on floor and ceiling effects for items subsequently dropped are presented in Appendix P. Other items showing a floor or ceiling effect (as defined) were reworded and retained.

6.4.4 A note about 7-point scales and framing

A rationale for the use of a 7-point Likert scale and the choice of response anchors is outlined in chapter 4. Currently there is little published evidence on the use of varied response anchors and potential impact on response selection or data quality (Weijters et al., 2013). The choice to use heterogeneous, item-specific, anchor response labels reflect the complexity of the underlying construct and the need for non-standardised questions.

6.4.5 Positive/negative wording

Whether the lower response anchor represented an absence or presence of a construct varied across the scale and was often a function of whether statements were positive or negatively phrased, with a higher score indicating greater engagement with self-management. Inclusion of reverse wording is cautioned by some, Suárez-Alvarez et al. (2018) and Kamoen et al. (2013) report that respondents express their opinions more positively when the question is worded negatively. Salazar (2015) suggests using both positive and negative items can affect the internal consistency of the scales. However, there are researchers that support the use in reducing response bias (Weijters et al., 2013). Prados (2007) cites an imbalance between items that assess positive beliefs and those that assess negative beliefs as a limitation in scale development.

Approximately a third of the items were negatively phrased, the rest being positive or neutral. Negative wording was used where a construct was more clearly represented in this way. An example being: “I feel more isolated than I did before I started dialysis”.

Four negatively worded items in which a higher score corresponded to lower engagement in self-management were reversed scored in the analysis if retained in the final scale. All items and response options, including the use of N/A were reviewed in the analysis.

6.5 SUMMARY COMMENTS

Numerous versions of many of the items were developed, assessed, and revised in a very iterative approach. Emphasis was placed on the inclusion of psychosocial domains, and less on domains related exclusively to clinical care, adherence, and other medicalised terms. Content validity was considered and formally assessed using data from the literature, qualitative interviews and panel consensus, as well as in pre-testing. If established in the early stages of development this ensures confidence in any inferences about self-management that might be made using the final scale (Morgado et al., 2017). The remaining sections of this chapter will move on from item development to describe scale development. Assessment of content validity continues in the next step of scale development; this thread is an important element of methodological rigour and helps ensure the end point is a valid measure of self-management as conceptualised in chapters 2 and 3.

6.6 SCALE DEVELOPMENT AND EVALUATION

Together, the cognitive pre-testing and administration of the scale (Figure 4.1), take the process from item development (a list of candidate items which is refined and reduced) to a comprehensive and meaningful scale with instructions, structure, and relevant response categories to be tested on a large dataset. This scale must then be tested and psychometric data relating to reliability and validity of the scale, collected from a sample of the relevant population which in this case, is people receiving treatment for haemodialysis.

6.6.1 Testing measurement validity

The final draft version of the fully formatted 7-point self-management scale, comprised 60-items (appendix Q). Unlike the order for the cognitive pre-testing, items were randomised for the large-scale survey. Whilst this approach has detractors, clustering items by theme “may lead to artificially high consistency between responses to a scale's items” (Robinson, 2018). Therefore, all but the first 3 and last 2 questions, were randomised. The first 3 items were positively phrased questions relating to the clinical team, following the rationale that early questions should be easy and pleasant to answer. The last two questions related to employment and were likely not relevant to all. Items of sensitive topics were interspersed throughout.

This version of the scale was submitted as a substantial amendment for REC approval (REC ref 17/EM/0451). Once approved (appendix R) it was collated with other measures and the demographics questionnaire for use in the validation survey.

6.6.2 Methods

6.6.2.1 Participants

As described in the methods chapter, participants were recruited from three renal centres (Lister Hospital, Royal Free Hospital and University Hospital, Birmingham) and had been receiving haemodialysis for at least three months in-centre and via satellite units directly. Packs were sent to all home HD patients.

6.6.2.2 Sample size

A relatively large and heterogeneous sample is optimal for the evaluation of a novel scale. (Clark et al., 1995; Clark & Watson, 2019) suggest 300 respondents (ideally a sample representing the target population) is sufficient when initial cognitive pre-testing has been undertaken. Similarly, Boateng et al. (2018) suggest 200-300 for factor analysis. However, the number of items in the scale and the number of dimensions is important. Whilst the target for the self-management study was 600, summations from Clark & Watson (ibid) and Boateng et al (ibid), suggest that a sample between 250 and 450 would be adequate. Hair et al. (2019) purport 5 respondents per item to be adequate, for a 60-item scale this equates to approximately 300. Ultimately, resources and local capacity were the main constraints in this study.

A minimum sample size of 100 participants was sought for the test re-test. This has been deemed “good” for ascertaining the size of the correlation between tests (Barchard et al., 2013; Terwee et al., 2012).

6.6.2.3 Procedure

A large-scale self-report survey (pen and paper) of participants receiving HD was undertaken, between November 2019 and March 2020, to evaluate the content, structure and reliability of the updated scale. The target sample size was 600, and the intention was to approach all individuals at the three centres currently dialysing for more than three months (over 2,000 packs were sent out to support recruitment). Alongside the self-management (SM) scale and demographics questionnaire, the End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ), PHQ-9 Depression Test Questionnaire and Self-Efficacy for Managing Chronic Disease Questionnaire (SEMCD-6) were included for the purpose of validation. Participants were invited for a follow-up survey. To assess instrument stability over time, those consenting were sent the SM scale plus a Change of Circumstances Questionnaire, 4 – 6 weeks later. Some data were extracted from NHS clinical records by centre staff; clinical data on 3-month average plasma phosphate and intradialytic weight gain and whether the patient had ever received a transplant, time since dialysis initiation, frequency, and duration of dialysis (in hours).

For the re-test sub-group, all were contacted via post by the renal centres and asked to repeat the self-management scale, plus a change in circumstances questionnaire. The latter was to ascertain whether the respondent had experienced any significant change in circumstances or life events. All returned data was double entered into an excel spreadsheet by two researchers. To further prevent data entry error, the data validation function within excel was used; value conditions and drop-down menus were set up.

6.6.2.4 Analysis plan

The purpose was to reduce items to a pragmatic number, whilst retaining the important items that explain the common factors identified (Fabrigar et al., 1999). Item analysis was conducted to explore the quality, distribution, and variance of each item. Negative items were reverse coded prior to analysis. Exploratory factor analysis (EFA) was used to identify a likely factor structure and reduce the number of items in the self-management scale to those which best describe the data.

Bartlett's Test of Sphericity and Kaiser-Meyer-Olkin (KMO) were used to assess suitability for factor analysis (criteria value $p<0.05$ and ≥ 0.8 respectively). The number of factors was determined using eigenvalues and varimax orthogonal rotation was used to examine the relationship among factors, the underlying principle of this method is that the factors are uncorrelated. Using this method is a traditional way of running exploratory analysis at the early stages of scale development, but oblique rotation using the Oblimin method, which assumes correlation, was conducted later as a further check.

The following statistics were used to decide which items to retain and omit in the final model. These included item-total correlations, correlation between factors, strength and specificity of factor loading, communality, consistency reliability (coefficient alpha). Criteria that guided decision making were:

1. Items per factor >2 (Maccallum et al., 1999; Raubenheimer, 2004).
2. Factor loadings cut off criteria of .35 were used initially, increased to >.50 for later iterations of the model in line with Comrey & Lee (1992) and Hair et al. (2019). Ideally, >.2 units difference between factor loadings (Stevens, 2009).
3. Cronbach's alpha (reliability coefficient) to be at least .80. for whole scale (Cortina, 1993; van Griethuijsen et al., 2015) and assessment of the coefficient for each item.

4. Communality (calculated as 1-Uniqueness). Ideal communalities being 0.7 or above MacCallum et al., 1999, 2001).
5. Inter-item correlations >.5 are indicative of high correlation and are considered for deletion. Virtually all the inter-item correlations in the final model should fall between .15 and .50 to ensure unidimensionality (Clark & Watson, 2019).
6. Four fit indices were used to evaluate the model: standardised root mean square residual (SRMR), root mean square error of approximation (RMSEA), comparative fit index (CFI) and Tucker Lewis Index (TLI). The chi-square statistic is also presented but is sensitive to sample size (Tong & Bentler, 2013) so considered in conjunction with other measures of model fit. As guidance, fit is considered acceptable if RMSEA and SRMR are ≤.10, and CFI and TLI are ≥.9 (Finch & West, 1997; Hu & Bentler, 2009 as reported in Clark & Watson, 2019).

What follows are the results of a preliminary and exploratory analysis which is systematic in its use of statistical data but also relies of the judgement of the author and research team to prune items from the scale.

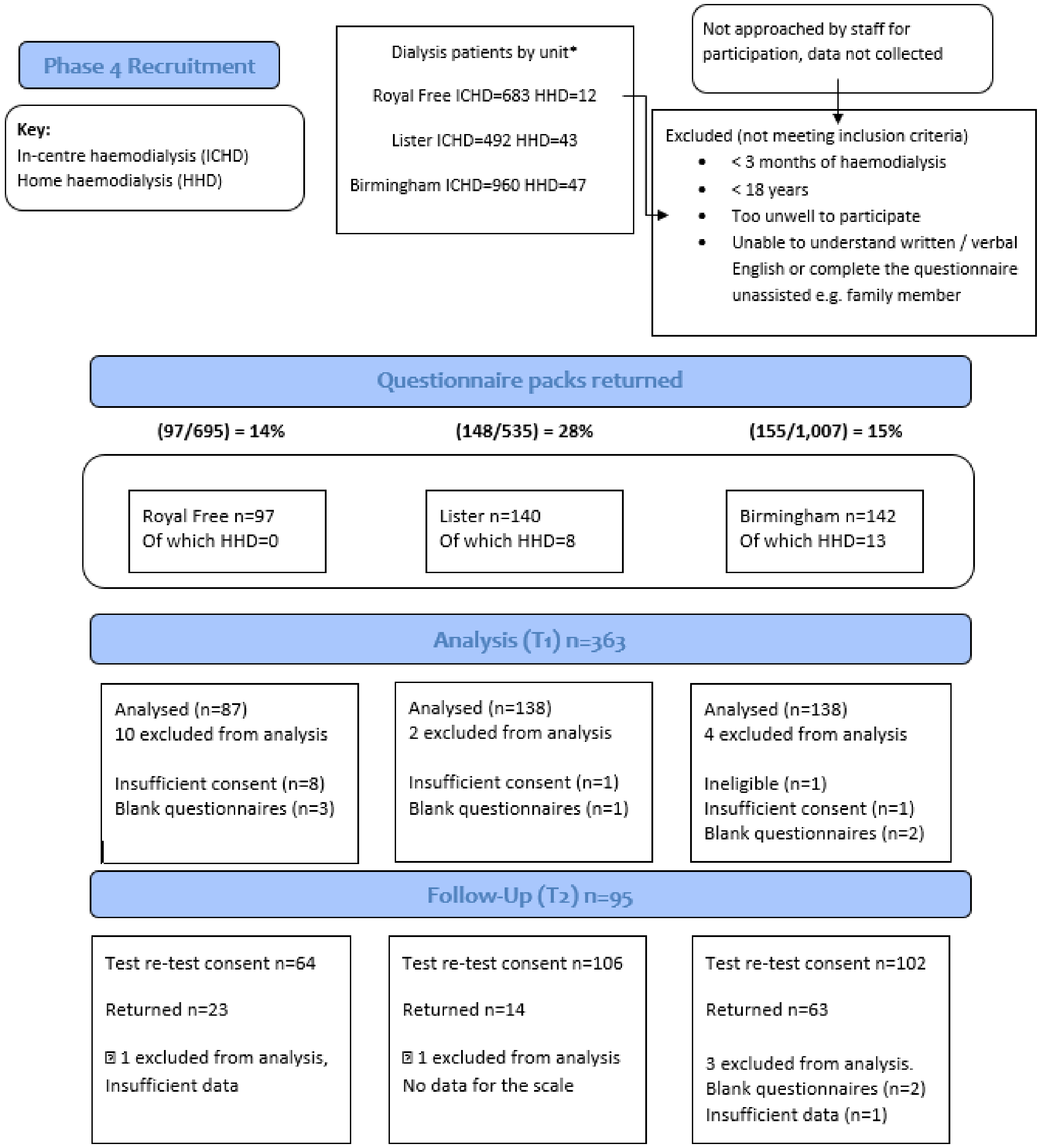
6.6.3 Results

6.6.3.1 Flow of participants

Three hundred and seventy-nine participants completed the scale and accompanying questionnaires, data for 363 patients was analysed. Data from 16 respondents were not included in the final analyses of the main survey; 6 returned blanks forms, 1 was not eligible and 9 provided insufficient consent (see Figure 6.4).

Using data collected by the renal registry, it was estimated that approximately one quarter of the haemodialysis population of the Lister site participated in the survey. Approximately one sixth for the other two sites. Some people at each site would not have met the inclusion criteria; it is not possible to report how many people were approached. Two hundred and seventy-two people were contacted in the re-test, 37% returned the completed scale (100/272). Data from 5 respondents could not be included in the re-test analyses.

Figure 6.4: Recruitment to survey.



* Data on the number of in-centre and home haemodialysis patients by renal centre is from the UK Renal Registry 22nd Annual report; data to 31/12/2018 (pp104 and 159). These numbers map to the study inclusion criteria; they should only include patients >18 years that have been on haemodialysis for 3 months or more. However, they will include unwell patients and those who don't understand written or verbal English so will be an over-estimate of the number of patients eligible.

6.6.3.2 Participant characteristics (survey)

Table 6.5 shows participant characteristics of the baseline survey, which are broadly representative of the UK renal registry population (data for 2019). Combining study data for patients attending in-centre and satellite dialysis, the median age is 65.5 years for the sample, compared with 67.4 years in the registry data, but the proportion of men is approximately the same.

The demographic and clinical characteristics of the population were described. Of the data analysed, 50 (13.9%) patients were in-hospital patients, 290 (80.3%) were satellite patients and 21 (5.8%) home haemodialysis patients. The male to female ratio was 2:1 and age range 21 to 90 years. Almost half the sample were married or living with a partner (52.5%), 10% lived in a household with children. The sample was ethnically diverse with 11.6% patients self-defining as Asian/Asian British and 11.6% as Black. Seventy-six percent of the sample reported one or more other LTCs with 39.4% having two or more alongside CKD. The most common LTCs self-reported were diabetes (36.6%); arthritis (28.9%) and heart disease (28.1%). Depression was reported by 15.7% of respondents and cancer, 13%. About one fifth (21%) of participants required some help completing the scale and associated measures and questionnaires, the nature of this help was not specified. The participant characteristics of the test re-test sub-sample did not differ significantly from baseline.

Table 6.5: Survey sample characteristics compared with renal registry ICHD population.

Characteristic[a]	Baseline survey sample[b]	Reference population (%)[c]	Table ref
Renal Centre (n=363)			
University Hospital Birmingham	138 (38.0)		
Lister Hospital	138 (38.0)		
Royal Free Hospital	87 (24.0)		
Age, yrs (n=363)			
20-39	27 (7.5)		
40-59	115 (31.8)		
60-74	136 (37.6)		
Aggregate group 18-74	76.9%	77.2%	2.4
75 or older	84 (23.2)	22.8%	2.4
Sex (n=362)			
Men	233 (64.4)	62.2%	5.3
Women	129 (35.6)		
Ethnicity (n=361)			
White	250 (69.3)	67.7%	5.3
Asian & Asian British	42 (11.6)	16%	5.3
Black African Caribbean & Black British	49 (13.6)	12.5%	5.3
Mixed and multiple ethnic groups	12 (3.6)	-	
Other ethnic group	7 (1.94)	3.8%	5.3
Time since diagnosis, yrs (n=356)			
Within last year	19 (5.3)		
1-5	118 (33.2)		
6-10	70 (19.7)		
≥10	128 (36.0)		
Since birth or childhood	21 (5.9)		
Length of time on dialysis, yrs (n=362)			
<1	65 (18.0)		
1-2 (inclusive)	97 (26.8)		
2-3	42 (11.6)		
3-4	40 (11.1)		
4-5	30 (8.3)		
5-10	58 (16.0)		
≥10	30 (8.3)		

[a] Data are presented as n (%).

[b] Data were missing for 13/17 variables and proportion of missing ranged from 0.3-9%. For 15/17 vars missing data <3%. Proportion missing data was highest for marital status and education.

[c] Source: Renal Registry 25th Annual Report UKKR (2019 data) England ICHD patients

6.6.3.3 Item-level descriptive statistics

Item response distribution and item mean, *SDs* and median are presented in Table 6.6. The mean scores for each item ranged from 2.56 to 6.58 (SD=0.99-2.48). Item total correlations were between 0.18 and 0.19.

Overall, the amount of missing data across all questionnaires was low, most items (58/60) had missing data ≤5%. The greatest proportion of missing was 6.1% for items 18 and 39: “I adjust my phosphate binder to the size of my meal” and “I am confident in the advice my GP gives me about my kidney disease”. Selection of the *don’t know* response ranged from 0% to 4.99% and for *not applicable*, 0-

17.9%. The exception was the two items about paid employment, approximately two thirds of respondents selected the *not applicable* option. This could be anticipated given the age and health status of the sample.

Data on the percentage of response scores at either end of the scale provide an indication of any floor/ceiling effects i.e., a non-normal distribution. The percentage of respondents reporting the lowest or highest score ranged from 1.1% to 40.4% and 10.9 to 76.6% respectively. There was some evidence of a ceiling effect; 13/60 items show >50% select response 7. This can be problematic as limited use of the full-scale range may mean information gleaned is limited. However, since the sample represents the target population, and this is exploratory rather than confirmatory analysis of a novel scale, and in a field in which there is no gold standard, no items were deleted at this stage and further analysis was conducted with all 60-items.

Table 6.6: Distribution of scale items

	Obs.	^{a}Mean (S.D)	Median	% score 1	% score 7	^{a}Don't know (%)	^{a}N/A (%)	^{a}Missing (%)
Item 1	358	5.99 (1.48)	7	1.45	57.6	6 (1.68)	8 (2.2)	5 (1.4) ^{c}
Item 2	357	6.22 (1.35)	7	2.54	61.3	2 (0.56)	2 (0.56)	6 (1.7)
Item 3	354	6.17 (1.30)	7	1.73	57.0	5 (1.41)	3 (0.85)	9 (2.5)
Item 4	356	6.02 (1.49)	7	2.31	55.3	6 (1.69)	3 (0.84)	7 (1.9) ^{c}
Item 5	353	5.25 (1.73)	6	5.1	33.1	3 (0.85)	2 (0.57)	10 (2.8)
Item 6	355	5.82 (1.60)	7	3.42	51.0	3 (0.85)	2 (0.56)	8 (2.2)
Item 7	356	5.65 (1.57)	6	2.82	42.3	0 (0)	1 (0.28)	7 (1.9) ^{c}
Item 8	357	5.03 (2.07)	6	11.2	35.7	3 (0.84)	7 (1.96)	6 (1.7) ^{c}
Item 9	351	3.13 (2.25)	2	40.4	13.7	8 (2.28)	60 (17.1)	12 (3.3)
Item10^{r}	355	2.56 (1.69)	2	3.7	38.9	2 (0.56)	3 (0.85)	8 (2.2) ^{c}
Item11	355	4.47 (2.24)	5	17.3	29.6	1 (0.28)	13 (3.66)	8 (2.2) ^{c}
Item 12	352	5.71 (1.45)	6	1.78	41.3	16 (4.55)	0 (0)	11 (3.0) ^{c}
Item 13	355	5.09 (1.82)	6	7.1	28.0	1 (0.28)	0 (0)	8 (2.2)
Item 14	354	4.88 (1.78)	5	6.3	25.7	2 (0.56)	2 (0.56)	9 (2.5) ^{c}
Item 15	347	5.76 (1.41)	6	1.5	40.2	2 (0.58)	3 (0.86)	16 (4.4)
Item 16	349	5.40 (1.77)	6	5.3	40.2	7 (2.01)	21 (6.02)	14 (3.9)
Item 17	345	3.90 (2.48)	4	30.0	28.2	7 (2.03)	9 (2.61)	18 (5.0)
Item 18	341	4.01 (2.36)	4	29.9	20.7	17 (4.99)	61 (17.9)	22 (6.1)
Item 19	349	5.31 (1.74)	6	6.0	31.5	10 (2.87)	7 (2.01)	14 (3.9)
Item 20	350	6.58 (0.99)	7	1.2	76.6	5 (1.43)	3 (0.86)	13 (3.6)
Item 21	349	3.53 (1.96)	3	23.0	10.9	0 (0)	2 (0.57)	14 (3.9)
Item 22	349	4.89 (1.93)	5	8.5	29.5	1 (0.29)	5 (1.43)	14 (3.9)
Item 23	348	5.51 (1.45)	6	1.7	34.4	2 (0.57)	0 (0)	15 (4.1)
Item 24	351	5.28 (1.80)	6	5.5	36.4	9 (2.56)	16 (4.56)	12 (3.3)
Item 25	348	4.41 (2.13)	5	14.9	22.5	3 (0.86)	32 (9.2)	15 (4.1)
Item 26	349	4.76 (2.35)	5	20.2	37.6	5 (1.43)	17 (4.87)	14 (3.9)
Item 27	351	5.88 (1.75)	7	5.3	59.4	5 (1.42)	4 (1.14)	12 (3.3)
Item 28	352	4.70 (2.15)	5	15.4	31.0	5 (1.42)	2 (0.57)	11 (3.0)
Item 29	353	4.73 (2.07)	5	11.8	28.7	2 (0.57)	3 (0.85)	10 (2.8)
Item 30^{r}	353	3.53 (2.08)	3	14.0	23.3	4(1.13)	6 (1.70)	10 (2.8)
Item 31	353	4.32 (2.21)	4	18.2	23.5	6 (1.70)	6 (1.70)	10 (2.8)
Item 32	351	5.28 (1.82)	6	6.2	37.6	6 (1.71)	7 (1.99)	12 (3.3)
Item 33	353	5.07 (2.16)	6	12.0	42.8	7 (1.98)	13 (3.68)	10 (2.8)
Item 34	353	6.13 (1.30)	7	1.1	57.3	1 (0.28)	2 (0.57)	10 (2.8)
Item 35	354	5.85 (1.51)	6	3.5	45.7	5 (1.41)	1 (0.28)	9 (2.5)
Item 36	352	5.23 (1.90)	6	6.9	35.1	7 (1.99)	12 (3.41)	11 (3.0)
Item 37	353	5.78 (1.56)	6	2.9	44.5	4(1.13)	5 (1.42)	10 (2.8)
Item 38^{r}	352	4.01 (2.10)	4	20.3	17.1	1 (0.28)	6 (1.70)	11 (3.0)
Item 39	339	4.79 (1.98)	5	9.2	28.6	6 (1.77)	48 (14.16)	22 (6.1) ^{c}
Item 40	347	4.26 (2.05)	4	13.4	20.1	2 (0.58)	3 (0.86)	16 (4.4) ^{c}
Item 41	347	5.26 (1.86)	6	7.0	36.0	2 (0.58)	3 (0.86)	16 (4.4) ^{c}
Item 42	350	6.01 (1.55)	7	4.1	57.2	3 (0.86)	8 (2.29)	13 (3.6) ^{c}
Item 43	348	6.11 (1.35)	7	1.5	57.8	1 (0.29)	2 (0.57)	15 (4.1) ^{c}
Item 44	352	5.52 (1.80)	6	4.5	43.9	9 (2.56)	8 (2.27)	11 (3.0) ^{c}
Item 45	348	4.14 (2.26)	4	21.4	23.6	11 (3.16)	16 (4.60)	15 (4.1) ^{c}
Item 46	350	5.82 (1.92)	7	7.9	61.8	0 (0)	10 (2.86)	13 (3.6) ^{c}
Item 47	348	4.68 (2.16)	5	12.7	32.0	4 (1.15)	6 (1.72)	15 (4.1) ^{c}
Item 48	348	4.78 (2.23)	6	14.7	34.7	3 (0.86)	20 (5.75)	15 (4.1) ^{c}
Item 49	348	6.17 (1.30)	7	1.2	58.8	7 (2.01)	0 (0)	15 (4.1) ^{c}
Item 50	350	5.87 (1.78)	7	5.6	59.1	3 (0.86)	11 (3.14)	13 (3.6)

Item 51	351	4.78 (1.94)	5	8.4	25.9	3 (0.85)	4 (1.14)	12 (3.3)
Item 52	351	5.18 (1.98)	6	9.7	37.3	7 (1.99)	14 (3.99)	12 (3.3)
Item 53[r]	352	2.88 (1.84)	2	6.6	30.0	2 (0.57)	3 (0.85)	11 (3.0)
Item 54	350	5.66 (1.55)	6	2.2	39.9	16 (4.57)	19 (5.43)	13 (3.6)
Item 55	349	4.61 (2.08)	5	11.5	27.1	6 (1.72)	4 (1.15)	14 (3.9)
Item 56	348	3.94 (2.38)	4	30.6	22.2	4 (1.15)	61 (17.53)	15 (4.1)
Item 57	347	5.96 (1.52)	7	3.5	54.0	0 (0)	6 (1.73)	16 (4.4)
Item 58	347	5.77 (1.47)	6	2.4	43.8	6 (1.73)	3 (0.86)	16 (4.4)
Item 59	345	3.82 (2.00)	4	16.2	12.6	0 (0)	238[b] (69.0)	18 (5.0)
Item 60	343	3.30 (2.19)	3	33.3	13.7	1 (0.29)	230[b] (67.1)	20 (5.5)

[a] Data are presented as *n* (%), include response 1-7 only, don't know, N/A and missing excluded.

[b] These items may be perceived as relevant only to respondents currently in employment (17.3% of the sample).

[c] Missing values for this item may not be missing at random when considering the sex of the respondent.

[r] Item reverse scored

Little's MCAR test was conducted to explore whether missingness across all 60 items was likely to be random ($p<0.05$) and suggests data are not missing completely at random. Further analysis was conducted in relation to a key variable, respondent's sex. It is possible to test all variables, but sex is often a key confounder particularly in health research. There was evidence to suggest that sex was relevant for 17/60 items. Despite this finding, the overall proportion of missing data is low, so the sex of respondent's was not considered when missing data were imputed later in the scale evaluation process.

6.6.3.4 Exploratory factor analysis

Exploratory factor analysis using varimax orthogonal rotation was applied without a forced structure to the sample data described above (n=363). The KMO value indicated adequate sampling (0.87), evidence that factor analysis is an appropriate approach. Bartlett test of sphericity was significant (chi square = 7253.886, df = 1770, p <0.001), which indicates the variables are correlated and is further evidence that factor analysis is appropriate. Cronbach's alpha coefficient for internal consistency reliability was .92, indicating very good reliability.

Eigenvalues greater than 1.0 are recommended by some as a lower bound for expecting a factor to be meaningful, but this can be less relevant when many items are analysed (Osborne, 2014) and can over-estimate the number of factors. This problem is illustrated in Table 6.7 which shows that using eigenvalue criteria alone, 17 factors would be retained. Horn's (1965) parallel analysis was implemented using the Monte Carlo PCA for Parallel Analysis statistical program downloadable in Stata. This method is viewed as the most accurate methods in determining the number of factors to retain (Dinno, 2009) and uses random generation, parallel to the actual dataset to determine factors and provide comparison eigenvalues. The results (Table 6.8) indicate 14 viable factors using the same cut off. Comparing the real data with the randomly generated, those factors in the former dataset with larger eigenvalues than in the latter, should be retained (Hayton et al., 2004).

Table 6.7: Principal component factor analysis, unrotated, number of factors unspecified.

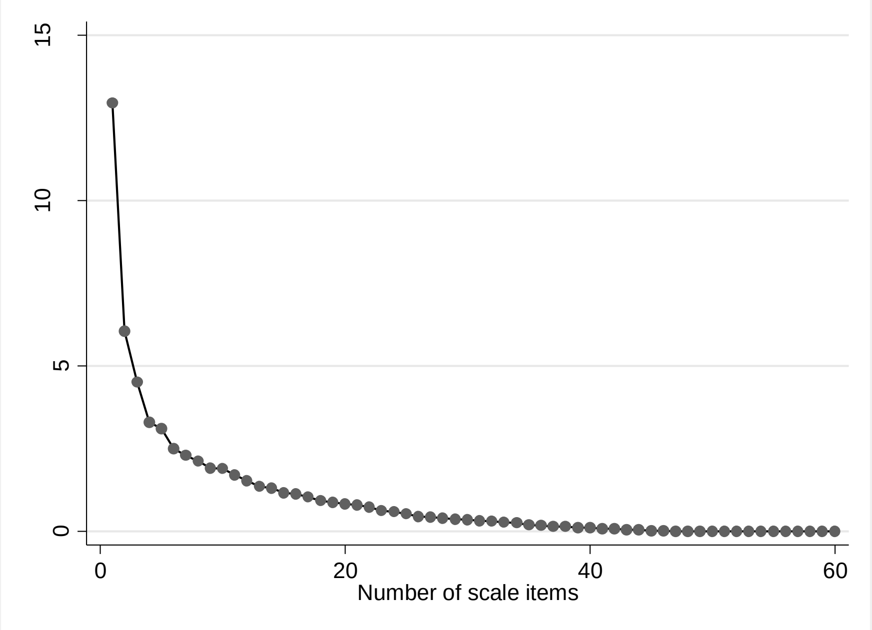
FACTOR	EIGENVALUE	DIFFERENCE	PROPORTION OF VARIANCE	CUMULATIVE
FACTOR 1	12.95	6.90	0.216	0.216
FACTOR 2	6.05	1.55	0.101	0.317
FACTOR 3	4.50	1.21	0.075	0.392
FACTOR 4	3.29	0.19	0.055	0.447
FACTOR 5	3.10	0.60	0.052	0.498
FACTOR 6	2.50	0.21	0.042	0.540
FACTOR 7	2.29	0.18	0.038	0.578
FACTOR 8	2.11	0.20	0.035	0.613
FACTOR 9	1.91	0.01	0.032	0.645
FACTOR 10	1.90	0.19	0.032	0.677
FACTOR 11	1.71	0.18	0.029	0.706
FACTOR 12	1.53	0.18	0.026	0.731
FACTOR 13	1.35	0.05	0.023	0.754
FACTOR 14	1.30	0.15	0.022	0.775
FACTOR 15	1.15	0.02	0.019	0.795
FACTOR 16	1.14	0.11	0.019	0.814
FACTOR 17	1.03	0.11	0.017	0.831

Table 6.8: Horn's Parallel Analysis for principal components 100 iterations, using p95 estimate.

FACTOR	ADJUSTED EIGENVALUE	ESTIMATED BIAS
FACTOR 1	12.54	.907
FACTOR 2	6.27	.852
FACTOR 3	3.82	.806
FACTOR 4	3.03	.747
FACTOR 5	2.76	.685
FACTOR 6	2.02	.624
FACTOR 7	1.77	.594
FACTOR 8	1.66	.570
FACTOR 9	1.46	.563
FACTOR 10	1.47	.495
FACTOR 11	1.26	.479
FACTOR 12	1.26	.442
FACTOR 13	1.02	.423
FACTOR 14	1.02	.378

In conjunction with the eigenvalues, the scree plot was examined (Figure 6.5). It shows a steep drop and obvious break at factor 4, indicating it may be pragmatic to discard factors after the breakpoint. The structure and strength of factor loadings were also considered. Three factors were retained because the fourth factor had only two items and showed significant cross loading. Twenty-two items of the 60 were dropped.

Figure 6.5: Scree plot of eigenvalues after factor (all 60 items).



After initial exploration using the retention criteria explained above, the number of factors were parameterised as 3, rather than 4, due to high correlation between factors 3 and 4 (>.7).

The steps of the exploratory analysis are shown in Table 6.9; the fit indices remain relatively stable over the iterations but broadly improve as items are removed, the output suggests a three-factor model is approaching a reasonable fit; with all goodness of fit statistics meeting the stated threshold (RMSEA and SRMR .10 or less and CFI and TLI, .90 or greater); χ2 was 703 on 296 *df*, with associated RMSEA of 0.07, CFI=0.87, TLI=0.86 and SRMR=0.07. There were a number of issues that were dealt with throughout the iterations. They included cross loading between factors (defined as < .200 units difference between factors) and high inter-item correlation within factors (above .50), refer to Table 6.10.

Table 6.9: Rotated factor loadings (3 factors specified)

Model	Retained	Added	Removed	Items	χ2	CFI	TLI	RMSEA	SRMR	α
Model 1				36	1603.016*	0.794	0.781	0.074	0.083	0.93
Model 2		Item 5	Item 2, Item 42	35	1518.964*	0.790	0.776	0.074	0.082	0.93
Model 3	Item 5		Item 35, Item 48	34	1518.964*	0.790	0.776	0.074	0.082	0.93
Model 4	Item 5		Item 7, Item 52	32	1267.015*	0.804	0.790	0.075	0.079	0.93
Model 5	Item 5	Item 7	-	33	1436.321*	0.795	0.781	0.075	0.080	0.94
Model 6			Item 7, Item 43	29	1156.915*	0.816	0.801	0.073	0.078	0.92
Model 7			Item 5	30	1013.656*	0.837	0.824	0.070	0.072	0.92
Model 8		Item 5	Item 23	30	1080.006*	0.818	0.803	0.073	0.078	0.92
Model 9	Item 5		Item 19	29	983.725 *	0.828	0.813	0.072	0.076	0.92
Model 10		Item 19	Item 8	29	1042.317*	0.814	0.798	0.076	0.080	0.92
Model 11		Item 8	Item 19	29	983.725 *	0.828	0.813	0.072	0.076	0.92
Final			Item 5, Item 53, Item 55	26	703.033*	0.869	0.857	0.066	0.071	0.91

*<0.001

Sample size varied from 311 – 317 respondents across all iterations

Model 1: ***F1*** (25, 29, 51, 13, 16, 38, 14, 53, 28, 21, 55, 22, 40, 10, 7, 4) ***F2*** (2, 3, 4, 6, 1, 15,54, 44, 35) ***F3*** (19, 41, 43, 8, 47, 23, 42, 26, 58, 52, 33)

Final Model: ***F1*** (25, 29, 51, 13, 16, 38, 14, 40, 28, 21, 22, 47 10) ***F2*** (8, 3, 6, 4, 15, 44, 54, 1, 33) ***F3*** (42, 58, 26, 52)

Table 6.10: Summary of items that were removed between model 1 and final model.

Scale ref	Factor	Content (abbreviated items)	Issue
Item 7	F1	Facing the challenges of kidney disease.	Cross loading across all 3 factors
Item 48	F1	Interference with relationships.	Weak loading <.4
Item 53_R	F1	Tiredness stops 'getting on' with life.	Dropped in final model due to low correlation with 3 other items within FI (corr <.25), <.4 item test & rest correlation and moderate factor loading (.5)
Item 55	F1	Difficulties for those who are close to me.	Dropped in final model to reduce items in F1, omission improved fit statistics
Item 2	F2		Inter-item correlation with items 3, 4, 6 and 1 (>.6)
Item 5	F2	Control over symptoms.	Cross loading across F1 and F2
Item 35	F2	Knowing when to consult the renal team about problems.	Weak loading <.4
Item 19	F3	Control over dialysis treatment.	Moderately high inter-item correlation with Items 19 and 23 (>.5)
Item 23	F3	Knowing enough to deal with day-to-day problems.	Weak loading <.4 and moderate correlation with item 19
Item 41	F3	Having good things to look forward to.	Weak loading <.4
Item 43	F3	Despite dialysis, trying to live a normal life.	Cross loading across F1 and F3

6.6.4 Patient Reported Instrument of Engagement in Self-Management (PRIESM) CKD-HD.

The final model comprised a three-factor solution with 26-items (Table 6.11). The final factors were labelled 'day to day managing/impact' (14 items), 'communication' (8 items) and 'clinical care' (4 items).

The model accounted for 93% of the variance in the sample data; with the 14 items in F1 explaining about 65% of the variance; the largest proportion. Item total correlations vary from .30 to .32, indicating the items correlate sufficiently without being repetitive in terms of measuring the broader self-management concept. Adequate unidimensionality was indicated by inter-item correlation <.6. Eigenvalues for the forced three factor structure were 7.73, 2.29 and 1.05 respectively.

Table 6.11: PRIESM CKD-HD - final model

	THEME: DAILY MANAGING/IMPACT	RESPONSE OPTIONS	
Q29	I find it difficult to look after myself the way I would like to.	Always	Never
Q38	Some days I feel distressed.	Hardly ever	Often
Q25	I have other health issues as well as my kidney disease and I find it difficult to cope with them all.	Very difficult	Not at all difficult
Q51	I feel that I cannot cope with all the things I need to do.	Often	Never
Q40	I sometimes feel overwhelmed by my kidney disease.	Strongly Agree	Strongly Disagree
Q14	I find it hard to cope with my kidney disease.	Completely	Not at all
Q28	I am angry about my kidney disease.	Very Angry	Not Angry at all
Q47	I see myself more negatively since I've had kidney disease.	Strongly Agree	Strongly Disagree
Q21	My kidney disease interferes with my life.	Too much	Not at all
Q22	I have activities and interests that keep me busy.	Strongly	Strongly Agree
Q13	Day to day I can manage most of the things I need to do.	Strongly	Strongly Agree
Q10	My symptoms interfere with the way I would like to live my everyday life.	Never	Always
Q16	Being on dialysis makes it difficult for me to get the care I need for my other health problems.	Often	Never
Q8	I feel more isolated than I did before I started dialysis.	Strongly Agree	Strongly Disagree
	THEME: COMMUNICATION		
Q3	When I talk to the renal team about my care I'm treated as a whole person rather than someone with	Never	Every Time
Q6	The renal team review my health and discuss any changes with me.	Hardly Ever	Enough
Q4	I have someone who will listen to me when I need to talk.	Not at all true	Completely True
Q15	I get the support I need to manage my health and treatment.	Strongly	Strongly Agree
Q1	I'm able to ask a doctor for more information if I don't understand what he or she said.	Never	Every Time
Q54	When discussing treatment options, my views are considered by the renal team.	Hardly Ever	Often
Q44	I am confident that there is good communication between all the specialists I see.	Not Confident	Very Confident
Q33	I wasn't as involved in the decision to start dialysis as I would have liked.	Completely	Not at all true
	THEME: CLINICAL CARE		
Q26	I check settings on the dialysis machine to make sure they are the same as usual.	Never	Always
Q58	I have an important role in managing my illness.	Strongly	Strongly Agree
Q42	I help decide how much fluid should be taken off.	Never	Always
Q52	The renal team encourage me to be involved in my own care.	Never	Always

Note: scale items are presented by magnitude of factor loading with themes/domains as determined by exploratory factor analysis (orthogonal varimax rotation)

Factor loadings (Table 6.12) ranged from .49 to .75, .27 to .77, and .45 to .58 respectively. The lowest loading item (item 33 – *I wasn't as involved in the decision to start dialysis as I would have liked*) also showed issues with cross loading and uniqueness (>.8), as well as some shifting between factor 1 and 2 during model iterations. Items 8 and 52 (*I feel more isolated than I did before I started dialysis* and *the renal team encourage me to be involved in my own care*) also had loading <.5 and showed some evidence of cross loading between factors.

All three items were retained on the basis that they are theoretically important in characterising self-management. In addition to this, item 52 was retained as the clinical care factor is underrepresented in terms of number of items compared with factors 1 and 2. All three items were rated highly relevant during the expert consensus process across both rounds of I-CVI. Involvement in decision making and feeling supported by the clinical care team are key components in self-management, this is supported by empirical evidence from the qualitative interviews and from the literature (Davis & Davison, 2017; Donald et al., 2018; Hussain et al., 2015; Ladin et al., 2017). In terms of item 8, feelings of isolation have become even more relevant for those with chronic disease since the COVID-19 pandemic (Tabachnick & Fidell, 2007) and research prior to COVID found that the antonym of isolation; social support, has been found to improve treatment adherence, quality of life and is associated with alleviating depression (Ahrari et al., 2014; Ibrahim et al., 2015; Jansen et al., 2014; Liu et al., 2018 et al., 2014; Liu et al., 2018). Further review of the wording of these items may be necessary in future versions of the scale.

Table 6.12: Final model – Rotated factor matrix (n=317), factors=3.

Item Ref	**Factor loading (F1)**	**Factor loading (F2)**	**Factor loading (F3)**	**Uniqueness**	**Obs**	**Item-test correlation**	**Item-rest correlation**	**Cronbach's α**
Item 29	**0.747**	0.058	0.067	0.435	348	0.641	0.596	0.906
Item 38r	**0.705**	0.115	-0.001	0.490	350	0.621	0.575	0.907
Item 25	**0.688**	0.117	0.053	0.510	315	0.624	0.578	0.907
Item 51	**0.677**	0.157	0.061	0.513	315	0.635	0.587	0.907
Item 40	**0.665**	0.190	-0.019	0.522	343	0.626	0.580	0.907
Item 14	**0.658**	0.191	0.199	0.491	350	0.696	0.656	0.905
Item 28	**0.630**	0.227	0.067	0.548	345	0.634	0.589	0.907
Item 47	**0.615**	0.184	0.092	0.580	338	0.625	0.579	0.907
Item 21	**0.614**	0.181	0.140	0.571	348	0.651	0.609	0.906
Item 22	**0.573**	0.007	0.398	0.514	343	0.605	0.556	0.907
Item 13	**0.568**	0.084	0.150	0.648	354	0.576	0.525	0.908
Item 10r	**0.532**	0.095	0.042	0.707	354	0.496	0.439	0.909
Item 16	**0.500**	0.312	0.213	0.612	321	0.644	0.599	0.906
Item 8	**0.486**	0.309	0.084	0.662	347	0.606	0.557	0.907
Item 3	0.097	**0.772**	-0.056	0.392	347	0.511	0.458	0.909
Item 6	0.155	**0.742**	0.207	0.382	351	0.605	0.556	0.907
Item 4	0.122	**0.700**	0.032	0.494	347	0.518	0.462	0.909
Item 15	0.343	**0.614**	0.089	0.497	343	0.641	0.596	0.906
Item 1	0.033	**0.539**	0.216	0.662	344	0.450	0.392	0.911
Item 54	0.107	**0.532**	0.317	0.605	316	0.498	0.444	0.909
Item 44	0.340	**0.508**	0.026	0.625	335	0.562	0.505	0.908
Item 33	0.229	**0.267**	0.207	0.834	334	0.440	0.381	0.911
Item 42	0.172	0.087	**0.579**	0.627	339	0.394	0.332	0.911
Item 58	0.220	0.196	**0.520**	0.643	340	0.499	0.441	0.909
Item 26	-0.028	0.150	**0.506**	0.721	327	0.281	0.214	0.913
Item 52	0.131	0.382	**0.447**	0.637	330	0.492	0.435	0.910

Extraction method: EFA. Rotation method orthogonal Varimax rotation. Eigenvalue >1.
r denotes reverse scoring

Oblique rotation using the oblimin method was run as a secondary check (Tabachnick & Fidell, 2007) and found a similar magnitude and pattern of factor loadings as ascertained using orthogonal rotation. There was some evidence of correlation between factor 1 (managing) and factor 2 (communication) but this does not exceed .7 (see Table 6.3) and the method of rotation made no difference to the structure of the final scale.

Table 6.13: Factor matrix.

	F1 Managing	F2 Communication	F3 Clinical Care
F1 Managing	1		
F2 Communication	-0.574	1	
F3 Clinical care	-0.099	-0.342	.1

6.6.4.1 Reliability

Cronbach's alpha was used to assess the internal reliability of the final scale and each subscale (factor). The managing subscale consisted of 14 items (α = .91), the communication subscale consisted of 8 items (α = .84), and the clinical care subscale consisted of 4 items (α = .66). The overall scale consisted of 26 items (α = .91), indicating highly reliable internal consistency of the scale (Table 6.9). Instrument stability was assessed using test re-test reliability at ≥ 4 weeks, a Pearson correlation coefficient r=0.84 (p<0.001) suggests good to linear agreement over time (at least in the short term). This suggests the scale might be useful in longitudinal research; however, analysis is based on a sample of 95 participants so further work to establish stability over time is needed.

6.6.4.2 Discriminant/convergent validity

Both average and domain scores were generated to explore the scale's validity with other measures (generation of these scores is discussed in chapter 7). Using SM scores, it was possible to explore discriminant validity using data collected in parallel on depression, self-efficacy, adherence and other long-term conditions. An inverse correlation was found between self-management and depression r(328) = -.74, p<0.001, which increased to -.80, p<0.001 when comparing the daily managing domain. An equally strong but positive correlation with self-efficacy was also evident r(337) = .75, p<0.001. The strength of the correlation increased slightly to .77 for the daily managing domain (Figures 6.6 and 6.7). Note, the proportion of missing data for the PHQ-9 was slightly higher than for the other measures of adherence and self-efficacy. Where one item was missing, an overall score was not calculated, in line with guidance from Kroneke et al. (2001) Analysis of the PHQ-9 is based on a sample size of 297, a percentage reduction of about 20%. Data on depression and self-efficacy are discussed further in chapter 7.

Figure 6.6: Managing domain of PRIESM CKD-HD and correlation with depression.

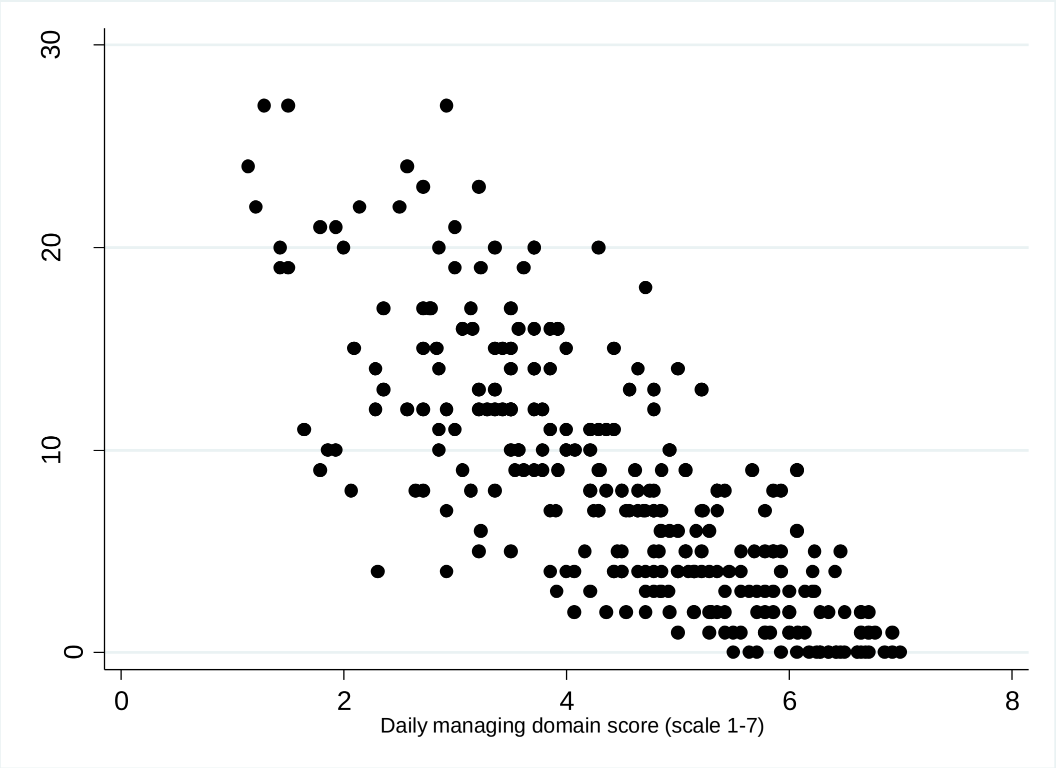
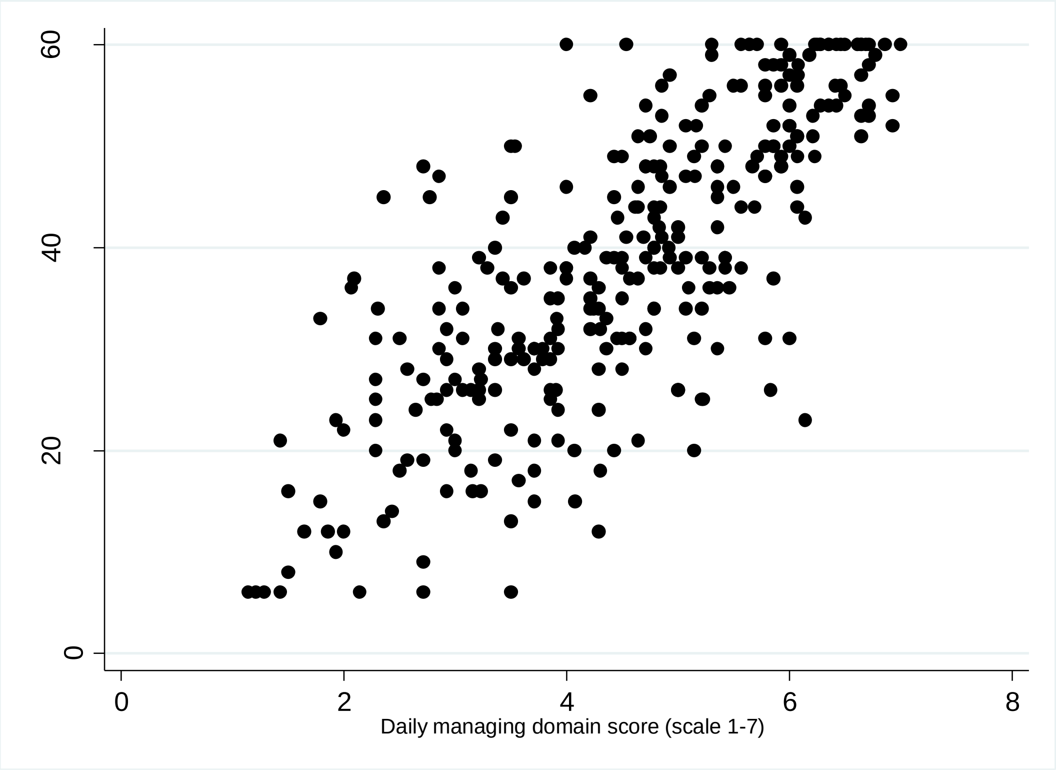


Figure 6.7: Managing domain of PRIESM CKD-HD and correlation with self-efficacy.



No correlation was found between the adherence measure ESRD-AQ (Kim et al., 2010) and PRIESM CKD HD r(359) = .16, p<0.01. This may be because adherence aligns with a more medical model of self-management and the PRIESM CKD-HD measure is weighted more towards psychosocial factors.

Data on average plasma phosphate and intradialytic weight gain (IWG) were collected as part of the study as they are routinely collected in kidney patients for diagnosis, monitoring and can be used as a proxy for adherence. Out-of-range plasma phosphate can be indicative of disease severity and a predictor of mortality (Jung et al., 2018). The range for average plasma phosphate was .81 to 3.38 mmol/L. The range for average IWG was -1 to 5.63kg. Means were 1.65mmol/L (SD±1.69) and 1.51kg (SD±1.00) respectively. No relationship with self-management score and IWG was evident.

When treating the data as categorical; a relationship between those with plasma phosphate out of range (high, >2 mmol/L) where the baseline is those within range (between 1.4 and 2 mmol/L as defined by (Cundy et al., 2014) and overall self-management score was identified. Self-management score is lower in those with a plasma phosphate mean >2 mmol/L compared with those within range (R^2= .01 *F*(2, 325) = 6.11, p=0.001). A similar association was found with the daily managing (R^2= .03 *F*(2, 325) = 4.58, p=<0.01) and communication domains (R^2= .05 *F*(2, 325) = 8.63, p=<0.001). Further data are provided in chapter 7.

6.7 SUMMARY

The best fitting model, as informed by absolute fit indices, was found to be a three-factor (referred to from this point as domains), 26-item model with items grouped to the following sub scales; daily managing/impact, communication, and clinical care. The three sub-scales have acceptable Cronbach's alpha scores, acceptable loadings on 23/26 items (>0.5) and acceptable eigenvalue sizes. Content, face validity and reliability were good and met accepted standards. Aside from being statistically robust, PRIESM CKD-HD correlates with two other similar constructs, depression, and self-efficacy.

Stability of the scale was assessed, and results suggest good linear agreement over time. This suggests that the scale is stable over time and might be useful in longitudinal research, however analysis is based on a sample of 95 participants so further work to establish this is needed.

6.8 CONCLUDING REMARKS

The PRIESM CKD-HD was developed for use in a HD population to ascertain current engagement in self-management behaviour and identify potential gaps in support. It is unique in that it is the first measurement of its kind to be underpinned by the tripartite model of health that attempts to quantify the concept through the lens of people receiving dialysis.

The intended endpoint of the scale development process was a concise and valid scale of self-management for use in a dialysis population which includes items that go beyond a clinical lens. Preliminary analysis has determined a 3-factor structure (referred to from this point as domains), comprising 26 positively and negatively worded items conceptualising self-management in terms of daily managing, communication, and clinical care. The model fit statistics provide an indication of the degree to which the estimated model represents the observed data. Some items with poorer parametric properties were retained because they were considered by the expert panel to be important to the content validity of the scale. This decision aligns with Sellbom & Tellegen (2019), they suggest cut-off values are there to guide rather than be rigidly enforced. Retaining these items led to lower model fit statistics, however the model fit statistics remain strong. Two reverse scored items remain in the final version of PRIESM CKD-HD, suggesting reverse scoring of some items did not impact the psychometric properties of the overall scale.

Although no interventions to improve engagement in self-management are routinely used, and developing one was not within the remit of this study, evidence of discriminant validity is provided in the next chapter. This provides evidence that the scale will be sensitive to change over time initiated by an intervention designed to improve self-management as characterised by this scale. It is possible that routine use of the scale may also cause a shift in patient engagement through normalising discussions and supporting better communication.

In conclusion, a person-centred approach to defining self-management is appropriate, and a scale to measure the concept in this holistic way, has been developed. As stated by Cronbach & Meehl (1955, p 297), “One does not validate a test, but only a principal for making inferences” and developing the concept underpinning the measure has involved multiple and inclusive approaches in an endeavour to ensure validity.

The PRIESM CKD-HD has the potential to be used in clinical care and research to identify gaps in support and help patients engage to the extent that they wish.

The following chapter will examine in greater detail, the sample population that is providing the baseline, normative data from which a SM score and individual domain scores have been generated. It will examine the level of engagement in self-management and how engagement appears to vary between sub-populations using the composite and domain level scoring. The next chapter will also discuss how using quantitative data to score self-management might be useful in clinical practice.

CHAPTER 7 : SAMPLE CHARACTERISTICS AND ENGAGEMENT WITH SELF-MANAGEMENT

7.1 INTRODUCTION

The previous chapter sought to describe the item and scale development of the PRIESM CKD-HD. This chapter will give a brief overview of the sample characteristics from the main survey described in chapter 6, describe the test scores and norm data across sub-groups in this reference population and then describe how the composite self-management score and domain scores are best presented to clinics and patients to aid use of the data in clinical practice.

7.2 SAMPLE PROFILE

The study sample is described in chapter 6 (Table 6.5) and comprised 363 HD patients of which 63.3% were male and 31% were from minority ethnic groups. Age ranged from 21 to 90 years, mean 62.8 years with a median age of 65.5. There was good variation in time since diagnosis, with 5% diagnosed within the year, and 36% having been diagnosed ≥10 years ago. The same was true for time since dialysis initiation with the proportions being 18% and 8.3% respectively. This low proportion at ≥10 years reflects expected mortality patterns.

Other characteristics are presented in Table 7.1, including some clinical data. Most respondents, (approximately 60%) lived with immediate family members and just over a quarter lived alone. In terms of relationship status, 21% of the sample reported being single, with a further 26% reporting being separated/divorced or widowed. Just over half the sample reported having a partner (married, civil or living with). Both household size and relationship status data can be used as a proxy for social support and these variables are used later to examine differences in self-management score.

Approximately one quarter of the sample reported having no formal qualifications, in contrast to 34% reporting level 4 qualifications (higher education and professional/vocational e.g., degree, master's degrees, Higher National Diploma (HND) or professional qualifications, for example teaching or nursing). Data on household income was collected as a proxy for deprivation and 17.5% of respondents reported their household income as not enough or inadequate. This may reflect pre-existing environmental, medical, and social factors that contribute to an increased risk of developing kidney disease but may also reflect the impact of kidney disease on the capacity to work. Morton et al. (2018) report a link between more advanced CKD and increased odds of falling into poverty.

In terms of clinical data, almost one quarter (22.6%) of respondents reported being on the transplant list and 8% reported not knowing. Stratifying the data by age, of those older (defined as aged ≥ 70 years), 8.6% were on the transplant list compared with 31.5% aged <70 years (X^2(4, N=362) = 34.5, p<0.001). Overall people from minority ethnic groups were twice as likely not to know whether they were on the transplant list (12.6% compared with 6%), this was significantly different (X^2(4, n=361) = 13.9, p<0.01). There is some indication that engagement in self-management relating to daily managing may be lower in those who don't know whether they are on the transplant list, and this is explored in the sub-analysis section.

The most common self-reported long-term conditions (LTCs) were diabetes (36.6%); arthritis (28.9%) and heart disease (28.1%). The data for heart disease and heart failure cannot be reported as an aggregate percentage as the Self-Reported Morbidity Questionnaire asks about these conditions separately, but together prevalence is likely to reach the 40% prevalence reported in other studies (Cozzolino M et al., 2017). Depression is reported by 15.7% of respondents and cancer, 13%. For other LTCs, 23.6% of respondents reported none, with the mean number for the sample being 1.5 and the range 0-8.

There was a three-fold difference in the proportion of 'younger' patients (<70 years) reporting no other conditions compared with those over 70 years; 24.4% and 75.6% respectively. However, the difference by age was less but reversed with higher LTC burden (≥2), 55.9% of those <70 years, compared with 44% over 70 years, perhaps skewed by the higher proportion of <70's with high multimorbidity burden, defined here as four or more other LTCs (X^2(2, n=362) = 9.78, p<0.01).

For number of other LTC, respondents from minority ethnic groups show a lower mean and this difference is statistically significant (R^2= .01 *F*(1, 359) = 6.66, *p=0.01*). When grouping other LTCs into 0, 1 or ≥2, the largest difference was in the proportion reporting no other LTCs which was 32.4% among minority ethnic groups compared with 19.6% among white respondents. This difference is statistically significant (X^2(2, n=361) = 7.08 *p=0.02*). This may be due to bias with self-reporting (Kim et al., 2018), underdiagnosis in minority ethnic groups (Hayanga et al. 2024) as well as reflecting a true difference.

Table 7.1: main survey participants – additional characteristics.

Characteristic[a]	n (%)[b]	Characteristic	n (%)
Relationship status	***(n=341)***	***Other LTCs***	***(n=363)***
Single	73 (21.4)	0	86 (23.7)
Married/civil/living with partner	179 (52.5)	1	134 (36.9)
Separated/divorced/widowed	89 (26.1)	≥2	143 (39.4)
Education[c]	***(n=335)***	***LTC by condition***	***(n=363)***
Level 4	115 (34.3)	Heart disease	102 (28.1)
Level 3	39 (11.6)	Heart attack	49 (13.5)
Level 2	27 (8.1)	Diabetes	133 (36.6)
Level 1	46 (13.7)	Cancer	47 (13.0)
Other qualifications	14 (4.2)	Lung disease	35 (9.6)
Apprentice	14 (4.2)	Liver disease	23 (6.3)
No qualifications	80 (23.9)	Arthritis	105 (28.9)
Employment status	***(n=352)***	Depression	57 (15.7)
Employed	61 (17.3)	***Transplant list***	***(n=358)***
Unemployed	14 (4.0)	Yes	82 (22.9)
Retired	184 (52.3)	No	239 (66.8)
Looking after home or family	8 (2.3)	Don't know	29 (8.1)
Other	85 (24.2)	Not applicable	8 (2.2)
Household income	***(n=354)***	***Previous transplant***	***(n=362)***
More than enough	32 (9.0)	Yes	58 (16.0)
Enough	132 (37.3)	No	304 (84.0)
Just enough	128 (36.2)	***Type of transport***	***(n=358)***
Not enough	53 (15.0)	Personal	178 (49.7)
Inadequate	9 (2.5)	Bus	18 (5.0)
Household size	***(n=362)***	Taxi	32 (8.9)
Live alone	103 (28.4)	Ambulance	95 (26.5)
Live with partner only	105 (29.0)	Not applicable	20 (5.6)
Live with children <18 yrs.	39 (10.8)	***Carer***	***(n=354)***
Live with children >18 yrs.	76 (21.0)	Yes	44 (12.4)
Other	39 (10.8)	No	35 (9.9)
		Sometimes	275 (77.7)

[a] Data are presented as n (%).

[b] Data were missing for 13/17 variables and proportion of missing ranged from 0.3-9%. For 15/17 vars missing data <3%. Proportion missing data was highest for relationship status and education.

[c] more information about the education categories is as follows: level 4: higher education and professional/vocational e.g., degree, Master's degrees, Higher National Diploma (HND) or professional qualifications (for example teaching or nursing); level 3: two or more A Levels (or equivalent qualifications e.g., four or more AS levels, NVQ level 3, BTEC National); level 2: five or more GCSE (grade A* to C or grade 4 and above) or equivalent qualifications e.g., NVQ level 2; level 1: one to four GCSE passes (grade A* to C or grade 4 and above) and any other GCSEs at other grades, or equivalent qualifications e.g., NVQ level 1; other qualifications (including foreign); apprenticeships; no qualifications (refers to no formal qualifications) Source: Census, Office for National Statistics (2011, 2021).

Before moving to how SM scores and compositive domain scores were generated, data on some items are presented with commentary on any variation by sub-sample.

7.3 SELF-REPORTED ISOLATION, EXPERIENCE OF SYMPTOMS, ANGER, DISTRESS AND FEELING OVERWHELMED

Eleven percent of the sample reported strongly agreeing with the statement ‘I feel more isolated than I did before I started dialysis’. There did not appear to be an association with age, sex or ethnicity and isolation, but 19% of respondents not in relationships (single) reported the greatest isolation (20%) (X^2(12, n=326) = 31.4, p<0.01). Isolation is less subjective than loneliness and relates to social contact; Moorthi & Latham-Mintus (2019) speculate that fatigue and increased medical visits associated with later stage renal disease can reduce social interaction and increase isolation.

Thirty-eight percent of respondents reported that symptoms always interfere with the way they would like to live their everyday life. Whilst this did not vary by age, sex, or ethnicity, it highlights that the impact of symptoms on everyday life affects over a third of respondents.

Fifteen percent of all respondents reported feeling very angry (the strongest response) about their kidney disease. There was a weak association with age, with 40% of those ≥ 70 years reporting no anger at all, compared with 25% of those < 70, this association was stronger when comparing those ≥ 60 years with <60 years, (X^2(6, n=345) = 13.3, p<0.05) suggesting older people are less likely to report feeling angry. This effect may be confounded by time since diagnosis and time since dialysis initiation. Older people may be further along in their kidney disease journey and more likely to feel acceptance.

In response to the item ‘some days I feel distressed’, 16.7% responded often, this is comparable with Weisbord et al. (2005) reporting moderate distress at 14% but lower than the prevalence reported by (Damery et al., 2019), which was 33% in a sample of ESKD patients including those on haemodialysis. People from minority ethnic group and people under 70 years were significantly more likely to respond often than those defining as white (21.7% compared with 14.9%), (X^2(8, n=347) = 15.7, p<0.05) and those over 70 years of age (19.5% compared with 12.0%), (X^2(6, n=348) = 12.9, p<0.05).

Only 13% of respondents strongly agreed with sometimes feeling overwhelmed by their kidney disease, but this differed by relationship status and age. Over 50% of all respondents describing themselves as single answered 1, 2 or 3 on the 7-point scale (1 being strongly agree), compared with approximately 30% of those married or in a civil partnership, or those separated (X^2(8, n=323) = 26.5, p<0.01). Those ≥60 years were more likely to strongly disagree with the statement “I sometimes feel overwhelmed by my kidney disease “; 24.2% than those < 60-year; 14.2% (X^2(6, n=341) = 13.4, p<0.05). This association follows the pattern for anger and distress. It is possible older respondents feel it is less socially acceptable to admit to these feelings, that with age comes a willingness to accept poorer health or perhaps that they have better coping strategies.

7.4 PERCEPTIONS OF TREATMENT AND INVOLVEMENT IN DECISION-MAKING

In response to the item ‘when I talk to the renal team about my care I’m treated as a whole person’, Approximately 58% reported every time compared to 1.7% reporting never. There was no statistical difference by age or sex but 47% of respondents from minority ethnic groups reported every time compared with 62.5% of white respondents ($X^2(6, n=346) = 14.1, p<0.05$).

In response to ‘I help decide how much fluid should be taken off’, 4.1% reported never and 57.2% reported always. Those over 70 years were more likely to report never deciding than those under 70 years (7% versus 2.4%) ($X^2(6, n=346) = 14.1, p<0.05$). There was no statistical difference by sex or ethnicity.

Approximately 12% of the sample said it was completely true that ‘they weren’t as involved in the decision to start dialysis as they would have liked’. This did not vary by sex or age but there was a significant association by ethnicity, 28.7% of minority ethnic groups said this was not at all true compared with 49.4% of white respondents ($X^2(6, n=338) = 13.0, p<0.05$). Data from Jayanti et al (2015) suggest that white ethnicity background was a significant predictor of preference for decision-making so the finding for PRIESM CKD-HD may not reflect decision making practices from the staff or renal centre perspective.

7.5 DEPRESSION, SELF-EFFICACY, ADHERENCE AND PHOSPHATE LEVEL.

The previous chapter showed a correlation between overall self-management score and both depression and self-efficacy. No correlation was found for adherence. This next section will briefly outline the prevalence of depression and level of self-efficacy and adherence as measured by validated measures in this sample.

7.5.1 Depression

Using the validated PHQ9 depression screening measure, the mean score was 7.88 ±6.30 (a score which indicates mild depression). Depression scores for males and females were broadly similar; 7.61 ±6.33 and 8.38±6.24 respectively, but differed by age (R^2=.04 F(1, 322) = 15.56, $p<0.001$), with depression score decreasing with age.

Across the whole sample, the most common symptom was fatigue, with 85.1% of all respondents reporting this on at least several days and 27.8% reporting this symptom nearly every day. When analysing the data by depression severity (Table 7.2), overall prevalence of depression is approximately 60%, severe depression is 6%. These data mirror broadly what was found by Anderson et al. (2023) in a UK haemodialysis population reported recently as part of the FITNESS trial. The data for PRIESM CKD-HD show slightly higher rates of moderately severe (9.9%) and severe depression (6.3%) which were 7.9% and 2.7% respectively in FITNESS.

Data from PRIESM CKD-HD data suggest patients ≥70 years show lower rates of more severe depression; 7.7% scoring ≥15 (moderately severe or severe depression) compared with 22.7% in the <70-year group.

Table 7.2: PHQ-9 grading, data on the PRIESM CKD-HD sample.

Grading	**< 70 years**	**≥ 70 years**	**n (%)**
Minimal (0-4)	67 (33.0)	61 (46.9)	128 (38.4)
Mild (5-9)	90 (44.3)	59 (45.4)	96 (28.8)
Moderate (10-14)			53 (15.9)
Moderately severe (15-19)	46 (22.7)	10 (7.7)	33 (9.9)
Severe (20-27)			23 (6.9)

X^2(4, n=333) = 17.9, $p<0.01$

7.5.2 Self-efficacy

Using the self-efficacy for managing chronic disease scale (SEMCD-6) the mean score was 38.5±14.3. There was some variation in the mean score by age when comparing those ≥ 70 and those <70 years of age, mean score 36.9±14.6 and 41.1 ±13.4 (R^2=.02 F(1, 340) = 6.87, $p<0.01$), but not sex or ethnicity. The highest proportion of respondents scoring 1 or 2 (indicating very low confidence) was reported in relation to interference from fatigue, which mirrors the findings from PHQ-9. Data by quartiles is shown in Table 7.3, with those in quartile one having the lowest levels of confidence.

Table 7.3: SEMCD-6 score quartiles, data for the PRIESM CKD-HD sample.

Self-efficacy score	< 70 years	≥ 70 years	n (%)
Quartile 1	61 (29.1)	29 (22.0)	22 (6.34)
2	58 (27.6)	26 (19.7)	81 (23.7)
3	45 (21.4)	39 (29.6)	113 (33.0)
Quartile 4	49 (21.9)	38 (28.8)	126 (36.8)

7.5.3 Adherence

Using a sub-sample of questions from the validated End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ) an ESRD-AQ score was calculated (range 0-1200). Adherence score does not appear to be associated with sex, but was associated with age (R^2=.04 F(1, 360) = 15.4, p<0.001). As described by Kim et al. (2010) and Naalweh et al. (2017), the data were grouped into three categories and the proportions in each category (n column, Table 7.4) are comparable with those reported by Naalweh et al. (2017) which were 4.1%, 40.5% and 55.5% respectively. Data for the PRIESM CKD-HD sample are presented by age category and show a clear relationship between increasing age and proportion with 'good' adherence level. Good adherence is highest in the ≥70 age group (X^2(2, n=362) = 18.36, 2 P<0.001). It was expected that adherence might also be associated with relationship status, as a proxy for social support (Ahrari et al., 2014; Cardol et al., 2023), however, this association was not reflected in the data.

Dietary adherence was observed in 29% of respondents, fluid restriction adherence 40%, adherence to HD sessions 87% but 24% reported shortening their dialysis session at least once in the last month. Adherence to medications was 77%.

As stated in chapter 6, adherence using this measure did not appear to be correlated with the PRIESM CKD-HD scale. This may be because adherence as measured by the ESRD-AQ is unlikely to correlate with the more psychosocial aspects of self-management that predominate in the PRIESM CKD-HD measurement.

Table 7.4: ESRD-AQ adherence levels, data for the PRIESM CKD-HD sample

Adherence level	20-39 years	40-59 years	60-74 years	≥ 75 years	n (%)
1 – poor	2 (7.4)	11 (9.6)	7 (5.2)	3(3.6)	23 (6.34)
2 - moderate	14 (51.9)	40 (34.8)	30 (22.1)	16 (19.1)	101 (27.8)
3 – good	11 (40.7)	64 (55.7)	99 (72.8)	65 (77.4)	239 (65.8)

7.5.4 Phosphate level

Plasma phosphate data was analysed as part of the study as it is routinely collected in kidney patients for diagnosis and monitoring and can be indicative of disease severity and a predictor of mortality. Data was grouped according to ranges used by (Cundy et al., 2014) as described in chapter 6. Phosphate level does not appear to be associated with sex, the mean was 1.65 for both men (SD±.39) and women (SD±.41) but a decrease in plasma phosphate was associated with age, (Table 7.5). However, the relationship varied according to whether phosphate levels were below or above the optimal phosphate range (Table 7.6) with a higher proportion of younger participants with phosphate above 2 mmol/L and a higher proportion of older participants with phosphate below 1.4 mmol/L. There was also some variation in phosphate mean by ethnicity; black respondents had a mean of 0.73 SD±.57 compared with 1.02 SD±.60 among Asian respondents and .88 SD±.66 in white respondents. Using regression analysis with Asian respondents as the comparator, the difference in phosphate mean among black respondents was statistically significant t(4) = -2.33, p = 0.02.

Table 7.5: Phosphate and age group statistics

n=325 (df=2)	Coef.	Std. Err.	t	P>|t|	F
40-59 years	-.165	.082	-2.02	0.04	9.41
60-74 years	-.300	.080	-3.73	<0.001	
≥ 75 years	-.372	.084	-4.41	<0.001	

Table 7.6: ESRD-AQ phosphate levels, data for the PRIESM CKD-HD sample

Phosphate level	20-39 years	40-59 years	60-74 years	≥ 75 years	n (%)
Below 1.4 mmol/L	5 (18.5)	25 (21.7)	42 (30.9)	27(32.1)	99 (27.3)
1.4 to 2 mmol/L	14 (51.9)	62 (53.9)	78 (57.4)	50 (59.5)	204 (56.2)
Above 2 mmol/L	8 (29.6)	64 (24.4)	99 (11.8)	7 (8.3)	60 (16.5)

From this overview of the sample, the next section will move on to look at the scoring of self-management using evidence from the model statistics (EFA).

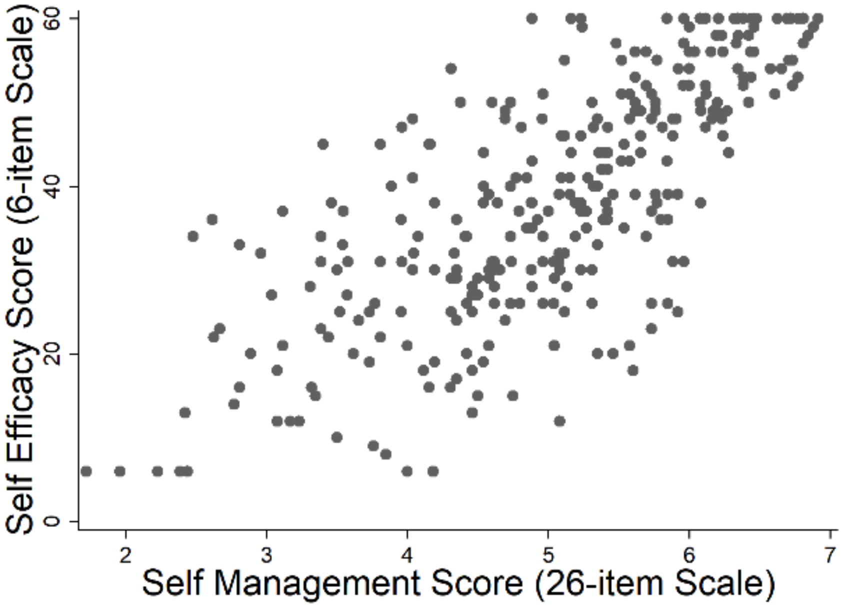
7.6 SELF-MANAGEMENT SCORING

Through a process of exploratory factor analysis explained in chapter 6, the 60-item scale that was tested in the large-scale survey was reduced to a 26-item scale, the PRIESM CKD-HD. Results from the EFA suggest that self-management is best considered as three domains: daily managing, communication, and clinical tasks. To use the scale as a way of determining areas of support need and prioritisation in follow-up conversations, composite self-management scores, as well as domain scores were generated.

Raw item scores from the scale were summed and the total score was standardised to a 0-7 range, with higher scores indicating greater engagement with self-management. Composite scores for each of the three domains were generated in the same way. The overall self-management score mean was 5.02 (SD±1.08), the daily managing mean was 4.51 (SD=1.36), for communication; 5.83 (SD±1.15) and for clinical care; 5.36 (SD±1.25). Median scores and IQR were 5.12 (4.35, 5.84) for overall score, 4.64 (4.64, 5.57) for daily managing, 6.14 (5.38, 6.71) for communication and 5.6 (4.60, 6.4) for the clinical domain.

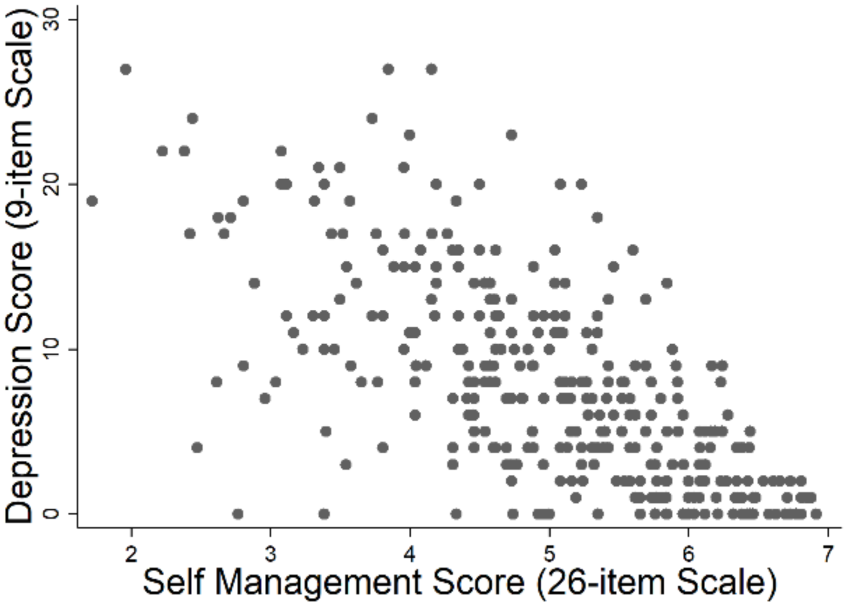
The previous chapter described the significant positive correlation with self-efficacy and the negative correlation with depression, the strongest correlation was with the daily managing domain (Figures 6.19 and 6.20, chapter 6). Figures 7.1 and 7.2 below, show the correlation for the overall score. There is also evidence in Table 7.7, that a lower self-management score (overall and for daily managing and communication domains) is significantly associated with plasma phosphate levels that are out of range (>2 mmol/L). PRIESM CKD-HD distributions of overall score and domain scores for the sample are shown in Figure 7.3 to Figure 7.6.

Figure 7.1 Overall score, PRIESM CKD-HD correlation with SEM-CD



r(311) = .75, p<0.001

Figure 7.2 Overall score, PRIESM CKD-HD correlation with PHQ9



r(328) = -.69, p<0.001

Table 7.7: Mean plasma phosphate level by PRIESM CKD-HD domain

	Overall	Managing	Communication	Clinical
Phosphate level				
Below 1.4 mmol/L	5.12 (SD±1.04)	4.60 (SD±1.37)	5.97 (SD±0.94)	5.45 (SD±1.26)
1.4 to 2 mmol/L	5.10 (SD±1.03)	4.61 (SD±1.29)	5.92 (SD±1.10)	5.36 (SD±1.24)
Above 2 mmol/L	4.56 (SD±1.20)**	4.00 (SD±1.44)*	5.24 (SD±1.46)**	5.19 (SD±1.28)
Baseline category: within range 1.4-2 mmol/L				

Figure 7.3: Distribution of overall self-management score (n=26)

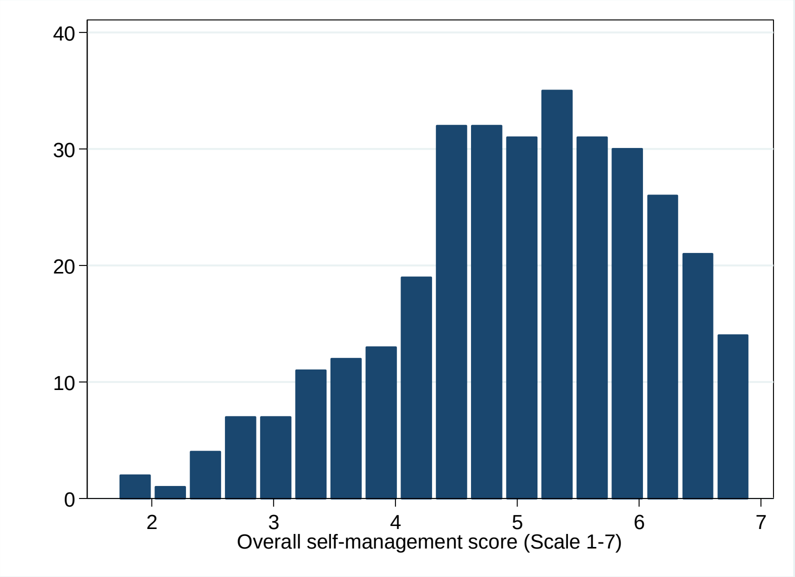


Figure 7.4: Distribution of domain 1 score (daily managing) n=14

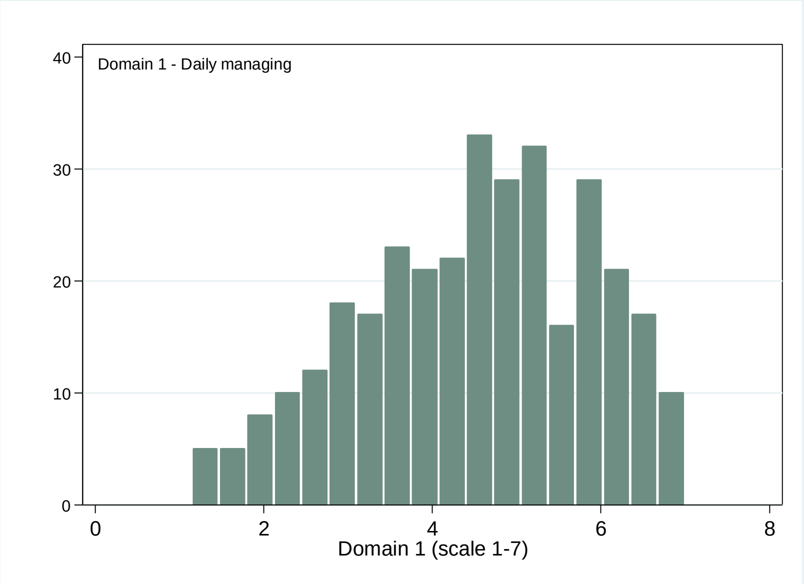


Figure 7.5: Distribution of domain 2 score (communication) n=8

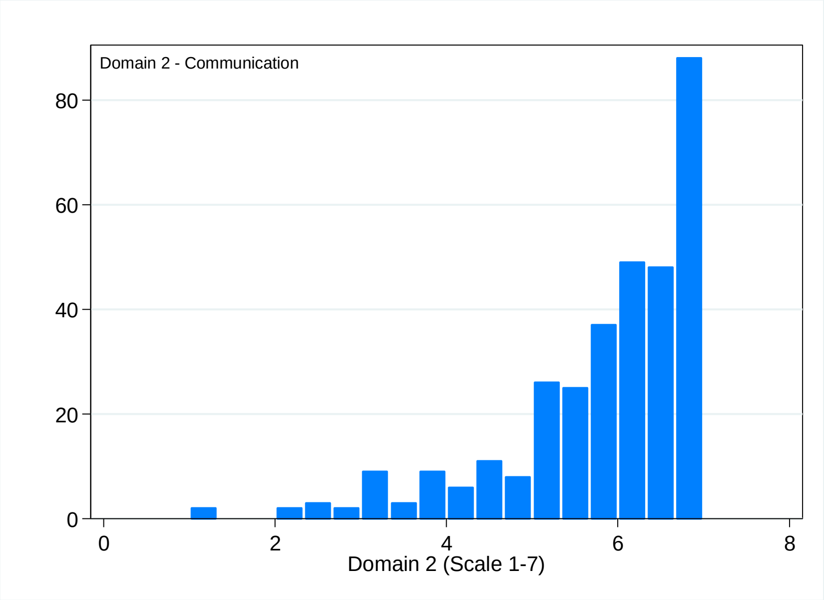
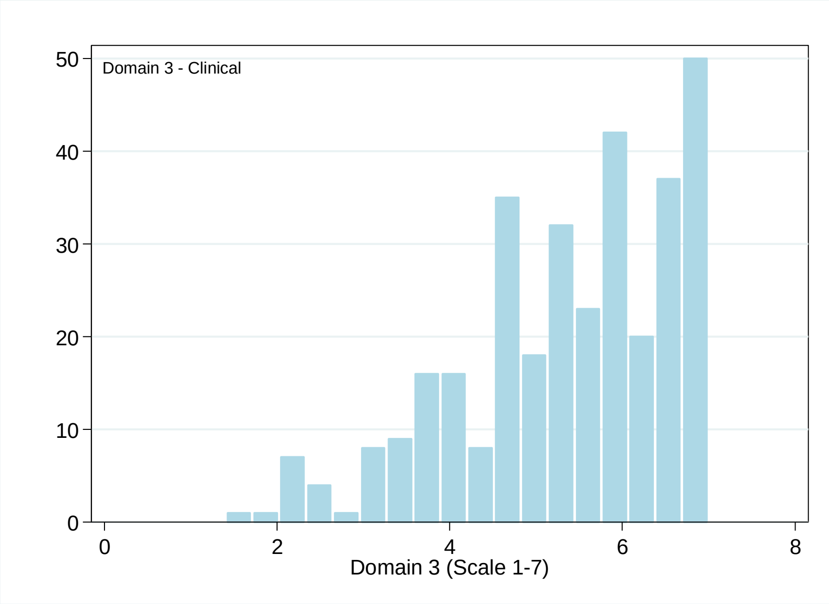


Figure 7.6: Distribution of domain 3 score (clinical) n=4



The distribution is skewed left for the overall 26-item score; over 70.4% of the sample score above the median. There is evidence of a ceiling effect for the overall self-management score. Mchorney & Tarlov (1995) suggest there is no ceiling effect when less than 15% reach the maximum score. In the PRIESM CKD-HD sample, 18.6% of respondents scored the maximum number on the converted 1-7 scale using 26-items (those scoring anywhere between 6 or 7). While this effect does give cause for concern in terms of differentiation between patients at the top end of the scale, it is less than 5% above the threshold and there is no evidence of a floor effect. These effects also appear to be less than for the validated measures of depression and self-efficacy.

The data for day to day managing more closely follows a normal distribution, with 53.1% of scores above the median.

This increases to 86.9% for communication, with 15% of the sample scoring 7 and the distribution showing a long-skewed tail left. This shows considerable evidence of a ceiling effect; 52% of respondents scored the maximum number and this is clear in the strong skew to the right evidence in Figure 7.5. This may be indicative of a social bias effect, especially as most of the questions in this domain relate to communication with the healthcare team.

The clinical score shows a slightly lower proportion scoring 7; 39%. This may be indicative of response bias but mask differences between sub-groups, which is examined later in this chapter. The clinical factor shows 78.4% of respondents scoring above the median. It should be noted that there are fewer items in this domain.

7.7 MEAN SCORE BY KEY VARIABLES

All sub-analysis presented here are preliminary and univariate, multivariate modelling of the data will be conducted on future studies as part of confirmatory analysis.

The overall self-management score as well as domain means are presented in Table 7.8, by sex, age, ethnicity, and relationship status. Age grouping is presented as four categories, but regression statistics are also presented for a binary category: ≥70 and < 70 years).

Table 7.8: PRIESM CKD-HD mean by sex, age group, ethnicity, and relationship status.

	Overall	**Managing**	**Communication**	**Clinical**
Sex				
Male (n=213)	5.05 (SD±1.04)	4.54 (SD±1.44)	5.86 (SD±1.16)	5.37 (SD±1.20)
Female (n=114)	4.98 (SD±1.14)	4.45 (SD±1.32)	5.79 (SD±1.11)	5.35 (SD±1.34)
Age groups				
20-39 (n=25)	5.00 (SD±1.14)	4.35(SD±1.81)	5.82 (SD±1.10)	5.71 (SD±0.91)
40-59 (n=105)	4.87 (SD±1.00)	4.24 (SD±1.30)	5.70 (SD±1.24)	5.47 (SD±1.18)
60-74 (n=124)	5.00 (SD±1.11)*	4.54 (SD±1.39)**	5.84 (SD±1.08)	5.18 (SD±1.31)
75-90 (n=73)	5.29 SD±1.05)	4.91 (SD±1.27)	6.02 (SD±1.12)	5.38 (SD±1.10)
Binary age groups				
< 70 years (n=204)	4.93 (SD±1.07)	4.34 (SD±1.38)	5.78 (SD±1.16)	5.40 (SD±1.21)
≥ 70 years (n=123)	5.18 (SD±1.06)*	4.79 (SD±1.29)**	5.91 (SD±1.11)	5.29 (SD±1.31)
Ethnicity				
White (n=229)	5.09 (SD±1.07)	4.58 SD±1.38)	5.90 (SD±1.11)	5.42 (SD±1.27)
Mixed (n=11)	4.80 (SD±1.03)	4.29 (SD±1.50)	5.57 (SD±1.25)	5.13 (SD±1.32)
Asian (n=36)	4.76 (SD±1.15)	4.27 (SD±1.28)	5.50 (SD±1.43)*	5.14 (SD±1.17)
Black (n=45)	5.04 (SD±1.02)	4.54 (SD±1.30)	5.85 (SD±1.08)	5.36 (SD±1.20)
Other (n=5)	4.45 (SD±0.86)	3.72 (SD±1.41)	5.48 (SD±1.36)	5.08 (SD±1.24)
Relationship status				
Married/civil/cohab (n=162)	5.15 (SD±1.08)	4.65 (SD±1.33)	5.98 (SD±1.01)	5.42 (SD±1.18)
Single (n=74)	4.84 (SD±1.02)*	4.28 (SD±1.45)	5.65 (SD±1.22)*	5.33 (SD±1.22)
Separ/divorce/widow (n=26)	4.97 (SD±1.11)	4.48 (SD±1.36)	5.77 (SD±1.18)	5.28 (SD±1.41)
Baseline categories: 75-90 years, white, in partnership.				
***p≤0.05 **p≤0.01**				

Univariate analysis indicates that for the mean overall self-management score there was no overall difference by sex or ethnicity. The data show that for females, the mean score across all domains and for overall SM score tends to be slightly lower than for males, but the difference is not statistically significant.

There was some indication that being older was associated with a higher overall and managing domain score and being single (in terms of relationship status) is associated with a lower score across all domains, but this is significant for communication specifically. Those that are separated also appear to have lower scores, but not as low as people who are single, and the differences are not statistically significant. Although not statistically significant, being single also appears to be weakly associated with a poorer managing score (p=0.06).

By age, mean score tends to be higher in the oldest age category compared with the youngest, for overall score and managing the domain. The difference between youngest and oldest is even more marked when age group is defined as binary. Regression analysis shows a significant difference between groups for the overall score and the managing domain, where older respondents (≥70 years) have higher scores. This trend is both interesting and unexpected but could reflect a stoicism and bias in reporting among the older age group.

Ethnicity data is presented based on Census broad ethnic groups, it must be noted that stratifying in this way means that numbers are low for some groups (particularly mixed and other).

Table 7.8 shows that white respondents have a higher mean than any other group across composite and all domain scores, this is not statistically significant, however. The mean score for communication appears to be statistically lower in those from Asian backgrounds.

Mean scores were all also examined by renal centre and site of dialysis (satellite, in-centre or home, these data are presented in Table 7.9 to Table 7.11.

Table 7.9: PRIESM CKD-HD mean by centre and dialysis location (baseline is centre 1).

	Overall	**Managing**	**Communication**	**Clinical**
Dialysis centre				
Centre 1 (n=127)	5.22 (SD±0.99)	4.85 (SD±1.22)	5.91 (SD±1.07)	5.29 (SD±1.33)
Centre 2 (n=121)	5.06 (SD±1.05)	4.46 (SD±1.37)*	5.94 (SD±1.11)	5.55 (SD±1.11)
Centre 3 (n=80)	4.64 (SD±1.17)**	4.03 (SD±1.43)**	5.52 (SD±1.30)*	5.17 (SD±1.29)
Dialysis location				
Satellite (n=259)	4.99 (SD±1.08)	4.47(SD±1.38)	5.81 (SD±1.13)**	5.33 (SD±1.24)*
In-centre (n=47)	5.13 (SD±1.14)	4.85 (SD±1.27)	5.61 (SD±1.30)**	5.21 (SD±1.32)*
Home (n=20)	5.28 (SD±0.72)	4.35 (SD±1.18)	6.6 (SD±.50)	6.03 (SD±1.14)
Baseline categories: centre 1, home.				
***p≤0.05 **p≤0.01**				

Table 7.10: Dialysis centre statistics

n=325 (df=2)	**Coef.**	**Std. Err.**	**t**	**P>|t|**	**F**
Overall, Centre 3	-.577	.151	-3.83	<0.001	7.46
Managing, Centre 2	-.388	.169	-2.30	0.02	9.33
Managing, Centre 3	-.815	.190	-4.29	<0.001	
Communication, Centre 3	-.390	.163	-2.38	0.02	3.78

Table 7.11: Dialysis location statistics

n=323 (df=2)	**Coef.**	**Std. Err.**	**t**	**P>|t|**	**F**
Communication, Satellite	-.786	.262	-3.01	0.003	5.60
Communication, In-centre	-.991	.301	-3.29	0.001	
Clinical, Satellite	-.693	.289	-2.40	0.02	3.28
Clinical, In-centre	-.818	.332	-2.46	0.01	

Mean scores by centre show overall score and daily managing means were higher for centre 1 and communication and clinical care means were higher for centre 2. The lowest mean was daily managing for centre 3. These differences are statistically significant. These differences cannot be explained with the current dataset but will be explored further in future work.

Mean score by site of dialysis was statistically different for communication and clinical with the strength of association being highest for communication. Home HD patients showed the highest mean scores, though the mean for daily managing was comparably low. Of note is the small sample of home HD respondents so these data should be interpreted with caution. Comparing satellite and in-centre respondents, dialysing in the latter showed a lower mean score for communication and clinical care. The reverse was true for overall score and daily managing.

7.8 SECONDARY SUB-ANALYSIS

The following data (Table 7.12 to Table 7.14) show some interesting variation in mean scores across domains in relation to other patient characteristics and clinical data such as comorbidity.

Table 7.12: PRIESM CKD-HD sub-analysis.

	Overall	**Managing**	**Communication**	**Clinical**
Education				
No qual or level 1 (n=166)	4.96 (SD±1.06)	4.48 (SD±1.33)	5.83 (SD±1.12)	5.16 (SD±1.28)*
Level 2 or above (n=144)	5.09 (SD±1.07)	4.58 (SD±1.37)	5.83 (SD±1.18)	5.53 (SD±1.21)
Employment status				
Employed (n=57)	5.05 (SD±.93)	4.53(SD±1.81)	5.80 (SD±1.10)	5.45 (SD±1.10)
Unemployed (n=13)	4.63 (SD±.91)	3.86 (SD±1.30)*	5.77 (SD±.93)	5.16 (SD±.96)
Retired (n=166)	4.63 (SD±.91)	4.78 (SD±1.32)	5.94 (SD±1.08)	5.36 (SD±1.30)
Other (n=87)	4.70 SD±1.07)**	4.01 (SD±1.41)**	5.63 SD±1.35)*	5.33 (SD±1.24)
Income				
More than enough (n=148)	5.27 (SD±.99)	4.88 (SD±1.22)	5.96 (SD±1.03)	5.44 (SD±1.25)
Just enough (n=118)	4.94 (SD±1.05)**	4.34 (SD±1.38)**	5.81 (SD±1.18)	5.44 (SD±1.17)
Not enough (n=54)	4.42 (SD±1.07)**	3.74 (SD±1.30)**	5.45 SD±1.33)**	4.89 (SD±1.32)**
Other LTCs				
0 (n=77)	5.22 (SD±1.13)	4.78 SD±1.41)	5.84 (SD±1.19)	5.62 (SD±1.19)
1 (n=120)	5.12 (SD±.99)	4.62 (SD±1.28)	5.98 (SD±1.07)	5.39 (SD±1.24)
≥ 2 (n=131)	4.40 (SD±1.09)**	4.24 (SD±1.38)**	5.68 (SD±1.20)	5.17 (SD±1.27)*
Status on transplant list				
Yes (n=216)	4.98 (SD±1.10)	4.47 (SD±1.40)	5.78 (SD±1.17)	5.33 (SD±1.27)
No (n=74)	5.21 (SD±1.03)	4.73 (SD±1.27)	5.95 (SD±1.19)	5.51 (SD±1.22)
Don’t know (n=26)	4.54 (SD±1.01)**	3.89 (SD±1.22)**	4.62 (SD±1.13)	4.93 (SD±1.29)*
Baseline categories: highest education, retired, more than enough, no LTCs, on transplant list.				
***p≤0.05 **p≤0.01**				

Table 7.13: Employment status statistics

n=319 (df=3)	Coef.	Std. Err.	t	P>|t|	F
Overall score, other	-.501	.140	-3.58	<0.001	4.88
Managing, unemployed	-.923	.381	-2.42	0.016	7.52
Managing, other	-.773	.175	-4.41	<0.001	
Communication, other	-.312	.153	-2.04	0.043	1.41

Table 7.14: Income statistics

n=317 (df=2)	Coef.	Std. Err.	t	P>|t|	F
Overall score, just enough	-.333	.126	-2.63	0.009	14.1
Overall score, not enough	-.853	.163	-5.24	<0.001	
Managing, just enough	-.541	.160	-3.38	0.001	16.5
Managing, not enough	-.818	.332	-2.46	<0.001	
Communication, not enough	-.512	.181	-2.83	0.005	4.00
Clinical, not enough	-.550	.196	-2.81	0.005	4.48

7.8.1 Education, employment status and income

Broadly, the overall score and managing domain score are higher for those with A-level and equivalent education and above compared with those with GCSE attainment or below, however this difference is not statistically significant. The mean score in the clinical domain mirrors this directional association and is statistically significant. In terms of current employment status, being retired is associated with a higher overall score and managing and communication domain scores, these differences are statistically significant. The lowest mean score for those self-reporting as unemployed was 3.86 for managing, and this finding was statistically significant (note numbers for this group are small). Those reporting ‘other’ include those with caring responsibilities. This group had a lower score mean across the managing and communication domains. Similarly, inadequate income was associated with lower mean score across all domains and was statistically significant (p<0.01).

7.8.2 Other long-term conditions and transplant list

Having two or more other long-term conditions is associated with lower overall, managing, and clinical domain scores. This may reflect the workload burden caused by managing more than one illness and potentially many symptoms. Data relating to the transplant list are also insightful; those who know they are on the list to receive a transplant show higher scores across all domains than those for whom there is uncertainty (reporting don’t know) or are not on the list. These differences are statistically significant for the group with uncertainty regarding their status. It could be argued that these findings relate to the hope, acceptance and joint decision-making narratives that have been shown to be important in previous chapters.

The summary below outlines the significant variables associated with self-management by overall score and domains.

7.9 OVERALL SCORE

There is strong evidence that low overall self-management score is strongly associated with not enough or inadequate income, having two or more LTCs and uncertainty about status on the transplant list. Being younger was also associated with a lower mean score. There was some indication of centre effects, centre 1 having a significantly higher overall mean score, compared with centre 3.

7.10 DAILY MANAGING SCORE

The data suggest that as for the overall score, income, age, transplant list status and two or more LTCs are significantly associated with daily managing score. Those retired (compared with those unemployed or caring for others), have a higher managing score. Centre effects are also evident and follow the same pattern as for overall score.

7.11 COMMUNICATION SCORE

Insufficient income was significantly associated with lower communication domain score. Those dialysing at home were found to have a higher mean score, compared with those dialysing in-centre or in a satellite unit and this was statistically significant. However, these data are based on small numbers in the home HD group (n=20) so should be interpreted with caution. Unlike all other domains, there was no association between two or more long term conditions and communication score. Also unique, was the indication that those from Asian backgrounds have significantly lower communication domain scores than those with White backgrounds.

7.12 CLINICAL SCORE

Unique to this domain, was the association between lower mean clinical score and lower educational attainment. As for communication, those dialysing at home have a higher mean score for clinical than those receiving treatment in-centre or at satellite units. Uncertainty about transplant list status and two or more LTCs were also associated with a lower clinical score.

7.13 IN SUMMARY

Broadly engagement in self-management overall seems to be relatively high in this population, as measured by PRIESM CKD-HD; over 80% of the sample score above the mid-point of the scale and this doesn’t appear to vary by age. However, there appears to be some variation between domain scores by sub-group, particularly by age and income, and to some degree, ethnicity and having one or more other LTCs.

The variation in self-management scores in relation to patient characteristics suggests the scale is valid and reliable. Particularly as related characteristics are commonly observed in other similar scales (Lai et al., 2021; Mirmazhari et al., 2022; Wild et al., 2017). It is important to caveat the findings within the context of small numbers (for some variables) and the absence of multivariate analysis. However, the findings are interesting, despite potential misconceptions, the data indicate that older people may be better engaged in self-management, even though their engagement in clinical aspects of managing is lower. It is possible that response bias may be at play, an effect that may be addressed by normalising conversations about psychosocial wellbeing and support needs. In contrast, those with inadequate incomes appear to struggle most with daily managing but do better within the communication and clinical domains.

7.14 USE IN CLINICAL PRACTICE (RAG RATING)

Using a broadly representative sample of the haemodialysis population with which to test this measurement is essential in beginning to establish norms and thresholds for using the data. Whilst further testing on other samples is required, this section outlines one way in which scores generated at the individual level for the PRIESM CKD-HD may be used to guide further conversations about support needs and how to address them. The measurement is a 7-point Likert scale, each item score and the overall and domain scores align with this 1-7 format. Arbitrary thresholds have been used to flag where support needs may be highest. Use of thresholds will be explored further when the scale has been used with other haemodialysis samples, but for now, a composite or domain score of ≤3 will be used to highlight need (red). Scores ≥5 are shown as green and indicate the respondent is relatively well engaged in self-management. Figure 7.7 shows high-level overall and domain scores, each row represents a respondent. Although the scale was designed to have a composite SM score and domain scores, in clinical practice it's likely that looking at individual responses to identify specific issues may be more useful.

Figure 7.7: Reporting of individual level data using rag score thresholds.

	Managing	Communication	Clinical care	Overall
P1	3.5	3.7	2.8	3.4
P2	5.2	5.9	6.4	5.6
P3	3.0	2.9	3.4	2.9
P4	2.3	2.6	3.0	2.4
P5	3.9	2	4.8	3.5
P6	3.4	3.3	2	3.1
P7	1.3	2.4	3.2	2.0

Figure 7.8 shows a breakdown of the item level data for an individual respondent, this enables staff to prioritize and identify which areas might need to be addressed in a follow-up conversation with the patient. Even a conversation about why a patient may have answered N/A to a question that appears to be universal in applicability may be useful e.g., 'When discussing treatment options, my views are considered by the renal team'. In this example, it is clear there is variation in how this person manages and drilling down into the domains and specific items reveals that the issues are mainly with daily managing and how the patient views their role in their healthcare and works with their renal team, rather than communication.

Figure 7.8: Item level data for an individual respondent (high scores indicate better SM)

Overall SM score	Managing	Communication	Clinical care
4.71	1.9	5.7	3.6
I feel more isolated than I did before I started dialysis.	7		
My symptoms interfere with the way I would like to live my everyday life^{R}.	1		
Day to day I can manage most of the things I need to do.	1		
I find it hard to cope with my kidney disease.	1		
Being on dialysis makes it difficult for me to get the other care I need.	4		
My kidney disease interferes with my life.	1		
I have activities and interests that keep me busy.	1		
I have other health issues as well as my kidney disease and it's difficult.	1		
I am angry about my kidney disease.	4		
I find it difficult to look after myself the way I would like to.	1		
Some days I feel distressed^{R}.	1		
I sometimes feel overwhelmed by my kidney disease.	1		
I see myself more negatively since I’ve had kidney disease	1		
I feel that I cannot cope with all the things I need to do	3		
When I talk to the renal team about my care I'm treated as a whole person		7	
The renal team review my health and discuss any changes with me		7	
I have someone who will listen to me when I need to talk		7	
I get the support I need to manage my health and treatment		4	
I’m able to ask a doctor for more information if I don’t understand		7	
When discussing treatment options, my views are considered by the renal team		7	
I am confident that there is good communication on between all the specialists I see.		4	
I help decide how much fluid should be taken off			6
I have an important role in managing my Illness			3
I check settings on the dialysis machine to make sure they are the same.			1
The renal team encourage me to be involved in my own care			1
I wasn’t as involved in the decision to start dialysis as I would have liked			7

Note: response varies according to sentiment of the question, with a higher score always reflecting better self-management. ^{R}Reverse scoring was undertaken prior to analysis where original item inversely scored.

7.14.1 Attitudes to the presentation of the PRIESM CKD-HD for use in clinical practice

To look at the utility of the scale generally and begin to think about how to best use the PRIESM CKD-HD data in clinical practice to enable conversations and identify support needs, a further study was conducted with stakeholders and including patients, using focus groups. This work is discussed in the following chapter, but four quotes are included here:

“I think that would be really useful, you can see it at a quick glance, which are the areas that need perhaps a bit more delving into” (Renal dietician).

“I mean that that sheet you had there is quite useful, I do think it's too long, by the way. But I think that actually having like a, like a headline....” (Renal consultant).

“I think the colour is a brilliant way of pinpointing the problem with patients” (Patient).

“I do think it will help because sometimes our brain moves very fast and when there are when you're reading, something it tends to direct you to a more focus thing, and you get to think more about what's happening” (Renal nurse).

These quotes give some indication that there may be a need for PRIESM CKD-HD and that the focus it offers and method for prioritising may have some value.

7.15 DISCUSSION

The data gathered via the large-scale survey provides an initial baseline and idea about thresholds for the PRIESM CKD-HD. The analysis presents some insight into how engagement in self-management may vary according to some patient characteristics or other factors that may have an impact. It provides further evidence of the validity and reliability of the scale, demonstrating that the overall scale and domain scores are related to other similar constructs that previously published work also identifies as being related to self-management such as self-efficacy, depression, and plasma phosphate control (Cardol et al., 2023; Milazi et al., 2020; Peters et al., 2019; Woodward et al., 2023)

It is envisaged that data from PRIESM CKD-HD may be used as a conversation starter, a means of identifying where the focus for the conversation needs to be. It is hoped that it’s use may help improve engagement with self-management via regular conversations about support needs that don’t focus only on treatment or clinical needs but include psychosocial elements. Normalising these conversations may allow patients to step away from the default of ‘I’m fine’. The use of the PRIESM

CKD-HD scale may in the longer term, contribute to the shift towards patient-centred care, ensuring equality and equity.

Findings from other studies suggest that lifestyle specific knowledge is currently absent from self-management support. Consequently, this may lead patients to choose "strategic non-compliance" so that managing strategies suit the 'messiness' of their everyday lives (Ellis et al., 2017, p.32).
The assumptions behind this work are:

1. in clinical practice there is currently no alternative to knowing the patient context beyond the informal efforts to get to know a patient, which may be neither systematic, or regular and may vary from patient to patient.
2. that pressures on services and staff mean that there is little time to sit down with every patient and talk.
3. Implementing PRIESM CKD-HD might enable those conversations about an individuals' social, emotional, and practical circumstances, or at least flag the need for support.

When patients see their results guide a conversation or decision, this will make it relevant, meaningful and perhaps more sustainable for continued use over time, if that is appropriate.

As explained in previous chapters, the conceptualisation of self-management needs to move beyond a focus on engagement in terms of clinical need, clinical outcomes, and adherence. The person must be at the centre of their dialysis treatment in terms of determining need, goals, and support gaps. The moral overtones of avoiding unhealthy behaviour should be replaced with an understanding of what other factors may be affecting or influencing the way a person makes choices about diet, fluid and exercise or manages rest and social interaction. Ways of managing beyond the dialysis chair, that help people with ESKD live their lives, really matter.

Distress, isolation, feeling overwhelmed, are all emotional responses to illness and life events that will impact behaviour. There is evidence that currently, patients aren't being asked directly about social and emotional elements of wellbeing that will impact their ability to self-manage or are part of their self-management strategy. These dimensions need to be more directly addressed, especially with patients that have not experienced a planned start and are having trouble adapting or processing important information. Shared decision making and supporting self-management are both key elements of shifting towards a partnership approach that can redress the balance towards a more psychosocial approach. Treatment and care in the context of what matters most to the individual, is critical.

This scale reframes the concept of SM in terms of what it means to patients and is a mechanism for improving conversations about psychosocial support needs. Further work is needed to verify the factor structure of the model on another sample to strengthen the argument that the scale is reliable. Conducting confirmatory factor analysis (CFA) on a second sample is a test of dimensionality and helps determine whether the measurement of items and their domains are the same across two different samples (Boateng et al., 2018).

The following chapter describes a qualitative study undertaken with stakeholders in which steps were taken to explore implementation; the barriers and facilitators to potential use of PRIESM CKD-HD in clinical practice.

CHAPTER 8 : SHIFT FROM RESEARCH TO PRACTICE, PRELIMINARY EXPLORATION OF IMPLEMENTATION

8.1 INTRODUCTION

The development of the PRIESM CKD-HD scale has been outlined in chapters 4-7. The purpose of the scale is to address a gap in current conceptualisation and measurement of self-management, as identified in chapters 2 and 3. This chapter integrates the work so far with the assumption that the PRIESM CKD-HD could be used in clinical practice to ascertain gaps in support and in research to identify changes over time in conjunction with a self-management intervention or change in clinical practice, policy, or provision.

To introduce this scale into practice requires a change in work practices, disruption to routines and not least, effort from staff involved and sometimes, reallocation of resources. It is crucial to understand what people need to use it (guidance, materials, domain scores, resources, training) and whether there is wider support to implement. Implementation is a complex process, particularly within the context of the healthcare setting (May et al., 2016) and affected by factors from the organisational context down to the individuals working and receiving care within it. Perceptions of the intervention (in this case, PRIESM CKD-HD) and capacity will influence the success of implementation.

Implementation research can be conducted at any stage; to look at the process, evaluate a change, or sustain and embed a new policy or intervention. All implementation research seeks to understand how a change or intervention might work in the real world (Peters et al., 2013) and is an essential step in bridging the gap between health research and clinical practice, to bring evidence-based research into routine practice to improve the quality and effectiveness of health services (Eccles & Mittman, 2006).

At this stage of scale development, the purpose is to understand whether the scale might be useful in the clinical setting, and the contextual factors that may affect wider implementation. Collecting information about the barriers and facilitators to implementation of the scale will inform the planning of any future studies. Establishing blocks in the road or possible levers in the early exploratory stages of implementation, enables the design of further studies to adequately address issues already identified (Nilsen & Bernhardsson, 2019).

In this chapter, two relevant implementation frameworks and a process of thematic analysis are used to explore qualitative data from key stakeholders, in an important subsequent step in scale development.

To note, this study was designed in 2020 when the pandemic determined alternative approaches to data collection. All stakeholder meetings, focus groups and interviews were conducted online between 2021 and 2022, the advantages and any limitations of this are discussed throughout the chapter.

8.1.1 Implementation theories, models and frameworks

Implementation science is a relatively new type of study that encapsulates many underpinning theories, models and frameworks that can be used to plan and evaluate an evidence-based change in practice (Nilsen, 2015). Broadly, these frameworks include the intervention, inner settings, outer settings (e.g., wider context), and individuals involved. Beliefs, attitudes, practices and actions, capacity, leadership will all influence how successfully change can be implemented.

The work described in this chapter is firmly situated in the first stage of implementation, the design and data collection were characterised by exploration, understanding the context of the healthcare setting and attitudes of key stakeholders, within a healthcare delivery system. The focus is on ascertaining need, understanding barriers and facilitators and exploring capacity (King's Improvement Science (KIS) website, 2013). Two frameworks were selected to inform analysis.

As a relative novice to implementation, I used the ImpRes guide as documented by Hull et al (2019) to inform my decision making. The Consolidated Framework for Implementation Research (CFIR) (Damschroder, 2020; 2022) and Promoting Action on Research Implementation in Health Services (PARiHS) (Kitson et al., 2008), were selected to guide the design and analysis and are examples of determinant (rather than evaluation) frameworks. They are used to examine what influences implementation outcomes. CFIR and PARiHS align with the aims of this research, their relevance to healthcare, and the focus of both on barriers and facilitators. CFIR incorporates people, process, and context (Table 8.1). Application of PARiHS has found evidence, context, and facilitation to be the biggest predictors of successful implementation (Rycroft-Malone et al., 2004).

Table 8.1: The Consolidated Framework for Implementation Research (CFIR)

Domain	Examples of contextual factors in each domain
Intervention characteristics	Stakeholder perception of the strength and quality of evidence: adaptability, complexity and costs of the intervention
Outer setting	Patient needs and resources: extent and scope of wider organisational networks; external polices; funding; peer pressure from other organisations to innovate
Inner setting	Type of networks: readiness for implementation (e.g., in terms of leadership engagement and available resources); implementation climate (e.g., organisational incentives and learning climate); culture.
Characteristics of individuals involved	Stakeholders' knowledge and beliefs about the intervention; individual staff's level of commitment to the organisation
Implementation process	Planning, engaging (e.g., of champions), executing the implementation plant, and reflecting and evaluating (using qualitative and quantitative feedback)
Source: Damschroder et al (2009)	

Table 8.2: Key elements for implementing evidence into practice (PARiHS Framework).

Elements	
Evidence	Research Clinical experience Patient experience Information from the local context
Context	Receptive context Culture Leadership Evaluation
Facilitation	Role Skills and attributes
Source: Rycroft-Malone et al (2004)	

Rather than operational, step by step models, these frameworks allow for local variation and acknowledge the complexities of implementation (E. A. Lynch et al., 2018). They also take a multi-level approach in terms of individual, community (e.g., organisation or team) and wider system.

As determinant frameworks, these are largely generic rather than specific and it has been noted that such frameworks are sometimes used retrospectively rather than prospectively to design implementation strategies (Helfrich et al., 2010). Thinking about potential frameworks in the pre-implementation stage is recommended (Moullin et al., 2020). Both frameworks were used to inform the development of focus group topic guide and the deductive element of coding. Using these models, the data were analysed with an implementation framework using codes for utility, acceptability, barriers, context, facilitators, strategies, and sustainability. Both frameworks will be referred to again, using detailed mapping to inform the choice of implementation strategies in future studies, with a focus on acceptability, fidelity, and feasibility, concepts defined in the literature as key to influencing uptake of interventions in the healthcare setting (Klaic et al., 2022).

It is likely that future work will incorporate other frameworks and guidance such as standards for reporting implementation studies of complex interventions (StaRI) as reported by Pinnock et al (2015). This set of standards has been developed for purposes of transparency and accuracy in reporting and incorporates a logic pathway that covers how the implementation strategy is expected to work and the mechanism by which the intervention or in this case, scale, will lead to change or improvement (ibid). Other more detailed models that allow consideration of suitable outcome measures such as RE-AIM (http://www.re-aim.org, Glasgow et al., 2001) or Normalisation Process theory (NPT) outlined by Mcvoy et al (2014), will also be considered in future studies to guide further implementation work, beyond the models considered and used here.

8.1.2 Qualitative approach

Qualitative methods work well in implementation research because they allow exploration of the complex contextual issues, attitudes, broader contexts and patient and provider experiences (Hamilton & Finley, 2019). Using focus groups particularly, is a valid way of addressing implementation science questions that seek to integrate research findings into healthcare practice, and policy (Hamilton & Finley, 2019; Holtrop et al., 2018; National Cancer Institute, 2020; Nevedal et al., 2021; Peters et al., 2013).

Focus groups have become increasingly used in health science research and are a useful mechanism for exploring participants perspectives, use of language and understanding of concepts (Wilkinson, 1998). They were the preferred method for this pre-implementation work as they can provide rich understanding of the care environment and important contextual factors (Hamilton & Finley, 2019) and the group setting removes the pressure one person may feel to have the answers (Stewart & Shamdasani, 2014).

8.2 METHODS

8.2.1 Study, design and sample

A qualitative study using online focus groups and interviews (as necessary) was used to explore the utility of the scale and potential barriers and facilitators to implementation. The choice of design was guided by recommendations on pre-implementation approaches, best methods for analysing data, recognising researcher-led bias, and given the wider context of the pandemic. A reflexive and critical stance was applied to the entire research process, including analysis and reporting. A process of debriefing after each focus group was supported by others in the research team, a mechanism for gaining real time insights into the process to strengthen the data (McMahon & Winch, 2018) that supports reflexivity (Hoover & Morrow, 2015).

The Covid-19 pandemic was ongoing at the time the study was designed. Given the likelihood that the pandemic would prevent the ability to safely conduct face to face meetings, the study was designed so all meetings and focus groups would be conducted online using video conferencing software. Guidance on best practice for online data collection was followed (Archibald et al., 2019; Eynon et al., 2009; Lobe, 2017), along with recommendations for adapting data collection during Covid-19 (Dodds & Hess, 2021). Enhanced technical support was available for those experiencing frailty or whose age may hinder ability to video conference (Moyle et al., 2020). Mixed professional/patient small focus groups were promoted as the preferred scenario, however interviews on teams or on the phone are valid alternatives (Sturges & Hanrahan, 2004) and were offered where participant preference necessitated. Accommodating interviews in place of focus groups was a pragmatic decision to ensure heterogeneity in inclusion of people with lived experience and to mitigate bias towards a younger sample (Barbour, 2007). Using this online format for focus groups is a strength as it offers greater convenience and opportunity for bringing together 'time poor' and geographically dispersed professionals and patients (Boland et al., 2022).

A stakeholder steering group was convened at the start of the study, as an integral part of the design. The purpose of the group was to provide feedback on the scale in relation to own experience or interest in self-management and guide the development of the materials and the topic guide for the focus groups. Two meetings were conducted online using Zoom. The group was geographically heterogeneous and professionally diverse and comprised a colleague from the renal registry, third sector, several methodologists, health psychologists, renal consultants, renal nurses and service users (n=19). Every member of the group was required to attend two online meetings and contribute to other work as necessary via email. Some had previously been involved in the scale development as part of the expert panel, and others were identified and approached to support this qualitative work. This group were not considered participants but a wider, advisory facet of the research team.

All participants for the small focus groups or interviews were recruited from four kidney centres: Royal Preston Hospital, Kings College Hospital, University Hospital Birmingham, Lister Hospital, the latter two having been involved in recruitment to the scale development phases. Sampling was stratified, convenient and purposive with the intention of achieving 1:1 ratio of clinical or allied health staff and people with CKD with a total of 6 participants from each centre. Target recruitment was 24 participants with representation from each category: nephrologist, nurse, social worker, dietician, counsellor/psychologist, and senior manager, as well as service users. Of those with lived experience, current or previous experience of HD was not a prerequisite for participation.

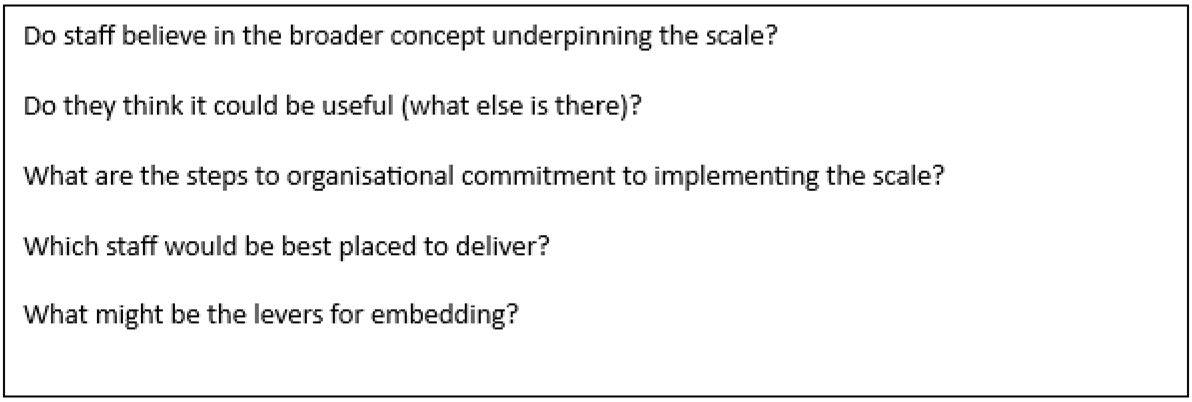
Potential clinical or allied health worker recruits were selected based on their role within kidney care, as well as interest in patient-centred approaches to SM or other relevant interests such as self-care, frailty, and supportive care. Participant experience covered a range of service settings such as advanced kidney care clinics, satellite dialysis units, renal genetic diagnostic clinic, and home HD. All participants had to be willing to participate in one interview or focus group.

CKD participants were not required to be currently receiving healthcare provision/services to be involved. Focus groups and interviews took place between July and August 2022.

8.2.2 Materials

A semi-structured topic guide was developed using relevant literature and discussions with the stakeholder group, see Figure 8.1 for an overview and appendix S for the full guide. Pre-read documents were sent to participants 2 days prior to the group meeting (Figure 8.2). PowerPoint slides were used during the focus groups to prompt discussion.

Figure 8.1: Summary of the focus group topic guide



Do staff believe in the broader concept underpinning the scale?

Do they think it could be useful (what else is there)?

What are the steps to organisational commitment to implementing the scale?

Which staff would be best placed to deliver?

What might be the levers for embedding?

Figure 8.2: Pre-read documents

The 60-item scale (Appendix Q).
The 26-item revised scale (Table 6.11).
A plain English summary of scale development (Appendix T).
The ground rules.
The Zoom Guide.

The aim of the focus groups was to explore:

1. whether the conceptualisation of the SM term as expressed by the scale is valid,
2. whether the SM score has utility in the clinical setting,
3. whether we should continue to an implementation study (is the tool deemed feasible, acceptable) and
4. what some of the barriers and facilitators to this may look like to inform the design and approach to implementation.

8.2.3 Data collection

Participants were recruited by the local PIs between May and June 2022 and provided with a participant information sheet. Written, informed consent was obtained via email by the lead researcher prior to the interview/focus group. The material in the pre-read documents formed part of the visual cues used during the group discussion so participants were not disadvantaged if they hadn't read prior. To establish rapport and minimise drop out, the lead researcher spoke to all participants directly and had at least two email exchanges with participants prior to the focus groups convening. One patient participant preferred to communicate via telephone and all the pre-read documents were printed out by the renal research lead and taken to her in clinic.

All focus groups and interviews were conducted online (two interviews were conducted on the telephone) and audio and/or video recorded via Zoom or audacity software with consent. All were convened at a time convenient for all and co-ordinated by the lead researcher. Dialysis commitments and work patterns presented some difficulties but drop-out was low. Participants were reminded at the start that they could leave the group or interview at any time. To ensure consistency all focus groups were facilitated and interviews led, by a single trained mixed methods researcher using the semi-structure topic guide.

Quotes from a previous study were used to illustrate the holistic concept of self-management that underpinned scale development (highlighted in appendix S) and the items of the scale were reviewed as part of the discussion. Although I assumed a position of transparency, every effort was made to stay as neutral as possible when facilitating the discussion. In line with Madill et al (2000), I was clear about my role in developing the self-management scale and my continued investment and enthusiasm in gathering further evidence for its potential use in clinical practice.

8.2.4 Focus groups

The focus groups were facilitated with support from a research assistant (DG or BR) who provided logistical support, notetaking and played a critical role in debriefing. Analysed documents included transcripts, field notes and recordings of debrief meetings. Written notes were compiled in real time by one of two research assistants (BR and DG) supporting each focus group. All focus groups were followed by a debrief meeting (within 24 hours) involving one or both research assistants involved in facilitating the groups. An opportunity for individual reflection occurred before the debrief, and key points from the discussion, group dynamic and level of engagement and issues with Zoom or anything related were discussed and documented.

Despite the physical distance between participants due to the online format, HMW and both co-facilitators felt good rapport was evident across the focus groups, a finding supported by others conducting online research (Archibald et al., 2019; Keen et al., 2022; Lathen & Laestadius, 2021). The use of the topic guide ensured that every group covered broadly the same area of discussion.

8.2.5 Interviews

The topic guides for the interviews were altered to reflect sole participation by patients with CKD, no interviews were conducted with clinical or allied health staff. Questions directed at staff were omitted and less emphasis was placed on implementation, question 14 relating to the requirements for a guidance document was removed.

Interviews were conducted solely by the lead researcher as it was felt the presence of an 'observer' may make the participant feel uncomfortable. Whilst rapport was quicker and easier to build in the interviews, the content of data reflected patient experience of the kidney journey and treatment and a tendency to think about the scale in terms of one's own context.

Field notes were not taken during the interview and debrief was not possible, however, the transcript and recorded audio files were used for reflection in a similar way to the focus groups.

Implementation frameworks were not referred to directly and the guide was used for the focus groups and adapted for the interviews to ensure the same core topics were discussed across the interviews and focus groups. There was variation in the order in which topics were addressed, to allow discussion to progress organically. Deviation was felt to be equally determined by both the facilitator and participants.

8.2.6 Ethics

The study received REC and HRA approval (refer to chapter 4). UH researchers followed the most recent guidance on how best to conduct online qualitative research, to uphold the dignity and privacy of participants and ensure the quality of the research.

8.3 ANALYSIS

The reflexive thematic analysis described by Braun & Clarke (2012, 2006, 2013, 2014, 2020, 2023) as a six-step process was used for analyses as this iterative, less linear process of coding is well suited to the application of both deductive and inductive methods of coding. This combined inductive and deductive hybrid approach has support (Bonner et al., 2021; Fereday et al., 2006; Sandelowski & Leeman, 2012) and allows a more comprehensive understanding of the implementation context, particularly barriers. This allows use of theoretical framework(s), alongside an inductive approach to examine language, beliefs, attitudes and experiences. A combined approach to the qualitative analysis means ideas can emerge from the empirical data, frameworks and theory from existing literature (Bradley et al., 2007).

Table 8.3: The six steps of reflexive thematic analysis.

Step	Process	Actions
Familiarising self with the data	The lead researcher (HMW) began by reading the transcripts. Familiarisation of the content, allowed key ideas, phrases and topics of interest to be recorded. This was completed as a paper and pen exercise.	Annotations and highlighting of key text. Reflecting on field notes and listening to audio recordings.
Systematic data coding	Initial coding of the data, done independently. The lead researcher coded all transcripts. BR and DG reviewed three of the transcripts.	Coding for three of the transcripts was discussed in an audio-recorded meeting and thoughts shared.
Generating initial themes	HMW generated initial themes from the codes and began the process of clustering themes. Annotations and memos were used to link field notes, observations, own thoughts, and the primary data. Coding stripes were used to enable easier visualisation of coding overlap.	Codebook reviewed by wider research team. A concept map was developed to look at overlap in codes.
Developing and reviewing themes	More refined coding. Some stratified analysis by participant role and centre. Looking for consistent and coherent patterns in the data.	Further developed the concept map. The wider research team met regularly to discuss developments using the codebook and refine themes.
Defining and naming themes	Themes are finalised, with definitions.	The research team continued to meet until the themes were finalised.
Writing	HMW produced the report. This was read and reviewed by BR and DG, as well as the wider research team. The quotes selected were reviewed for appropriateness and interpretation.	A full report was produced and shared with PIs for comment. The full methodological process was included.

The six-stage process is outlined in Table 8.3 and was followed to enable analysis of the qualitative data. Using NVIVO 12 software (QSR International, 2016), supported data immersion and active reading. It also optimised research reflexivity as detailed notes could be recorded via the annotation function. This brings the researcher into the process and allows for context that might be missing to be logged in the data. Codebooks at each stage are evidence that a rigorous process was followed, and coding changes consistent resulting in plausible findings (Nowell et al., 2017).

Data from the focus groups were analysed using a deductive framework informed by the CFIR and PARiHS frameworks and using an inductive approach to examine use of language, beliefs, experience and attitudes (as described in the methods, chapter 4). Analysis was led by the researcher, but oversight was provided by the wider researcher team (methodologist and renal consultant) and other guidance beyond Braun & Clarke was followed, for example around using matrices for comparative analysis and sharing portions of data with the wider study team to check interpretation (Bazeley, 2009). At each step of coding, the process was discussed, and the codebook shared.

For each code, frequencies were generated, and data was stratified by participant role and renal centre to identify similarities and differences and ensure thorough interrogation of the data.

Themes were reviewed by the wider research team and analysis was reported in line with COREQ guidelines, as for chapter 5.

8.4 RESULTS

8.4.1 Participants

Twenty-seven participants were recruited to the study, comprising 19 healthcare professionals and 8 service users from four kidney centres participating in 3 interviews and 10 focus groups conducted between 4th July and 26th August 2022. Ten focus groups and one interview were conducted via zoom and two interviews via telephone in accordance with participant preference and lasted between 60 and 90 minutes.

Contact details for 31 people were provided by centre PI's, of those, 1 decided not to participate, 1 could not participate due to illness and 2 provided consent and then changed their minds. None of the participants dropped out during the group. Four of the focus groups included both service users and staff, two further groups were scheduled to include a patient, but one withdrew their participation and the other had to rearrange due to other commitments.

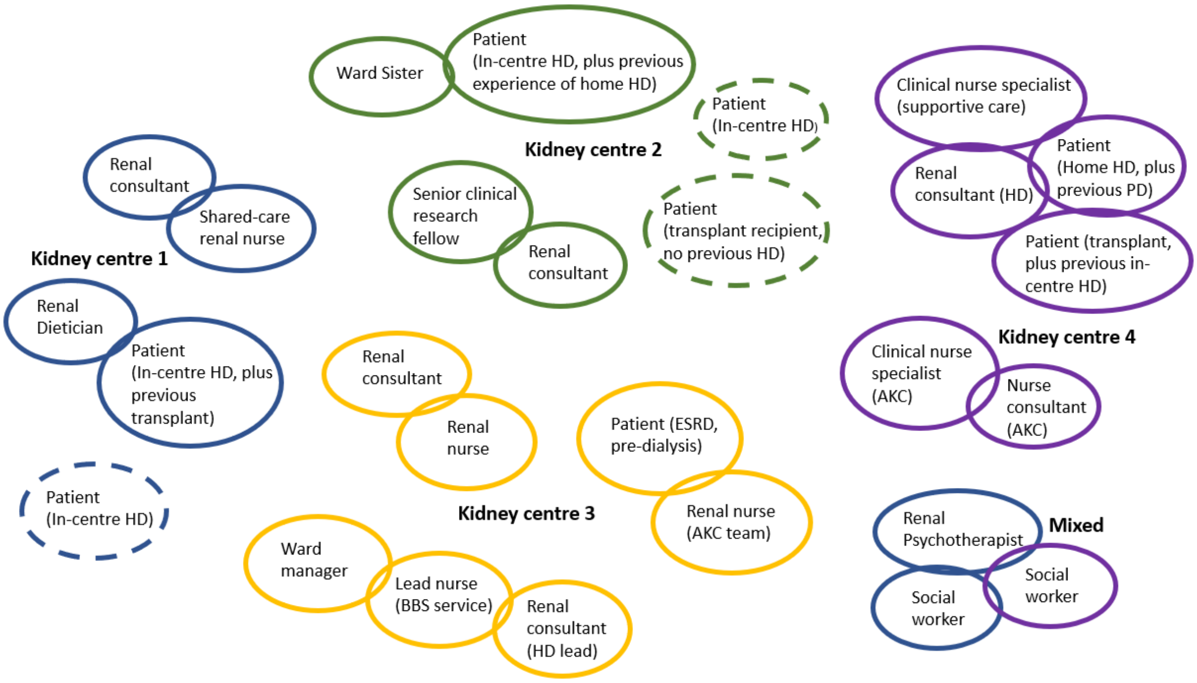
Seven of the focus groups were dyadic, and a further 3 groups involved 3 or more participants (Figure 8.3: Composition of the focus groups.). Target recruitment (n=24) was exceeded likely due to the efforts at the centre level to recruit, direct contact initiated by the lead researcher with each participant prior to the focus groups, and the online format of data collection.

Of the 8 participants with CKD, at the time of data collection, two had no experience of haemodialysis (one was a transplant recipient and the other end stage pre-dialysis), five currently receive in-centre dialysis and one has HHD. Thirty percent of the overall sample is male with a 50:50 split between male staff and service users.

Table 8.4: Participants by kidney centre and participant description.

	KC - 1	KC - 2	KC - 3	KC - 4
Renal nurse/sister	1	1	3	3
Renal consultant	1	2	2	1
Ward/Service Manager	-	-	1	-
Dietician	1	-	-	-
Psychologist/psychotherapist	1	-	-	-
Social Worker	1	-	-	1
Service user	2	3	1	2
Total	**7**	**6**	**7**	**7**

Figure 8.3: Composition of the focus groups.



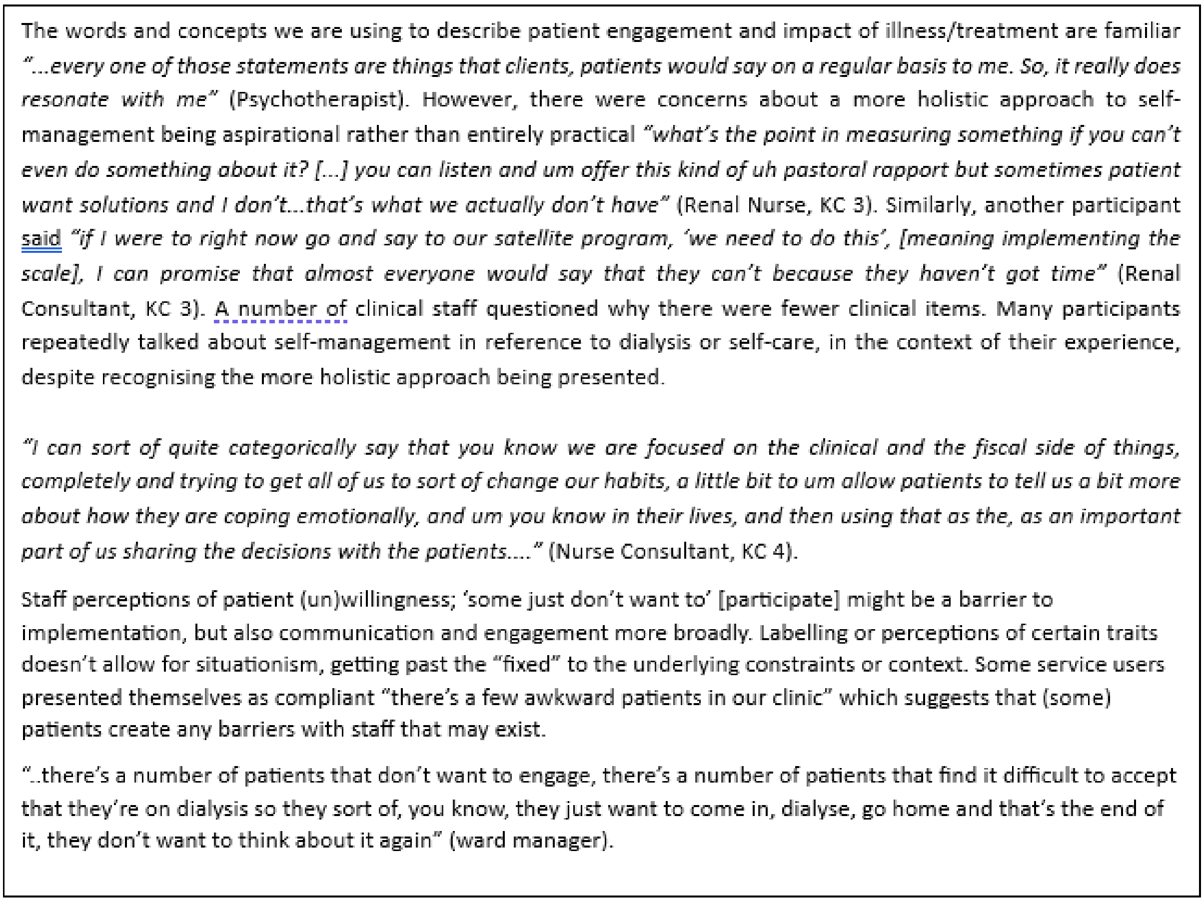
8.4.2 Themes

Four main themes were identified that describe the context within which staff and patients interact and how self-management is understood and engaged in (Table 8.5). Common sub-themes that run throughout the narrative are resource – mainly referred to in terms of lack of time – and intention. Figure 8.4 presents some thoughts around the way the scale defines self-management.

Table 8.5: Themes and subthemes

	Subthemes	Coding frequency
1. The wider context	1.1 Lack of time.	94
	1.2 Current intention to provide psychosocial support.	93
	1.3 Resource and capacity, including workforce gaps.	52
	1.4 Opportunities to improve adherence.	27
	1.5 Impact of Covid-19 and fragmentation of support.	26
	1.6 Rigidity of the system.	16
2. Shared understanding	2.1 Does this make sense?	60
	2.2 Trust and rapport.	57
	2.3 How are you now?	49
	2.4 Shared decision making.	32
3. Self-management as medical, moral, and marginal	3.1 Self-management defined through a medical lens or according to medical priority.	97
	3.2 Beyond the doctors and nurses	57
4. Disease, treatment, and life workload; psychosocial and physical capacity	4.1 Underserved groups.	39
	4.2 Still processing.	33
	4.3 Treatment burden.	31
	4.4 Service context.	28

Figure 8.4: The concept, more than adherence to treatment and self-care.



The words and concepts we are using to describe patient engagement and impact of illness/treatment are familiar *"...every one of those statements are things that clients, patients would say on a regular basis to me. So, it really does resonate with me"* (Psychotherapist). However, there were concerns about a more holistic approach to self-management being aspirational rather than entirely practical *"what's the point in measuring something if you can't even do something about it? [...] you can listen and um offer this kind of uh pastoral rapport but sometimes patient want solutions and I don't...that's what we actually don't have"* (Renal Nurse, KC 3). Similarly, another participant said *"if I were to right now go and say to our satellite program, 'we need to do this', [meaning implementing the scale], I can promise that almost everyone would say that they can't because they haven't got time"* (Renal Consultant, KC 3). A number of clinical staff questioned why there were fewer clinical items. Many participants repeatedly talked about self-management in reference to dialysis or self-care, in the context of their experience, despite recognising the more holistic approach being presented.

"I can sort of quite categorically say that you know we are focused on the clinical and the fiscal side of things, completely and trying to get all of us to sort of change our habits, a little bit to um allow patients to tell us a bit more about how they are coping emotionally, and um you know in their lives, and then using that as the, as an important part of us sharing the decisions with the patients...." (Nurse Consultant, KC 4).

Staff perceptions of patient (un)willingness; 'some just don't want to' [participate] might be a barrier to implementation, but also communication and engagement more broadly. Labelling or perceptions of certain traits doesn't allow for situationism, getting past the "fixed" to the underlying constraints or context. Some service users presented themselves as compliant "there's a few awkward patients in our clinic" which suggests that (some) patients create any barriers with staff that may exist.

"..there's a number of patients that don't want to engage, there's a number of patients that find it difficult to accept that they're on dialysis so they sort of, you know, they just want to come in, dialyse, go home and that's the end of it, they don't want to think about it again" (ward manager).

8.5 THEME 1: THE WIDER CONTEXT

The first theme explores the wider context of service delivery and suggests the implementation context is weak. The capacity for patients and staff to engage in discussions about the psychosocial elements of self-management, gauge participation, or identify support needs, is low. Lack of resource, mainly time but also pathways and specialist staff, influences perceptions, intentions, and commitment to these activities. Whilst shifts towards assessing psychosocial support needs are being made, this is challenging in the clinical context.

8.5.1 Sub theme 1.1: Lack of time

The single biggest operational issue is time, and this was identified by service users and healthcare staff as a central factor which underpins many issues and was a common theme throughout the groups. There is no quick fix for solving problems, and without the time to dedicate this presents a persistent barrier.

"Having just done a dialysis clinic this morning, I think the biggest problem is going to be trying to separate out what the sort of operational issues are that stop you from doing this and the biggest problem is time" (Renal Consultant, KC 2).

"I feel, when I was there the nurses did their very best and I couldn't fault them with how they looked after us but to me they were running around like headless chickens that, you know, they had so much to do, you know, in a given time...." (In-centre HD patient, RC 2).

8.5.2 Sub theme 1.2: Current intention to provide psychosocial support.

The idea of a holistic approach to self-management is supported and was part of the narrative across all thirteen focus groups and interviews.

There is evidence that some staff informally assess patient wellbeing using cues or by engaging in conversation. Ten of the thirteen focus groups/interviews mentioned tools or measures for assessing patient needs. Specifically, five groups referred to use of the distress thermometer to assess recent experience of psychological distress (scale 1 to 10) and the sources of the stress (practical, family and emotional problems). Its simplicity makes it easy to use in diverse populations where the first language may not be English, and a number of groups referred to this. However, there was suggestions that these assessments tend to be deprioritised as other pressures dominate.

"Um we do try and have a formal process of having these conversations we have an assessment tool that we use ideally every three months that has gone on the back burner due to COVID" (Renal Nurse, KC 2).

8.5.3 Sub theme 1.3: Resource and capacity, including workforce gaps.

Within the narrative, time is intrinsically linked to resource and capacity. Staff are often worried about the lack of resources which can act as a barrier to engaging in these conversations when there is no clear next step.

"I have a section within, within my letter for psychosocial but do I touch on many of these things every three months, um if I'm worried about their vascular access for example I probably don't, so um. You know I think there's a very definite place, a place for this, I think I think the next step, though, is ensuring you have a solution to them". (Renal Consultant, KC 4).

There were mixed views about the skills or ability of staff to engage with patients to assess their psychosocial support needs. Some saw it as part of a specialist role and others felt the nursing team capable. Again, some of the concern seemed to be related to the lack of resources or pathways to refer to, long waiting times and workforce issues more broadly. Shortfalls were reported not just in specialist services, but also among front line clinical staff. The perception is that this stressful work environment links back to the lack of time, not lack of effort. Anything beyond 'usual care' is even harder to accommodate. As one consultant explains time and resources is at the "crux of it" and the lack of resource was raised in direct relation to the self-management scale itself: as a barrier to implementation.

8.5.4 Sub theme 1.4: Opportunities to improve adherence

In many of the focus groups, direct links were made between a better understanding of the patient's context (using the scale) and an opportunity to improve engagement and even adherence. For those not engaging, use of the scale may help to answer the question: why is that? This insight into what staff may consider "non-adherence" could provide a catalyst for change. Reducing non-attendance and evidence for improving flexibility around treatment for working or patients with caring responsibilities were two important elements of this theme.

"*of course, there are things affecting them, but we don't hear about them, but we just sort of reach a sort of blockade and it's only on digging that we find out that it's those personal things that are stopping someone from attending or whatever*" (Nurse Consultant, RC 4).

8.5.5 Sub theme 1.5: Impact of Covid-19 and fragmentation of support

As referenced in 1.2, some existing measures of broader patient wellbeing were being used less frequently or not at all during the pandemic. Staff training in this area seemed also to be deprioritised and there was some suggestion that forms of peer support and patient education days stopped during the pandemic or became rather more informal and pre-dialysis education became more difficult.

Some things improved for in-centre patients, honest communication was encouraged, regular treatment visits counteracted social isolation, sharing of information, reassurance, and access to the COVID vaccine. One group also reported supporting more self-care in terms of weight, blood pressure and salt and fluid restriction and diet *"...we are actually talking to them about looking after themselves outside of the clinical area"* (Renal Nurse, KC 3).

Post-pandemic, there was suggestion that now is the right time for more patient engagement, and that wellbeing is viewed with increased importance and good quality care. Beyond just the delivery of life-saving treatment.

"…actually, the time is right for this sort of work we've done, because actually there's a huge push you know towards more patient engagement, more people doing home dialysis you know, trying to kind of, kind of move away from the pandemic period where we were all…. That it was just we, just getting the dialysis done, we were short of staff, it was actually just survival basically [laughs]. And actually moving towards actually trying to deliver better care for people now, getting back to good quality care, rather than just survival dialysis care for people, which is what it was during the pandemic" (Renal Consultant, KC 1).

This suggests there may be a step forward in terms of the collective mindset around psychosocial support even if this is not matched in terms of resources and capacity.

8.5.6 Sub theme 1.6: Rigidity of the system

The focus on medical outcomes is what drives the whole system. There is tension between getting the job done and taking a more holistic approach to patient need. The system doesn't support an approach which optimises person-centred care.

"...systems are set up at organisation levels at NHS level so actually they look at medical outcomes rather than the person-centred ones…" (Renal Consultant, KC 3).

From the perspective of the service user, the system is hard to access. Specific examples relating to transport, involvement in peer support and accessing blood tests and other clinical results were discussed, but this patient sums it up more broadly:

"*So the thing about the NHS is all the staff are lovely more or less, I mean there are exceptions, but nearly all the nurses and doctors are great, all the um, porters and whatnot are fabulous, the ambulance people are fabulous, the people who actually do the admin are fabulous, it's just the actual system is horrific"* (In-centre HD patient, KC 1).

8.6 THEME 2: SHARING COMMUNICATION

Utilising opportunities for shared communication may lead to better joint decision making, greater satisfaction with care and more engagement with all aspects of self-management. This is supported in the literature and was a view expressed by participants. Shared communication refers to a dialogue in which patients are heard and understood and information is repeated, checked and decisions revisited.

8.6.1 Sub theme 2.1: Does this make sense?

Service-users will receive information throughout their journey. Key times identified by participants include introduction to the CKD service, close to starting dialysis and then post-dialysis initiation. At these times, patients will speak to a variety of people and under differing circumstances. The importance of revisiting information opportunities and education, in terms of checking understanding, decisions and choices and how they align with clinical and patient goals is at the centre of this theme. Information sharing should be done at regular and repeated intervals; this idea was mentioned directly by 10 participants and was highlighted as particularly important for patients who have experienced a precipitous start on dialysis and others who may have poorer communication skills or less confidence to ask.

One nurse (KC 2) talked about the education in terms of "*filling in gaps rather than a comprehensive process*" and this mirrors what is said here:

"I think there's a gap, missing there for those that present acutely where we actually never go back and fully discuss with them, consent them or explain to them what what's happened because everything you know, quite rightly, has to be done quickly to get them well and safe and stable, um but I think there's a failure, then sometimes to actually revisit some of those things and address those questions because they're already plugged into the system" (Renal Consultant, KC 2).

Clearly communicating information that will support self-management in clear terms, using simplified language is important "....b*ecause if we're asking them to actually look after themselves and be part of their own health care, they have to have that understanding or otherwise there's going to be a huge link missing".* This reiterates the importance of information sharing as part of supportive and ongoing care.

8.6.2 Sub theme 2.2: Trust and rapport

Within this theme, were three main aspects; how you build trust, with whom rapport can be strongest and why it's important in terms of enabling honesty and more effective communication.

There is opportunity during the contact time when patients are put on dialysis (in-centre and in satellite units), or supported with self-care, to build rapport. However, whether the opportunity is utilised may be linked to time and type of dialysis-site.

"I think you know some satellite units are more of a sausage factory than others, you know your patient turns up at one end, gets put on the dialysis machine and disappears at the other end and not a great deal of human interaction happens in between those two points" (Renal Consultant, KC 3).

Despite this, a common thread was the importance of nurses in building relationships, rapport and patient confidence and as a source of informal psychosocial support. When speaking directly about using the self-management scale in clinical practice, this participant recognised the importance of existing relationships in implementation.

“*I would see it as coming from the nurses, I think they're, the ones who would have most time with the patients, see them most often (...) and I think have that relationship. I think it's something you need to have, a relationship with a patient, to actually have that conversation*” (Renal Nurse, KC 2).

One nurse participant recognised the role of specialists in this area but concluded that the familiarity and rapport nurses have with patients may enable them to get to the bottom of any issues, *“pick up on things”* (in-centre HD patient, KC 2) and have more honest communication.

When talking about another patient reported measure, this participant said:

“I have had patients who filled it in, that I’ve read through and thought oh actually what I’m seeing from you isn't what you've actually written down. And you know I don't feel that you’re giving me the right information, you don't have to share it but, I’ve got more concerns about you then you're writing down” (Renal Nurse, KC 2).

An established rapport may enable deeper questioning, a useful asset in the conversation that follows completion of the scale. Wording and language are important facets of building trust and allowing honesty.

“*I think for somebody to see it [referring to the scale] in their own language, again, you've already made a different style of engagement. You’ve made, you've given trust to that patient, but you're honouring the fact that in them sharing information you've made it as easy as you can*” (Psychotherapist).

The importance of translating any scale or tool to be implemented in clinical practice was made in 8 of the groups, that in translating, it’s possible to increase inclusivity in terms of access and uptake.

8.6.3 Sub theme 2.3: How are you now?

Asking ‘how are you <u>now</u>?’ is an important part of continuity of care and is important when patients’ capacity and circumstances may change daily. This can be informal and frequent and is described as part of the nursing role. A bit of a chat can help you feel “heard and happier for that” and patients may find it supportive in the care context. However, the service context may not always allow it.

“I think communication is absolutely vital, I think um one thing we miss as nurses, particularly on a busy unit is making time and actually picking up on the clues with patients that you know, would come in. We ask the patient how they are and in some ways, we hope they say fine and then we can just quickly whizz on” (Renal Nurse, KC 2).

This quote makes an important reference to the lack of time, and the dilemma nurses face knowing that sitting down and speaking with the patient is important, but the time and capacity available to them on busy unit makes this less feasible. If rushed, asking ‘how are you?’ without intent to listen can be a clear signal that there is no time for an honest or lengthy response.

8.6.4 Sub theme 2.4: Shared decision making

A summary of this sub-theme can be characterised as assumptions, misconceptions, judgement, and restricted choices. Patients may be involved in decision making, but situations change with time and experience. If decisions are not reviewed patients may feel stuck with decisions, they may have made some time ago *“that’s what they decided, it doesn’t get revisited”* (renal consultant, KC 2), and important opportunities for reflection or change may be missed.

There may be conflict where the personal values of patients, their goals or circumstances don’t align with clinical values or staff’s beliefs about what is best.

“The man said to me ‘I feel because I was in my forties, I’ve always been told you’re having dialysis, because if you say you don’t want it, therefore you must be suicidal. And he said that just made me think, jeez I better… I don’t want to be, I don’t want to be put in the psychiatric system, so I just kept my mouth shut’, yeah, and I think well, it’s not surprising you don’t turn up for dialysis then” (Psychotherapist).

This is an interesting illustration of where the misconceptions and values of the clinician impact communication, trust, and rapport, and are not aligned with what the patient believes he wants. This also suggests a link between the psychosocial elements of shared decision-making with clinically important things such as adherence.

8.7 THEME 3: SELF-MANAGEMENT AS MEDICAL, MORAL, AND MARGINAL

Due to the necessity of intensive treatment, kidney care remains broadly stuck focussed on the medical paradigm but attempting to make a shift to psychosocial awareness, support and care as an essential part of service delivery. Within a system under pressure, self-management is viewed in the narrowest sense and responsibility for broader engagement is deferred to willing nurses and patients.

8.7.1 Sub theme 3.1: Self-management defined through a medical lens or according to medical priority

It is easier to see, understand and deal with issues related to clinical care and this can often be a barrier to better communication and a more holistic, multidisciplinary, collegiate approach to care, which remains on the margins described in these three quotes:

"Um, and there is a kind of you know, the really fast pace across all of our dialysis units and...what we're trying to do, uh we're trying to incorporate this routine holistic assessment of our patients, which hasn't been happening for [pause] ever and you know we we've been trying to kind of introduce that by looking at different ways of assessing patients' needs" (Renal Nurse, KC 4).

"the patients relay it to us, and they relay it to other members of staff, but it's almost, I mean we can listen, and sometimes we can intervene. But it's almost like as if there's nowhere for it to go" (Psychotherapist)

"I think we're still in this, still struggling to transition from, you know, disease centred care to person-centred care" (Renal Consultant, KC 3)

There was a distinction between participants that tended to talk about self-management in binary terms, patients either engage or don't; perceived as a choice, and those that saw the process as more determined by context, preference or as a gradual or partial process. Patient participants were more likely to express the view that self-management is a responsibility, both in terms of staff to support and patients to show willing and engage. Patient willingness was sometimes talked about in terms that may be viewed as moralising.

"you do get patients that just can't be bothered to do anything, it's just go in, get treatment and go home, you're always going to get those. Unfortunately, despite the best efforts to get them to be part of you know something that's going on and they don't really realise, or don't want to" (In-centre HD patient, KC 2).

"but you know the patient needs to be willing to participate, for us to be able to engage with them and try and help them out" (Renal Nurse, KC 3). This second quote suggests that if patients are perceived as less willing to engage, staff may be less inclined to 'help them out', blame is shifted to patients.

However, the lack of time; the most frequent sub-theme within the wider context, was one of the main reasons cited for the focus on dialysis-related tasks within the dialysis setting. This narrative suggests that whilst the feedback on the acceptability and appropriateness of the items in the scale is positive, the feasibility of introducing the scale in a busy environment is less straight forward.

"I just think it's workable, as long as it doesn't consume too much time of staff. That's always been the struggle for us every time we introduce something new, the staff will always feedback we don't have time for that because it's always a rush in the dialysis unit" (Renal Nurse, KC 1).

8.7.2 Sub theme 3.2: Beyond the doctors and the nurses

Staff most visible and available to patients are the nurses and doctors. As one consultant put it, "*everyone else just flies in and out*" (KC 3). The use of MDT meetings to discuss support needs exists in some centres but it's unclear how common it is for the patients themselves to attend such meetings.

Holistic care appears to be viewed primarily as a specialism rather than a standard approach, with psychosocial elements of care and support being more suited to particular teams or roles. It was interesting how dialysis nurses were described with respect to this:

"But that's (...) the nature of AKCC work, you know, communication and (...) patient psychosocial support is a big part of the role, whereas haemodialysis nurses are, tend to be by and large I don't want to offend anyone, um you know more task orientated and not nearly as comfortable or skilled in having you know conversations with patients about things that are distressing them or things that they're finding difficult" (Nurse Consultant, KC 4).

This is contrary to other views that suggest the name nurse knows the patient best.

"I think, the (...) nice thing about dialysis is you know, you see these people for several hours three times a week so certainly for the nursing staff, they, they really get to know their families um really well and I think that that understanding of their personal life definitely exists and (...) whilst they might not be able to do anything you know the nurses have a real understanding of all the various factors that are going on" (Renal Consultant, KC 2).

This suggests there is a place for implementing the scale, in a more routine way which is actionable, and that some groundwork may already be there in terms of rapport with nurses and a pre-existing understanding of some patients' lives more broadly.

In terms of the wider multidisciplinary team, aside from gaps in the workforce, the way people work together was also discussed.

“there's a disconnect between all the different services which um I hope is improving, but I think is still you know very, very tricky” (Renal Consultant, KC 4)

Patients may feel stuck with no solutions, no change, no action. This idea is supported by the sentiment expressed in this quote *“I think that's what a lot of people find frustrating, because sometimes they can feel as if they're being pinged from pillar to post”* (Psychotherapist).

Here, a social worker explains the nature of the issue is not always clear, is it a medical problem, is it a mental health issue? A sense of underlying frustration for the patient can be heard in this quote from the psychotherapist to whom the patient was speaking *“but I’ve told everyone else, and nothing has changed”.* The issue appears to be, that both the problems and the team are viewed through a dichotomous lens which might indicate the broader team is not working as a coalition but rather more disjointedly.

“I mean it’s difficult to get any MDT type clinic um set up in any scenario and, (...) in an ideal scenario, this would be very flexible around the patient and that’s ***probably*** *just not how clinics work” (Renal Consultant, KC 2).*

Use of the word “probably” indicates she thinks perhaps it shouldn’t work like that, but it can’t be changed. Across all the transcripts, change is often described in ways that make it sound very difficult, if not impossible. The system doesn’t support an approach which optimises person-centred care.

Patients within this category were described as those that may show poor engagement with self-management on a measure such as the one developed, those with high life workload, and those less able to express support needs. Some patients may fall into more than one, or all, of these categories and find particular benefit in being asked “how are you now?”.

8.8 THEME 4: DEMANDS OF DISEASE AND TREATMENT AND PSYCHOSOCIAL CAPACITY.

The impact of treatment and life workload varies between patients, as does capacity, and currently this may be difficult to identify and address. Whilst engagement in self-management was broadly viewed as empowering and linked to greater feelings of control and confidence for patients, engagement in terms of dialysis is determined, to a greater or lesser extent by clinical staff and organisational constraints.

8.8.1 Sub theme 4.1: Underserved groups.

Patients within this category were described as those that may show poor engagement with self-management on a measure such as the one developed, those with high life workload, and those less able to express support needs. Some patients may fall into more than one, or all, of these categories and find particular benefit in being asked "how are you now?".

Even when staff are aware of patients with high "workload" which may impact their capacity to engage, it may not be possible to make changes in treatment provision to accommodate. This is further exacerbated by a lack of flexibility in the system and may affect treatment adherence.

"we have some patients who are very young and waiting for transplant, you know and trying to juggle um you know, trying to accommodate them working a full time job and dialysis and explaining to them, the importance of you know, good compliance with dialysis but also, fully understanding that you know, that they've got a job, and they need to earn money and...the stresses on...the slots as well to be accommodating for that just don't exist so..... I think these are...all issues that so many of our patients face and um and you can totally understand how it affects every form of management definitely" (Renal Consultant, KC 2).

In more than one group, home HD was presented as the gold standard of self-management and the ultimate treatment goal *"the ultimate dialysis aim for me is, you know, number one transplant but number two a home therapy so actually, is this person suitable for a home therapy and how quickly could we get them onto home therapies..."* (Renal Consultant, KC 2). However, both patient and staff participants illustrated that self-management is more than dialysis and assumptions about support needs of those deemed to be competent in self-management, may be misconceived.

"you could have a patient that you know, scores, really, really well in terms of clinical care ongoing communication, but actually you find that they feel really distress because their whole house is taken up with equipment and they're really struggling because it infiltrates every aspect of their life" (Renal Consultant, KC 2).

"I just feel home patients are just being left to their own device and they're not interested um to hear from us" (Home-HD patient, RC 4).

Possible reasons for not being heard, sometimes referred to implicitly, included misperceptions by staff, fear of being perceived as a difficult patient, fear that challenge may compromise the relationship or future care, poor communication skills, low trust or confidence, lack of time (staff have little time to be anything other than reactive and so interact with the most visible patients) and language barriers.

8.8.2 Sub theme 4.2: Still processing

Patients need time to process the experience of dialysis and what the impact will be on their lives. Adjustment and acceptance are important elements of the process and are connected to the patient's ability to process information and engage. Many participants talked about the importance of revisiting aspects of the education and decision-making process when the patient is ready. Internalising information can be particularly difficult for patients that arrive at hospital with acute illness (as discussed in theme 2).

"...you think that you've been really clear but we're not always ready to receive the information" (Pre-dialysis, KC 3).

*"what we really fail at is as clinicians and doctors, that I think is then going back to the patient when things have improved, you know, yes, there is their acute illness, yes, they're still on dialysis their feeling better at that point, we should be then saying this is what dialysis is, involves, please still come to our open day" (*Renal Consultant, KC 2).

In terms of engagement with self-management, this period of processing might be best viewed as 'struggling at the moment' rather than 'don't want to' or 'never going to'. This connects with the underserved who may include service users who find it hard to communicate or talk about more difficult issues they may be having beyond treatment.

8.8.3 Sub theme 4.3: Treatment burden

A high symptom burden and a poor treatment experience will affect mental health and attitude, and possibly even adherence to treatment. What clinical staff view in terms of the capability of the patient may not consider the broader context in terms of workload and capacity.

"You know, what you might be capable of doing or...we think you might be capable of doing, you might not want to do, so it's all to do with your mental health isn't it and, and where you're at and what constraints and stresses and strains you've got, erm elsewhere" (Renal Nurse, KC 3).

One nurse participant talked about the tendency to view time spent managing treatment as just the 3 or 4 sessions of dialysis per week. The impact of treatment is likely to take out a lot more time, the day spent on dialysis and the day after recovering. The worst case is they have only one clear day to get on with the business of life before the cycle starts again.

This is important in terms a patient's capacity to engage in self-management and whether and how they seek support in managing the burden on treatment.

8.8.4 Sub theme 4.4: Service context

Many participants felt that the service context does not easily permit a supportive environment due to time pressures and lack of flexibility. Periods of waiting are common, combined with a sense of regiment and rush during treatment.

"The whole thing is really about creating a culture actually and the supportive environment for people to do shared care it's just…and so much of it is about the kind of the way the dialysis units are run, the way the services are run, you know, the way that, you know, part of it is about the time you have with patients as well, and actually the treatments are rushed, you know, you don't have time, then it just doesn't, you're not, creating an environment to allow these sort of things to thrive actually" (Renal Consultant, KC 1).

The impact is explained here; the focus is on the process of dialysis rather than delivering a more holistic service. This fits with theme 3.1 in that care provision is viewed from a very medicalised position in which choice and control feels limited. Rigidity and constraint may reduce perceptions of choice and control.

8.9 DISCUSSION

This study marks the first step in exploring the implementation context relating to a novel measure of self-management for people receiving HD, with a view to bridging the gap between research and practice.

Whilst the importance of patient engagement in self-management and psychosocial factors in living with kidney disease, have become more established in recent years (chapters 2 and 3), supporting patients in this way is a less integral part of care. Measures such as the distress thermometer are used but don't include a mechanism for prioritisation or gauging severity of symptoms and are not implemented regularly. The findings from the focus groups indicate that participants see a gap in terms of assessing and supporting self-management and there is some consensus in the relevance of this novel scale and its utility.

The scale offers the potential to identify and prioritise areas of support need and better understand level of engagement within the patient's wider context. However, some clinical staff seemed unsure about how the scale would be implemented and whether it would be used (despite feeling it might be useful). The link between identifying gaps in support and then better supporting patient engagement SM in the areas that most align with patients' goals or improve outcomes remains unclear. As this participant puts it, further evidence of impact will underscore the need for implementation.

"I think times are changing, and this sort of research is really valued and I think.... just building evidence to support um this this sort of work in terms of you know, patient outcomes, but also if you presented this to a business manager, you know the....economic impact of understanding these patients concerned, engaging them in care, reducing DNA's, making their dialysis better, getting them transplanted is so valuable" (Renal Consultant, KC 2).

8.9.1 Strengths and limitations

- Recruitment and participation levels were high, at least in part due to the online approach to data collection which allowed the study to continue during the pandemic. There were minimal technical problems, and any issues were managed effectively. Those unable or not wishing to use Zoom took part in a telephone interview.
- Composition of the focus groups was mixed, including both clinical and allied heath staff, and experts by experience to avoid confirmation bias. It is commonplace for doctors to talk to each other, however the spaces for shared dialogue between doctors and patients are more of a rarity. Patients talking together does not provide the opportunity for other "experts" to be challenged or given the opportunity to listen. Through careful facilitation and use of vignettes, this more novel approach sought to maximise the breadth and diversity of opinions within the group. Group sizes were small, often two participants. This ensured high levels of engagement but changed the dynamic somewhat. Service-user participation was slightly lower than 50%.
- Use of inductive and deductive reflexive thematic analysis allowed a more comprehensive exploration of the implementation context, particularly barriers.

- Staff participants with an existing interest in the broader concept of SM were identified for inclusion in the study. Direct experience of current practices relating to SM support were deemed important in terms of relevant insights to this work. However, this bias, and the views of the lead researcher were recognised via a process of reflexivity.

8.9.2 Barriers and facilitators

Implementing a change into healthcare provision is a complex process, there are many preceding steps. The research evidence must be strong before implementation can be justified. Further evidence is needed that the scale is psychometrically sound and could be useful in the clinical setting to identify support needs and change in self-management engagement over time. However, this qualitative work provides a starting pointing for understanding the implementation context at the individual level, kidney team/culture level, organisational level (NHS) and beyond. Understanding the implementation context is important because it can inform better study design and begin the process of stakeholder engagement which is key for sustained and embedded change.

Consensus in the view that the scale may fill a current gap in assessing support needs or issues and that it signals a shared ethos and commitment to psychosocial support (enhanced through training) could facilitate use of the PRIESM CKD-HD. By utilising existing skills and knowledge of patients (nurses) in delivery and value to patients (feeling heard), could also be important. Not least, the use of the PRIESM CKD-HD may support desired improvement in integration and collaboration within MDT's and provide a starting point for improving rapport and communication between patients and clinical teams.

Some of the key barriers to implementation identified by the participants included time and resources including workforce issues, a tendency to de-prioritise tasks not viewed as directly related to clinical care, perceptions of patients as unwilling to engage and perceptions of staff that it's not part of their role, lack of clarity around referral and patient pathways, and lack of team cohesion. This quote sums up the link between time, prioritisation, and perceived responsibilities "I mean time is definitely a barrier, you know, quite a lot of staff see it as a barrier um some staff, I think it's how they perceive their role. And perhaps that they don't see that either it's permissible to go and have those conversations or that actually we're expecting it to be part of the role to go and have those conversations" (Renal Nurse, KC 2). This suggests a shift is needed from a focus on the dialysis procedure to a more holistic approach.

8.9.3 Opportunities

Various opportunities that may arise from the introduction of a systematic approach to assessing engagement in self-management and identifying support needs were evident in the data. Not least, the scale offers legitimacy to talking beyond conversations about treatment. Others include the possibility of improving open and honest communication, better supporting and reprioritising psychosocial practices, legitimising the use of time for this purpose, working more collegiately as a 'renal team' beyond the doctors and nurses, and providing baseline data from which to assess the impact of any future SM interventions.

8.9.4 Next steps

Further work will be needed to really assess the local capacity to implement, perhaps using concept mapping with stakeholders to identify sound strategies for implementation (Powell et al, 2015). Contextual and organisational differences across centres and services will mean variation in implementation across centres is inevitable, "one way" is unlikely to work (Grol & Wensing, 2013).

This exploratory study is an important first step in establishing community stakeholder engagement (Moullin et al., 2020). Maintaining these partnerships and building others will be essential in galvanising support and creating consensus around an approach/design for a future pilot or feasibility study, the preceding step before routine use can even be considered. Future directions are discussed further in chapter 9.

8.10 IN CONCLUSION

Whilst PRIESM CKD-HD is many steps from routine use in clinical practice, this work begins to tread the path to the goal, widespread adoption. it is both statistically robust and has been viewed favourably, although not without criticism, by key stakeholders. Patients particularly, see the value. Any systematic change within the NHS is difficult, "healthcare is a complex and adaptive system" (Braithwaite, 2018) and the degree of engagement depends on the demands of making sustained change. Individual level factors such as patient and staff perceptions, beliefs and behaviours operate and are influenced by the context of the clinic culture and wider organisational priorities. The level of commitment to prioritising patient goals and supporting self-management, alongside workload and staffing levels will affect the implementation of PRIESM CKD-HD in any future feasibility or pilot study.

To make both the psychosocial shift to more holistic care and for a change in care practice to occur, a convincing case, intention, sincerity, and a collegiate team are some of the things needed. In the final chapter, I will review the work so far and outline important next steps.

CHAPTER 9 : GENERAL DISCUSSION

9.1 AN OVERVIEW OF FINDINGS

This thesis synthesises current research and adds further empirical data to offer a new way of viewing self-management in CKD-HD patients. The work presented in the preceding chapters supports the proposition that a person-centred approach to defining self-management is appropriate, that it is possible to develop such a measurement and that the PRIESM CKD-HD, the development of which is outlined in chapters 5 to 7, has the potential to be used in clinical care and research to identify gaps in support. There is some evidence that key stakeholders working within or receiving care from renal centres in England, see the tool as useful in terms of better engaging with patients beyond direct clinical care, to better understand support needs (chapter 8).

Chapters 2 and 3 pointed to the need for a new conceptualisation of self-management, rooted in the person-context and experience of those receiving haemodialysis treatment in the UK. Consequently, a sequential, 3-phase mixed methods design was developed. Key stakeholder engagement, including those with lived experience, was included as part of every phase. This is consistent with guidance and best practice for psychometric scale development, with an emphasis on content validity. Therefore, the measure developed here is both relevant to the target population and describes and measures self-management using inclusive and patient-focussed terms.

This thesis documents the increasing interest in and relevance of self-management as a concept. By embracing the complexity of the term, the PRIESM CKD-HD seeks to provide an alternative measurement for operationalisation of self-management, relevant to HD-recipients receiving care in the UK.

The work in these chapters has sought to cover and give detail to the entire process of scale development and the various processes involved. It has been recognised by Jebb et al (2021, p1) that the process from "defining the concept to testing nomological relationships" – is such a substantial undertaking that to cover each of the stages absolutely is challenging. Despite this, the work presented here has tried to ensure sufficient detail of the key processes of item development, scale development and scale evaluation to demonstrate sufficient rigour and provide the reader with confidence in the conclusions.

This is the first study to develop a HD-self-management measurement underpinned by the tripartite model of health, rooted in the narrative of the patient experience, that reprioritises psychosocial aspects of managing within the measure. It has substantial implications for contextualising self-management beyond the clinical context, to identify gaps in support. There is no other English-language tool which allows a composite or sub-scale scores to be derived across psychosocial domains relating to self-management which pinpoints the specific issue and level of engagement, with the purpose of identifying gaps in support. Both the qualitative patient interviews (item development) and the large-scale quantitative survey (scale development) demonstrated successful recruitment of large, heterogenous, and representative samples, comparable with UK renal registry data and broadly representative of the dialysis population. Across both studies and in all qualitative activities, target recruitment was met or exceeded, the data show a wide age range of participants, variation in time on dialysis and levels of co-morbidity. Of the 27 participants sampled for the qualitative interviews, less than half (44%) described themselves as White British. Similarly, for the large-scale survey, 32% of participants were from minority ethnic groups. The implication is that the results are broadly generalisable to HD-CKD patients receiving treatment in the UK.

9.2 SPECIFIC FINDINGS

9.2.1 The lived experience

The qualitative interviews reiterated themes found in other kidney research reporting the lived experience (Finnegan-John & Thomas, 2013; McKie et al., 2023; Reid et al., 2016; Young et al., 2022), although the number of papers with direct relevance to a UK haemodialysis population or covering a range of psychosocial themes, was limited. Key themes included support from and communication with healthcare providers, experience of symptoms (physical and emotional), treatment decisions and choices, living a meaningful life, and empowerment and control. Most of the broad themes had consensus from the expert panel, and the items retained in the 60-item scale included at least one item from most domains. The narrative of managing in different contexts took the concept beyond the dialysis chair and highlighted the importance of the social, psychological, and emotional investment in strategies and behaviours. Whilst the topic guide used for the interviews focussed on the experience of living, with little overt reference to the dialysis process itself, it was sufficiently "open" to allow discussion around shared-care opportunities or involvement in dialysis. It is interesting that participants did not address this more of their own accord, although as a non-medic conducting the interviews, this may have had an impact. It was clear that the perception that not all people want to "self-manage" is refuted by evidence and the introduction of a broad concept of self-management that illustrates diversity in the approaches taken to managing is needed. Any new conceptualisation must include behaviours or related attitudes not always recognised or valued e.g., social interaction, acceptance or taking time to rest.

9.2.2 The scale

The model of best fit was found to be a three-factor, 26-item model with items grouped to sub scales, daily managing and impact, communication, and clinical care. Aside from having strong psychometric properties, PRIESM CKD-HD correlates with two other similar constructs, depression, and self-efficacy and shows variation by patient characteristics such as age, income and having one or more other long-term conditions. This adds further evidence as to the reliability and validity of the scale. These findings support other research that show that these concepts are related (see chapter 7).

As measured by the scale, managing and communication account for more of the variance than clinical care, indicating that these themes are more important to patients. Clinical care happens in a well-defined space and time, whereas the work of living and managing on a day-to-day basis may be of broader importance to patients. Several items relating to clinical care were included in the 60-item scale, including questions about medication, fluid control, needle placement and an interest in learning more about dialysis. The more clinically focussed domain was adequately represented in the draft, but statistical analysis showed it was a weaker statistical fit than the communication and managing domains. Despite this, the number of these items retained was maximised so that the scale included a clinical aspect, the content of which can be further explored in future studies. Twenty-one of the 26-items are included within the factors about managing and communication, which means the overall score will be biased in favour of the more psychosocial aspects of self-management. Therefore, factor level scores are useful in understanding gaps in support at a more granular level, that enables prioritisation.

Preliminary evidence suggests the scale is stable overtime and therefore useful in providing baseline data that can be compared with data collected at other key points of transition on the patient pathway. Home HD and PD programmes are focussed to some degree on self-management and the ShareHD programme has been developed to optimise shared dialysis care and build patient confidence, feelings of control and independence to dialyse in-centre or at home (Wilkie & Barnes, 2019). However, very little standardised support for self-management in the UK exists beyond that. Developing an intervention was not within the remit of this study, however PRIESM CKD-HD provides the potential for consistent, appropriate and effective evaluation of any self-management intervention and detect change over time. It is possible that routine use of the scale may also cause a shift in patient engagement through normalising discussions and supporting better communication.

9.2.3 Exploring the utility of the scale in research and practice

Using qualitative methods to explore acceptability and potential approaches to implementation, some key barriers and facilitators emerged. Barriers included time and resources and how this relates to workforce issues, a tendency to de-prioritise tasks not viewed as directly related to clinical care, perceptions of patients as unwilling to engage and perceptions of staff that it's not part of their role, lack of clarity around referral and patient pathways, and lack of team cohesion.

Key facilitators identified, include perceptions that the scale can fill a current gap in assessing support needs and a growing consensus in the need to understand psychosocial support needs, both indicate the time is right for PRIESM CKD-HD. The scale is an opportunity to galvanise towards a more holistic assessment of need and use the measure to present the case for resource, better referral pathways and more collegiate working between teams, as well as acknowledgement of the support needs of patients. More collaborative partnership working is likely to benefit staff and patients, and use of the scale may provide an opportunity for this as well as upskilling staff.

Implementation science models suggest that involving key stakeholders as early as possible and thoroughly exploring the implementation context is an essential first step in pre-implementation of a pilot or feasibility study. Knowledge of organisational capacity and structure, as well as attitudes and opinions of stakeholders across four kidney centres has been explored.

9.3 METHODOLOGY – STRENGTHS AND LIMITATIONS

9.3.1 Measurement error

The use of qualitative patient data to understand the concept and cognitive pre-testing of the scale, both reduce the potential for measurement error in the final scale. The careful use of multiple approaches optimises data capture from more than one source to define the overarching themes and item development helps ensure good content validity. By adopting specific words used by the target population in item generation (Coleman et al., 2011; p. 1069 as cited in Morgado et al., 2017), the scale can be made more accessible and easily understood by respondents. By incorporating all these elements, common limitations of other scales have been avoided.

9.3.2 Scale generalisability and applicability

Satellite-based patients were over-represented in the qualitative study that preceded scale development (78%) and similarly, there was lower representation of in-hospital and HHD patients in the main survey. Whilst this could result in a scale less relevant for more sick and elderly patients and those having dialysis at home, correlation with depression and self-efficacy indicates the PRIESM CKD-HD has not incurred this problem. Both samples were broadly representative of the HD-population and the scale is felt to be generalisable to all HD-participants. It is possible that relevance extends to pre-dialysis patients and that the scale could be adapted for use at various other points on the kidney journey. This idea was supported in the pre-implementation work outlined in the previous chapter, for example the scale may also be useful at the introduction to the CKD service (diagnosis), when close to starting dialysis (modality choices) and then post-dialysis initiation. This requires further exploration.

There is no measure of self-management with good evidence of reliability and validity which aligns with the broad conceptual definition presented in chapter 3. Therefore, it was not possible to test the novel scale using another validated measure. Using the BHDS scale (Reston, 2015) was a possibility, although as described previously, the measurement is clinically focussed. The Patient Activation Measure (PAM) has also been used as a proxy for self-management as outlined in chapter 3. Whilst these measures may have supported further psychometric testing, this would have added to the respondent burden and risked not all data being collected.

9.3.3 Online data collection

The qualitive data collection that explored the implementation context occurred during the pandemic and was only made possible using online data collection in the form of focus groups. This offered greater convenience and opportunity for bringing together ‘time poor’ and geographically dispersed professionals and patients (Boland et al., 2022), a strength that was reflected in the sample size and extremely low drop-out rate. It is the view of the author that the high level of participation was due in part to the online format, and it did not appear to compromise engagement of the group with the facilitator and each other. Other research has noted the potential for digital exclusion or issues with digital literacy when conducting research online with older adults (Bolin et al., 2023) and it is possible that more digitally able people were approached for recruitment by the renal centres. However, three patients expressing a preference, were telephone interviewed.

9.3.4 Comparing development of PRIESM CKD-HD with other scales

The development of PRIESM CKD-HD was designed to fill a gap, which was identified through analysis of existing measures. As highlighted in chapter 3, most other kidney-specific measures lack relevance (not a HD sample) or generalisability (not validated in a UK population) and fail to meet the criteria that are a prerequisite for good scale development such as input from patients and other key stakeholders via qualitative and quantitative consensus methods. Vogt et al. (2004) point out that involving the target population in scale development is a valuable approach in content validation but rarely done. This continues to be the case and is an area in which PRIESM CKD-HD has made significant advances.

9.4 GENERAL STRENGTHS AND LIMITATIONS

Self-management remains a complex concept, which impacts and is influenced by many overlapping factors. Given the breadth of the factors considered, it is possible that some similar or related concepts are missing or poorly represented. For example, the use of decision aids to support joint decision making and shared care, both related concepts. Not all relevant elements could be adequately described in this thesis, furthermore, untangling relationships between factors and mediating elements is beyond the current scope. However, existing research points to a relationship between depression and various types of adherences, mediated by social support. Alongside this, is the growing evidence of the importance of factors such as social support and patient-provider communication in relation to quality of life, perceptions of control and making shared treatment decisions. Whilst uncertainty still exists around links and mechanisms, it is increasingly hard to turn away from their relevance in the healthcare setting.

Many patients arrive at dialysis initiation abruptly, this was clear from the qualitative analysis conducted as part of study two. The example below is indicative of the psychological impact of illness and treatment.

"*You know 50% of our patients will come in as like crash landers or things go wrong and they've been in hospital for other areas, reasons, and then they find themselves on dialysis and... they may see you know 10 different doctors in that time, not necessarily renal doctors and trying to really explain to someone why they're now suddenly being on this machine that they might not get off of, is very different to the consultation and the communication, you have when you've got time you know*" (Renal Consultant, KC, 2).

A key strength of this work is that despite the complexity, the PREIM CKD-HD has been developed with the purpose of accepting the challenges and moving towards a more holistic way of understanding patient's needs including those that are social and emotional. The challenge has been to use a mix of general and more focussed items to identify specific issues. For example, stakeholders (chapter 8) identified that in the 26-item scale, items about caring responsibilities or family commitments were not included. In this example, "day to day I can manage most of the things I need to do" may be sufficient to capture specific issues. Other items omitted included "my illness and/or its treatment interferes with my relationships" but that might be captured by "my kidney disease interferes with my life" and would come to light as part of the subsequent conversation.

Linked to this, is the comprehensiveness of the scale and the extent to which individual experience can be captured by a population level description. The conceptualisation of self-management was considered in its broadest sense using evidence from the literature, data from the patient interviews and the expert panel. However, it may be that what is particularly important for some people in terms of general self-management is not sufficiently general to be included in item development or retained in the process of item reduction. Balancing the breadth of relevant items with the burden of completion on respondents was challenging but the broader evidence (the correlation with other associated concepts) suggests the PRIESM CKD-HD is valid and reliable. By using the scale to identify the problem areas, challenges and difficulties can be identified and used to direct conversation that are needed to help support people.

9.5 IMPACT AND IMPLICATIONS- MOVING FORWARDS

There are several ways this work can be further developed. These are listed below and described throughout the remaining chapter.

1. Further exploration of how the scale can be use in different contexts e.g., pre-dialysis, before and after treatment decisions and to evaluate self-management related interventions.
2. Explore effectiveness, what further evidence is needed?
3. Feasibility of implementing the scale at the local level with the purpose of refining implementation strategies for potential roll out.
4. Digitalisation of data collection with implications for the timely delivery of data, with clear interpretation and mechanisms for sharing.
5. Development of a toolkit with guidance and training.

6. Explore whether the scale can be used to enhance patient-provider communication as well as shared decision making.

Further studies that explore how engagement in self-management varies or changes at different points on the patient pathway would be useful. Just like education related to disease and dialysis, psychosocial "check-ins" should be ongoing. Whilst the focus of this thesis is on those on haemodialysis, engagement in self-management is important well before this. The scale may be relevant earlier in the disease trajectory, prior to dialysis but as referral to specialist hospital services becomes necessary. Adaption of the scale for use at different time points may be appropriate but would need to be explored.

The proportion of home haemodialysis patients was small, some items of the 60-item draft scale used in the large survey would have been better if nuanced for HHD patients, for example “I feel I have control over my dialysis treatment”, “I check the settings on the dialysis machine to make sure they are the same as usual” and “I take responsibility for parts of my treatment that might otherwise be done by the renal team”. It’s likely, therefore, that the scale is most relevant for in-centre and satellite clinics and may need further adaption and testing to explore its relevance to home HD patients. Although with some minor adaptions the author believes the scale should be appropriate for use with this population.

The use of the scale in research to assess the impact of self-management interventions or to provide quantification of the level of need for support across sub-sections of the haemodialysis population could be useful. However, the more difficult question in applied health is how can we better help the individual?

People with chronic kidney disease are managing profound and significant changes in life and this measure may enable us to understand more about the challenges broadly, outside the clinical setting. Managing social status and mental health alongside fluid and food management cannot be separated as they have cultural significance. In applied health science, implementing in practice is a necessary but challenging fundamental that can be supported by good research practice.

The concept of the thesis is that people are always self-managing and yet there remains a significant evidence gap around the extent to which this wider concept has relevance to clinical practice. The evidence base around the link between psychosocial factors and clinical issues and the relationships and processes that bring these things together need to be developed. Similarly, there are a number of situations where transitions in care happen, and as yet there is not much work focused on understanding how these transitions are related to relevant psychosocial issues in the person's experience. So, by widening the concept of self-management, this scale opens up the potential for research addressing some of these more fundamental questions about what it means to live with and (self) manage a long-term condition, and the consequences for clinical outcomes. This would allow the development of a more robust theoretical framework around these issues than currently exists.

Can this tool improve patient outcomes or be used to show an improvement in patient outcomes as the result of an intervention? This is yet to be answered. Few patient-reported outcome measures are used at the point of care (Nelson et al., 2015) and this in part, reflects the challenges of implementing change within the NHS setting. Establishing evidence of effectiveness and feasibility is essential for wider role out, we need to know the tool works and can be used in clinical practice. Whilst the specific tool may be valued and shown to be effective, the NHS presents a challenging context for implementation, and barriers may be general and related to use of PREMs/PROMs more generically as well as relating to specifics of the scale. Working with local champions in co-producing future studies, engaging other staff at the local level and further understanding the barriers and facilitators to implementation is key to improving the likelihood of impact. We know that the challenges are likely to be resource focussed, practical and ideological. Staff time, expertise, sense of self-efficacy around supporting psychosocial health and training needs are all barriers to implementation, but there may be specific differences at the local level. Tailoring implementation to the local context will be essential in any further study. As will, developing guidance and training to support staff to use the measure as intended and gaining consensus around the value of the scale. Fear that measures will add to workload rather than reduce it, can be offset with evidence of staff and patient benefit.

Digitalisation of the scale removes the need for manual data entry and score generation but questions around technological exclusion and the potential impact on universality are important. The PRIESM CKD-HD has been developed as a paper and pen scale, so digitalisation of the scale requires consideration.

Health literacy is a key consideration for patient reported measures intended for universal use within a target population, that will also reach those that may already be under-represented in terms of their support needs. Health literacy is defined as the extent to which individuals are able to access, understand, judge and communicate information to maintain good health (Begoray & Kwan, 2012). Almost one quarter of respondents (23.9%) in the large survey in this thesis reported no qualifications and lower education is a predictor of lower health literacy (Taylor et al., 2017). Of note is that lower educational attainment was associated with a lower mean score on the clinical sub-domain of the PREISM CKD-HD. Jebb et al (2021) remind us that readability of scales is key and that items in the scale should be short and simple to avoid unintended exclusion related to comprehension. Formula for assessing readability exist such as the Flesch Reading Ease and SMOG formulae, and although not without their limitations, are quick and easy to use (Boulos, 2005). Work by van der Heide et al. 2018) extends the concept beyond individual attributes to the interaction between these attributes and performance of healthcare systems and health professionals. This idea resonates with what has been found in the PRIESM CKD-HD work and suggests that health literacy can be better supported by skilled staff and a conducive system. This requires further exploration related to how the scale might enhance patient-provider communication.

Despite good apparent psychometric properties, it is still possible to create incoherent constructs (Borsboom, 2005). Whilst the model fit statistics for the PRIESM CKD-HD are on the border of an acceptable fit, less stringent thresholds were used in acknowledgement that the concept of self-management is both complex and contested within the wider research and clinical context and that cut-off values are there to guide rather than be rigidly enforced (Sellbom & Tellegen, 2019). The PRIESM CKD-HD scale scores correlate with other measures and vary according to patient characteristics, which is suggestive of a robust scale. The current structure of the scale is hypothesized using a single, albeit large, sample. Any further studies would provide the opportunity to conduct confirmatory factor analysis (CFA) to further explore whether the structure of the scale requires refinement (Zheng et al., 2010) perhaps in conjunction with other tools such as PAM which has been used more recently to measure the impact of SM interventions in kidney (Magadi et al., 2022) as well as other LTC populations (Hemming & Munir, 2022). Like PRIESM CKD-HD, PAM appears to be negatively associated with depression (Cukor et al., 2021) and self-efficacy, as well as hope and health status (Golubinski et al., 2020).

Cronbach's alpha was .92 for the overall scale and ranged from .66 to .91 for the three factors. This high alpha value (> 0.90) may suggest redundancies and be indicative of the need for a reduction in the number of items (Tavakol & Dennick, 2011). However, the perceived content validity is high, and a wide range of domains are included in the measure, ensuring coverage of important content. More important to explore is the much lower alpha, and thus potentially weaker reliability of the clinical domain. Developing a short form scale and exploring the clinical domain will be considered as part of future work.

9.6 THE WORK WITHIN THE BROADER CONTEXT

The PRIESM CKD-HD has been developed at a time when interest in patient engagement is increasing and the importance of shared decision making, and provider-patient communication is established but the concept of self-management still lacks consensus (Van De Velde et al., 2019) . The impact of social factors on health continues to be underestimated (Haslam et al., 2018) and are not prioritised in healthcare (Coulter & Oldham, 2016) despite evidence that they are protective against mortality and can mediate behaviours linked to diet, fluid and medication adherence, as well as being relevant and important to patients.

In shifting away from a more clinical definition of self-management it is perhaps unsurprising that adherence showed poor correlation with the SM measurement. The relationship between the various measures of adherence and self-management is complex.

Adherence was measured using the ESRD-AQ scale, as well as clinical data on blood plasma phosphate and interdialytic weight gain (IDWG) as surrogates of adherence. There is some evidence of a link between self-management score and phosphate levels, but none with IDWG and the ESRD-AQ scale. IDWG is difficult to interpret and a poor measure of adherence if not corrected for body size (BMI) and residual kidney function.

Higher phosphate levels are associated with kidney disfunction and are generally only detected in late stages of CKD. Both low and high levels are associated with higher risk of mortality irrespective of age (Ye et al., 2021). Research suggests that as you get older, control of phosphate improves and levels are generally lower (ibid), perhaps relating to reduced appetite and possible malnutrition. This theoretical link was borne out in the data presented in this thesis, which aside from age, also found an association between better phosphate control and higher self-management score.

For people on haemodialysis self-managing may be less about taking their tablets and more about the psychosocial elements identified in PRIESM CKD-HD. This is reflected in the poorer fit with a more clinical proxy for self-management such as adherence, but better correlation with depression and self-efficacy. It is logical that in identifying issues important in individuals' lives, this novel holistic measure is less aligned with measures of adherence.

NICE guidelines published in May 2020 suggested patients should be encouraged to self-monitor and self-manage and be given access to their medical data (NICE, 2020). The recommendations from the GIRFT (referenced in chapter 1) are being implemented by the Renal services transformation programme (RSTP), launched in June 2021. A key aim is to improve psychosocial health, alongside driving up equity in access and quality of care. It is critical that any improvements or impact can be measured to evidence impact, the PRIESM CKD-HD may be able to do that. Currently psychosocial need is not being systematically assessed or addressed in kidney care.

9.7 CHANGES TO CLINICAL PRACTICE

In health sciences, research doesn't always have the impact it should on practice (Chaudoir et al., 2013). Too few patient-reported outcome measures are routinely used in care, a fact that is mirrored in CKD-HD self-management. None of the self-management measures identified in chapter 3 are used in clinical care and moreover, other psychosocial measures such as the distress thermometer are used sporadically within, and not consistently across renal centres. It appears that there is no systematic way of communicating what happens beyond the dialysis chair and how treatment and illness impacts functioning and psychosocial wellbeing, and indeed how functioning and psychosocial wellbeing impacts clinical care.

A single, consensual, conceptual framework of self-management which maps to a measure, ensures accurate and consistent assessment which can be useful in terms of research but also improving provider-patient communication and collaboration in a more shared approach to care. Van De Velde et al. (2019) places partnership with provider, social support and social network, person-centred care and information and communication at the heart of self-management. This concurs with findings from Boonstra et al (2022) which suggest that person-centred strategies help maintain self-management, particularly among those with limited health literacy. These aspects are all incorporated in the novel SM scale outlined in this thesis.

9.8 CONCLUDING REMARKS

Currently, there is no patient reported measurement of self-management used in research or clinical practice that is underpinned by the tripartite model of self-management. The work presented here addressed that gap through the development and validation of a novel scale, developed from the patient perspective, and using expert consensus and ongoing input from members of the research groups' network. The measure correlates with existing validated measures of self-efficacy and depression. What is unknown is how it correlates with clinical outcomes or patient activation (PAM), often used as a proxy measure for self-management. There is preliminary evidence that the scale may be useful, the long-term aim is to take the measure and turn it into a relevant tool within clinical practice. Assuming it can be used routinely in clinical practice, further evidence of its reliability, validity and potential use longitudinally, is needed.

We were able to show some time ago that care and clinical outcomes are affected by whether a patient experiences depression. Where a measure of depression (or distress) may provide an indication that something is wrong, a scale such as PREISM HD will provide more nuanced information about the challenges a person is facing and may be more useful in practice. It should be possible to identify a person who is struggling with social support, feels emotional distress, is overwhelmed, or is having difficulties with communication. It is possible that these things will impact their engagement with self-management and how they view treatment, illness and life more broadly. As with important determinants of health, these factors and the underlying cause may be viewed as unrelated to care and not the direct responsibility of clinical staff. However, increasingly, we understand how important these elements are and if services provided alongside clinical care (e.g., social care and psychosocial support) aren't adequately resourced, having a measure which quantifies need is likely to be useful.

Others report unmet need for psychosocial support in renal care, and link this to insufficient psychosocial staffing (Seekles et al., 2020), an issue also reported anecdotally in this work (chapter 8). Despite being a barrier to implementing the scale in practice because of the perceived lack of solution, it may be that even being aware of psychosocial issues, may be useful. The impact of mental health has received a higher profile since COVID-19, and while resource issues within the NHS are well documented, adequately conceptualising self-management and assessing engagement could be deemed even more important. A means of measuring and identifying potential gaps in support, may further highlight the need for adequate resourcing in terms of workforce, skills and strengthening referral pathways.

Supported self-management requires identification of the broader context of the individual, what matters to them, where they are struggling and where the gaps may be in terms of what they need. The wider context, within which individuals exist, will impact actions or perceptions made visible in the clinical setting. If this wider context remains unknown, the opportunity to support self-management may be missed and misconceptions may prevail. To assess where people are now, to focus the conversation on what matters to them is key.

In conclusion, routine, and systematic use of the PRIESM CKD-HD as part of clinical care could contribute to a shift in the way we define and understand self-management, that aligns with the Health Foundations tripartite model of health. Where the Health Foundation triangle takes the concepts and places them in a single framework, this thesis demonstrates in a fundamental way why this concept is so important. Everyone is self-managing even where the choices they make do not fit with what the clinical service might want them to do. When we ask people how they manage their condition, little of their attention is directed to the clinical setting. The impact of the condition, for the patient, is beyond the clinic and this thesis provides strong evidence that where the focus is only on the clinical setting, services will be missing elements of care that are fundamentally important for the patient. Where the aims of treatment move beyond preserving life, to enabling people to live well with a (long-term) condition, this shift in perspective becomes more important. The thesis, and the evidence it contains provides vital evidence to move this idea forward.

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APPENDIX

APPENDIX A References that specify measurement items.

Measurement	Study	Link
Kidney Disease Behaviour Inventory (KDBI) & Perceived Kidney/Dialysis Self-Management Scale (PKDSMS)	Wild et al (2017)	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5610608/
Behaviours in Haemodialysis Scale (BHDS)	Curtin et al (2004)	https://pubmed.ncbi.nlm.nih.gov/15453230/
Partners In Health (PIH)® instrument	Walker et al (2013)	https://www.researchgate.net/publication/274636158_Improving_self-management_in_chronic_kidney_disease_A_pilot_study
CKD-SM Instrument	Lin et al (2013)	https://pubmed.ncbi.nlm.nih.gov/22642723/
Chronic Kidney Disease Self-Care Scale (CKDSC)	Wang et al (2019)	https://onlinelibrary.wiley.com/doi/abs/10.1111/nep.13475

APPENDIX B Ethical approval.

NHS
Health Research Authority

Professor Ken Farrington
Consultant Nephrologist
East and North Hertfordshire NHS Trust
Renal Unit, Lister Hospital
Coreys Mill Lane
Stevenage
SG1 4AB

Email: hra.approval@nhs.net

05 December 2017

Dear Professor Farrington

Letter of HRA Approval

Study title:	**Development of a self-management behaviour scale for people with Chronic Kidney Disease (CKD) on haemodialysis in the UK**
IRAS project ID:	**221766**
REC reference:	**17/EM/0451**
Sponsor	**East and North Hertfordshire NHS Trust**

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 the HRA website.

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 through IRAS.

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.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the HRA website.

Your IRAS project ID is **221766**. Please quote this on all correspondence.

Yours sincerely

Kevin Ahmed Assessor

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

Copy to: *Prof Phillip Smith, Sponsor Contact, East and North Herts NHS Trust*
Ms Rishma Bhatti, R&D Contact, East and North Herts NHS Trust

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
HRA Schedule of Events	1.0	05 December 2017
HRA Statement of Activities	1.0	05 December 2017
IRAS Application Form [IRAS_Form_14112017]		14 November 2017
Letter from funder [BRS award letter]	1.1	13 December 2016
Letter from sponsor [Self-management questionnaire sponsor letter]	1.1	13 November 2017
Non-validated questionnaire [Change of circumstances questionnaire]	1.1	03 November 2017
Participant consent form [Consent form interviews (Phase one and three)]	1.2	05 December 2017
Participant consent form [Consent form focus group (phase one)]	1.1	03 November 2017
Participant consent form [Consent form questionnaire (phase four)]	1.1	03 November 2017
Participant information sheet (PIS) [PIS Phase One Interviews]	1.2	05 December 2017
Participant information sheet (PIS) [Phase Three Cognitive interviews]	1.2	05 December 2017
Participant information sheet (PIS) [PIS Phase One Focus Groups]	1.1	03 November 2017
Participant information sheet (PIS) [PIS Phase Four Questionnaire]	1.1	03 November 2017
Participant information sheet (PIS) [PIS Phase Four Test Re-Test]	1.1	03 November 2017
Research protocol or project proposal [DCKD Self-management study protocol]	1.1	03 November 2017
Summary CV for Chief Investigator (CI) [CV Professor Ken Farrington]	1.1	03 November 2017
Validated questionnaire [ESRD-AQ]	1.1	03 November 2017
Validated questionnaire [Self Efficacy Questionnaire]	1.1	03 November 2017
Validated questionnaire [PHQ-9]	1.1	03 November 2017
221766 17.EM.0451 PR Application FO		01 December 2017

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Prof Philip Smith
Tel: 02038262162
Email: phillip.smith5@nhs.net

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	The participant documents have been updated to comply with HRA standards.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites. The sponsor is not requesting, and does not require any additional contracts with study sites.

Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	External study funding has been secured from the British Renal Society. Study funding will be provided to sites, as detailed at Schedule 1 of the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

All participating NHS organisations will undertake the same study activities. There is therefore only one study site ‘type’ involved in the research.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A Principal Investigator should be appointed at study sites.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

NHS
Health Research
Authority

Ms Helen Munro Wild
Research Fellow
University of Hertfordshire
Health Research Building
College Lane Campus, University of Hertfordshire
Hatfield
AL10 9AB

Email: approvals@hra.nhs.uk

13 May 2021

Dear Ms Munro Wild

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Engaging patients and professionals in the shift from research to practice. How can a multidimensional self-management behaviour scale be used to support renal patients on haemodialysis in the UK?**
IRAS project ID:	**292773**
REC reference:	**21/PR/0144**
Sponsor	**University of Hertfordshire**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions 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.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **292773**. Please quote this on all correspondence. Yours

sincerely,
Juliana Araujo Approvals

Specialist

Email: approvals@hra.nhs.uk

Copy to: *Ms Ellie Hubbard*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		06 Aug 2020
HRA Schedule of Events [SoE SM_Scale_ResearchIntoPractice_ScheduleEvents_Lister&Birmingham_IRAS_292773_v2.0_25012021 Validated]		21 April 2021
HRA Schedule of Events [SoE SM_Scale_ResearchIntoPractice_ScheduleEvents_Preston&Kings_ IRAS 292773_v2.0_25012021 Validated]		21 April 2021
Interview schedules or topic guides for participants [Draft focus group topic guide – to be used in phase 2b with patient and professional consent form and PIS v1.0 25012021.]	1.0	25 Jan 2021
IRAS Application Form [IRAS_Form_29012021]		29 Jan 2021
IRAS Application Form XML file [IRAS_Form_29012021]		29 Jan 2021
Letter from funder [SM_Scale_Funding_IRAS_292773]		28 Nov2019
Letter from sponsor [SM_Scale_Sponsorship_IRAS_292773]		20 Jan 2021
Letters of invitation to participant [SM2_StudySummary_IRAS_292773]	2.0	29 May 2021
Organisation Information Document [SM_Scale_OID_Lister&Birmingham_IRAS_292773]	v1.0	25 Jan2021
Organisation Information Document [SM_Scale_OID_Preston&Kings_IRAS_292773]	v1.0	25 Jan2021
Other [Clarifications on the recruitment process]		22 Feb 2021
Other [SM_Scale_EmailConfirmation_IRAS_292773]	N/A	11 Jan 2021
Other [DCKD_SM_Consent_Phase4_IRAS_221766]	1.1	03 Nov 2017
Other [Response to ethics committee]	1.0	04 March 2021
Participant consent form [SM_Scale_CF_Professional_IRAS_292773]	v3.0	30 April 2021
Participant consent form [SM_Scale_CF_PatientInterview_IRAS_292773]	v3.0	30 April 2021
Participant consent form [SM_Scale_CF_Patient_IRAS_292773]	v3.0	30 April 2021
Participant consent form [SM_Scale_CF_StakeholderGroup_IRAS_292773]	v3.0	30 April 2021
Participant information sheet (PIS) [SM_Scale_PIS_Patient_IRAS_292773]	v3.0	30 April 2021
Participant information sheet (PIS) [SM_Scale_PIS_PatientInterview_IRAS_292773]	v3.0	30 April 2021
Participant information sheet (PIS) [SM_Scale_PIS_Professional_IRAS_292773]	v3.0	30 April 2021
Referee's report or other scientific critique report [Second academic review from Dr Claire Thompson]		30 March 2021
Research protocol or project proposal [SM_Scale_Protocol_IRAS_292773]	1.0	25 Jan 2021
Summary CV for Chief Investigator (CI) [SM_Scale_CV_IRAS_292773]		25 Jan 2021
292773, 21/PR/0144, SE05 HRA Approval PRS email confirmation template.eml		29 Jan 2021
292773, 21/PR/0144, SE11 Application Valid – Full REC review - non-commercial.eml		19 Feb 2021
292773, 21/PR/0144, SE32 Status Update - Provisional Opinion.eml		17 March 2021
292773, 21/PR/0144, SE37 - Status Update - Response incomplete.eml		27 April 2021
292773 21 PR 0144_Favourable_Opinion_on_Further_Information_13.05.2021.pdf		13 May 2021

APPENDIX C Topic Guide outline for interview.

Note on formatting - main questions in bold, sub-questions italicised, prompts as bullet points.

Demographic information (collected via clinical records as part of the eligibility process)

Age, sex, ethnicity, and time on dialysis (vintage)

Topic 1: Self and experience

1 **I wonder if we might begin with you telling me a little bit about you and your kidney disease. Please tell me about yourself.**

Prompts:

- Overview age/family/interests/important things in life
- CKD diagnosis – when,
- History on dialysis; years?

Topic 2: Symptoms and treatment

2 **And to help me to understand what living with kidney disease is like, can you tell me about the symptoms you experience?**

2.1 How do you deal with your symptoms?
2.2 *What do you do when symptoms are really bad?*

Prompts:

- Consequence of the illness,
- Dialysis specifically
- Including other comorbidities
- Who supports them?
- Who do they discuss with?
- What support do they have?

c. *Some people describe dealing with quite difficult emotions at different stages of their kidney disease, how do you cope with any you experience?*

3 **Can you tell me about your experience of treatment?**

3.1 If you wanted to change your treatment or stop dialysis, what would you do?

Prompts

- How does it impact their life?

Topic 3: Daily managing

4 **How do you look after yourself day to day?**

4.1 Who helps?

4.2 What things cause you the most worry? These things may or may not be related to your kidney problems.
4.3 And what things are you happy that you've got under control?

Prompts

- In relation to kidney disease but also beyond.

5 Can you tell me about the types of advice are you given about how to stay well?

5.1 *What are your thoughts on it?*
5.2 *Does this advice help you live the life you want for yourself?*

Prompts

- Who gives what advice?
- Are the messages coherent and in agreement?
- The impact or consequence of doing or not doing these things?

6 It sounds like there is a lot involved in managing kidney disease – is there anything you do or don't do that you know might help you at all? Are there any things you do that may not be the best thing for your kidney care?

Prompts

- What are the barriers?

7 What would you recommend someone else do to manage some of the experiences and symptoms you've talked about?

7.1 *What would you say is the one thing you do best to help you manage your kidney disease and treatment?*

Topic 4: Treatment decisions

8 Can you tell me about any treatment decisions you've had to make since having kidney disease?

8.1 *Are there any decisions you'd go back and change if you could?*

Prompts

- How were the decisions made?
- Who with?

Ending

9 Is there anything else you would like to say about what matters to you that hasn't been discussed?

9.1 Do you have any other comments about what we have discussed or feedback on the interview process?

APPENDIX D Demographics questionnaire for main survey.

Study Number: RD2017-86
Patient ID Number: LISTERP4_100

Chronic Kidney Disease Questionnaire – Information about you

We would like you to answer the questions below so that we can collect some details about you. This information will help us best understand the responses you provide for the self-management behaviour scale. Your answers will be kept strictly confidential and anonymised.

Demographic Information

1. What is your ethnic group? Choose one section then tick one box that best describes your ethnic group or background.

a. White

☐ English/Welsh/Scottish/Northern Irish/British
☐ Irish
☐ Gypsy or Irish Traveller
☐ Any other white background, write in below

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

b. Mixed/multiple ethnic groups

☐ White and Black Caribbean
☐ White and Black African
☐ White and Asian
☐ Any other Mixed/multiple ethnic background, write in below

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

c. Asian/Asian British

☐ Indian
☐ Pakistani
☐ Bangladeshi
☐ Chinese
☐ Any other Asian background, write in below

d. Black/African/Caribbean/Black British

☐ African
☐ Caribbean
☐ Any other Black/African/Caribbean background, write in below

e. Other ethnic group

☐ Arab
☐ Any other ethnic group, write in below

2. What is the current name of the country in which you were born? Write in below.

3. What is your current marital status?

☐ Single
☐ Married/civil partnership
☐ Living with companion
☐ Separated

☐ Divorced
☐ Widowed

4. Which of these qualifications do you have? Indicate all the options that apply or the nearest equivalent. If you have qualifications you gained outside the UK, tick the ‘foreign qualifications’ box and the nearest UK equivalent (if known).

☐ 1-4 O levels/CSEs/GCSE’s (any grades), Entry Level, Foundation Diploma.
☐ NVQ Level 1, Foundation GNVQ, Basic Skills
☐ 5+ O levels/CSE’s/GCSE’s, School Certificate, A level/AS levels/VCE’s, Higher Diploma
☐ NVQ level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma
☐ Apprenticeship
☐ 2+ A levels/VCEs, 4+ AS levels, Higher School Certificate, Progression/Advanced Diploma
☐ NVQ level 3, Advanced GNVQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Diploma
☐ Degree or higher degree (for example BA, BSc, MA, PhD, PGCE)
☐ NVQ level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher Level
☐ Professional qualifications (for example teaching, nursing, accountancy)
☐ Other vocational/work-related qualifications
☐ Foreign qualifications
☐ No qualifications

5. What is your current employment status?

☐ Employed
☐ Unemployed (but seeking work)
☐ Retired
☐ Looking after home or family
☐ Other (including student, long-term sick or disabled)

6. Does your household income meet your everyday need for things such as accommodation, food, clothing and other necessities?

☐ More than enough money
☐ Enough money
☐ Just enough money
☐ Not enough money
☐ Inadequate household income

Information about your illness

7. When did you first find out you had kidney problems?

☐ Within the past year
☐ 1-5 years ago
☐ 6-10 years ago
☐ 10+ years ago
☐ Since birth or childhood

8. Are you on the transplant list?

☐ Yes
☐ No
☐ Don’t know
☐ Not applicable

9. What is the total number of pills you have to take each day?

- ☐ 1-9
- ☐ 10-19
- ☐ 20 or more
- ☐ Don't know
- ☐ Not applicable

10. Please indicate if you have any of the following problems by putting a tick in the first column. If you do have the problem, tick the subsequent columns if applicable. Tick all that apply.

	Do you have the problem? (Please tick)	Do you receive treatment for it? (Please tick)	Does it limit your activities? (Please tick)
Heart disease such as angina or poor heart function	☐	☐	☐
Previous heart attacks	☐	☐	☐
Diabetes	☐	☐	☐
Cancer	☐	☐	☐
Lung disease	☐	☐	☐
Liver disease	☐	☐	☐
Arthritis	☐	☐	☐
Depression	☐	☐	☐
Other medical conditions (please			
___________________________	☐	☐	☐
___________________________	☐	☐	☐
___________________________	☐	☐	☐

Other questions

11. Who lives with you in your home? Tick all that apply.

☐ I live alone (skip to question 12)
☐ Wife/husband/partner
☐ 1 or more children **under** 18 years
☐ 1 or more children **over** 18 years
☐ Other family members
☐ Friends
☐ Other

12. How many people live with you in your home?

☐ 1
☐ 2
☐ 3
☐ 4
☐ 5 or more

13. Approximately how long does it usually take you to travel to your dialysis treatment (one way)?

☐ Less than 30 minutes
☐ Between 30 minutes and one hour
☐ More than one hour but less than two
☐ More than two hours
☐ Five or more hours
☐ Don't know
☐ Not applicable

14. What type of transport do you currently use to get to the renal unit?

☐ Personal transport (self-drive or family member/friend)
☐ Bus
☐ Taxi
☐ Ambulance
☐ Other, please specify ____________________________
☐ Don’t know
☐ Not applicable

15. Is there someone who **relies on you** for their care?

☐ Yes
☐ Sometimes
☐ No

16. Did you receive help to complete this questionnaire?

☐ Yes
☐ No

Thank you for completing this questionnaire. We really appreciate that you have contributed your valuable time.

Please return the completed questionnaires and information about you in the stamped address envelope enclosed or to any member of the clinical team at your renal unit.

APPENDIX E Theme ranking.

	Not at all relevant								**Very relevant**		**Proportion**		**Value and order**		
	1	2	3	4	5	6	7	8	9	10	>5	>6	n	Score	Rank
Theme															
Access to support	0	0	1	0	0	1	0	3	1	12	0.94	0.89	18	179	1
Barriers	0	0	1	0	0	0	2	3	4	8	0.94	094	18	171	2
Cause of kidney disease	0	0	2	2	2	4	2	3	1	3	**0.68**	**0.47**	19	169	3
Change/transition	0	0	0	0	0	0	3	0	5	9	1.00	1.00	17	166	4
Communication with clinical staff	0	0	0	0	0	1	1	0	4	12	1.00	0.94	18	166	5
Co-morbidity	0	0	0	1	2	0	1	4	3	7	**0.83**	**0.83**	18	164	6
Coping strategies	0	0	0	0	0	0	1	2	7	8	1.00	1.00	18	164	7
Control	0	0	0	0	0	1	0	2	6	9	1.00	0.94	18	164	8
Dialysis	0	0	1	2	1	0	1	2	4	8	**0.79**	**0.79**	19	162	9
Future	0	0	0	0	0	3	2	5	2	6	1.00	0.83	18	162	10
Holidays	0	1	0	0	1	3	5	2	1	4	0.88	0.71	17	161	11
Hope	0	0	0	0	0	0	1	1	4	12	1.00	1.00	18	158	12
Illness perceptions	0	0	0	0	0	2	4	6	3	4	1.00	0.89	19	157	13
Impact of illness on family	0	0	0	1	1	0	1	5	4	7	0.94	0.94	18	157	14
Information	0	0	0	0	0	1	0	0	2	14	1.00	0.94	17	156	15
Managing	0	0	0	0	0	0	0	0	1	17	1.00	1.00	18	155	16
Meaningful life beyond dialysis	0	0	0	0	0	1	1	4	4	9	1.00	0.94	18	155	17
Perceptions of self and identity	0	1	0	1	0	1	1	3	4	7	0.88	0.82	17	150	18
Resilience	0	0	0	1	0	0	3	6	2	7	0.95	0.95	19	150	19
Risk taking	0	0	0	0	0	2	3	4	4	4	1.00	0.88	17	148	20
Self-care	0	0	0	0	0	2	1	0	5	10	1.00	0.89	18	141	21
Symptoms	0	0	0	0	1	0	2	3	5	7	0.94	0.94	18	140	22
Time	0	3	0	2	1	3	3	3	2	1	**0.67**	**0.50**	18	135	23
Transplant	0	1	1	0	4	0	0	0	0	5	**0.68**	**0.58**	19	125	24
Transport	1	2	0	1	2	1	0	4	0	6	**0.65**	**0.59**	17	125	25
Treatment decision/choices	0	0	0	0	1	0	0	2	7	8	0.94	0.94	18	117	26
Work (employment)	0	0	1	0	1	1	3	7	3	3	0.89	0.84	19	110	27

APPENDIX F Key discussion points from the consensus workshop.

1.	Many themes and sub-themes overlap and may interact. It is important to look at how they are currently measured and understand from the literature the evidence for associations between the various psychosocial factors.
2.	The themes cover a range of important factors, and the wording should be carefully considered. Items around impression management, whether positive or negative is related to psychological support and self-worth and should be carefully phrased. Family support is crucial. Worrying about how you appear to your doctor becomes less important when a patient begins engaging more with care.
3.	The opportunity to self-manage will determine how patients answer questions. May not be just about their attitude to self-management, need to understand the renal-centre context. Is there a culture of encouraging self-management? Where is the unit at in terms of supporting self-management? There will be variation at the centre level.
4.	There are broad truths within considerable heterogeneity in terms of kidney disease pathway and the context of implementation. Could the scale be adapted for use as a longitudinal tool, to capture the bigger picture, change over time, and/or the treatment journey. There is likely to be a difference between patients who have a progressive disease and those who have a shock diagnosis (urgent starter). The amount of support people need may depend on the level and rate of disease regression. Urgent starters go straight onto haemodialysis, but they need the time to let the information sink in. Need to revisit patients to catch them at the point when they're ready to engage. All of this needs to be considered in development of the scale. How to quantify what is going on with the patient's care at any given time point?
5.	Need to consider when and with who to use the scale to ensure support at appropriate times, from pre-treatment onwards. Could the final scale be used pre-dialysis? With adaptation?
6.	As healthcare professionals and researchers, we need to accept that not everyone wants to self-manage. Some may want just to receive treatment three days a week and then get on with it. Have a 4-hour sleep, and let the staff take the strain.
7.	I'm fine thanks, tends to be a default setting. We need a scale that really gets beneath the surface. Do patients know they're not fine?

APPENDIX G Example of candidate scale items.

Theme	Question	Source	Reference
Managing	I have a good balance between the demands of my illness and what I want to do with my life.	Expert panel	N/A
	My kidney disease interferes too much with my life	KDQOL13	Hays et al (1997)
	Since dialysis, how much does pain interfere with the usual jobs you do around the house	KDQOL13 (adapted)	As above
	I struggle with the day-to-day impact of my disease and treatment on everyday life. Managing, coping.	Literature review	Parker et al (2017)
Social and emotional support	How much of the way you deal with your condition is dependent on other people?	Expert panel	N/A
	I feel limited in my ability to see friends	PROMIS	Cella et al (2007)
	There are people in my life who provide me with emotional support	Literature review	Jansen et al (2014)
Support (MDT)*	My relationship with staff generally supports what I want to achieve.	Expert panel	N/A
	Dialysis staff encourage me to be as independent as possible	KDQOL13 (adapted)	As above
	How satisfied are you with the medical support on your dialysis unit?	Literature review	Robinski et al (2016)
Hope	When I think about the future, I have hope.	Expert panel	N/A
	How well are you responding to you treatment?		
	I've been giving up the attempt to cope.	Brief Coping Orientation to Problems Experienced (Brief COPE) (adapted)	Carver 1997; Baumstarck et al (2017)
	I feel that the burden of dialysis outweighs the benefits.	Literature review	Hussain et al (2015)
Communication (MDT)*	I speak to staff about my concerns when I have them.	Expert panel	N/A
	I am confident in my ability to ask a doctor for more information if I don't understand what he or she said	Perceived Efficacy in patient physician interactions (PEPPI)	Maly et al (1998)
	I am comfortable asking my doctor questions	Diabetes self-management instrument (adapted)	Lin et al (2008)
	I trust the doctor to offer the right treatment choices for me.	Literature review	Hussain et al 2015

Coping strategies	Do you feel largely positive despite ups and downs?	Expert panel	N/A
	I am the type of person who just gets on with it.		
	I seek support to overcome difficulties		
	Do you feel able to rest when you need to?	Literature review	Picariello et al (2018)
	I have started doing new activities since I started dialysis.	Literature review	Rees et al (2018)
	I often feel that I cannot cope with all the things I need to do	Perceived stress scale (adapted)	Cohen (1994)
Control	Day to day I generally have a degree of control that allows me to function in a way that’s acceptable to me.	Expert panel	N/A
	How much control do you feel you have over your illness?	Brief Illness perceptions Questionnaire	Broadbent et al (2006)
	The main thing which affects my condition is what I myself do.	Multidimensional Health Locus of Control (MHLC) scales	
Information	I am able to get the information I need.	Expert panel	N/A
	I know how my kidney disease is likely to change over time.	Knowledge Palliative Care Questionnaire	Davison (2010)
	Asked for change in treatment based on information you learned on your own?	BHDS	Curtin et al (2004)
	I worry that I do not have all the information about all aspects of my care available to me	Literature review	Cramm et al, 2015
Self-care	I believe I will be better off if I am involved in my care	Expert panel	N/A
	How often have you ever helped decide how much fluid should be taken off?	BHDS	As above
	I have a record/keep a diary about choices and habits that help me follow fluid restrictions/low salt and phosphate diet.	Literature review	Smith et al 2010
Treatment decisions/choices	Have you felt informed about the decisions you have made relating to your illness(s)?	Expert panel	N/A
	I feel included in the decisions about my care		
	I know when I can break the rules/cut corners to enable me to live life as I want.		
	Does the renal team enable you to participate in decisions about your kidney care as much as you want?	PREM 2018	Hawkins et al (2022)

	I was provided with sufficient pre-dialysis information to make a decision about starting dialysis.	Literature review	Harwood & Clark, 2013
Meaningful life	My life has a purpose beyond dialysis	Expert panel	N/A
	I am still able to do things now that I did before.		
	Have you had a holiday in the last year?		
	There are things that I used to do before dialysis that I cannot do anymore that I would have been doing otherwise	Kidney Disease Loss Scale (adapted)	Chan et al (2009)
	I feel I live a life rather than live an illness	Literature review	Whittemore et al 2007
Symptoms	Do you sometimes feel overwhelmed by your symptoms? My symptoms are a barrier to managing my condition	Expert panel	
	Sometimes my feelings of distress are so intense they completely take over	Distress tolerance scale	Simons & Gaher (2005)
	I often experience symptoms that interfere with the way I would like to live my life day to day.	Literature review	Flythe et al 2015
Impact on family	Are you able to contribute to your family as you used to (breadwinner, parenting)?	Expert panel	N/A
	Does your illness cause tension in your relationships?		
	I have trouble meeting the needs of my family.	PROMIS	Cella et al (2007)
	I am concerned that my caregiver will "wear out" because of the demands of caring for me.	The self-perceived burden scale	Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)Cousineau et al (2003)
	My family and/or partner are often worried or anxious about me	IPOS - Renal P3	Raj et al (2018)
Change/transition	I have trouble coping with new things	Expert panel	N/A

	I am coping well with the demands of my condition(s).		
	The transition to dialysis was a shared decision between me and my doctor.	Literature review	Bear & Stockie 2014
Illness perceptions/identity	Does your condition define you?	Expert panel	N/A
	Have you ever hidden your illness from people in a social situation, or at work?		
	Does your illness make you feel angry/emotional?		
	I feel myself longing to be my old self	Kidney disease loss scale (adapted)	Chan et al (2009)
	Sometimes I do not go to family or social events involving food and/or alcohol as I don’t want others to know about my health problems.	Literature review	Oquendo et al (2017)
Multi-morbidity	Have you leant self-management skills in your other illnesses that help you with your CKD?	Expert panel	N/A
	The burden of all my medical conditions makes it hard for me to engage in looking after myself.		
	Are your other illnesses more of a bother than your kidney disease?		
	I find the provision of my healthcare sometimes complex and inconsistent.	Literature review	Havas et al (2017)
Work	Does being on dialysis stop you from working?	Expert panel	N/A
	I can manage my condition around my working activities		
	Because of dialysis my ability to work is impaired	WSAS (adapted)	
Acceptance	Are you angry about your illness?	Expert panel	N/A
	Do you believe your illness will be cured?		
	I’ve learnt to live with my kidney disease.	Brief Coping Orientation to Problems Experienced (Brief COPE) (adapted)	Carver 1997; Baumstarck et al (2017)
	When I began dialysis, I felt mentally prepared for it.	Literature review	Monaro et al (2014)

APPENDIX H I-CVI round 1, theme definitions.

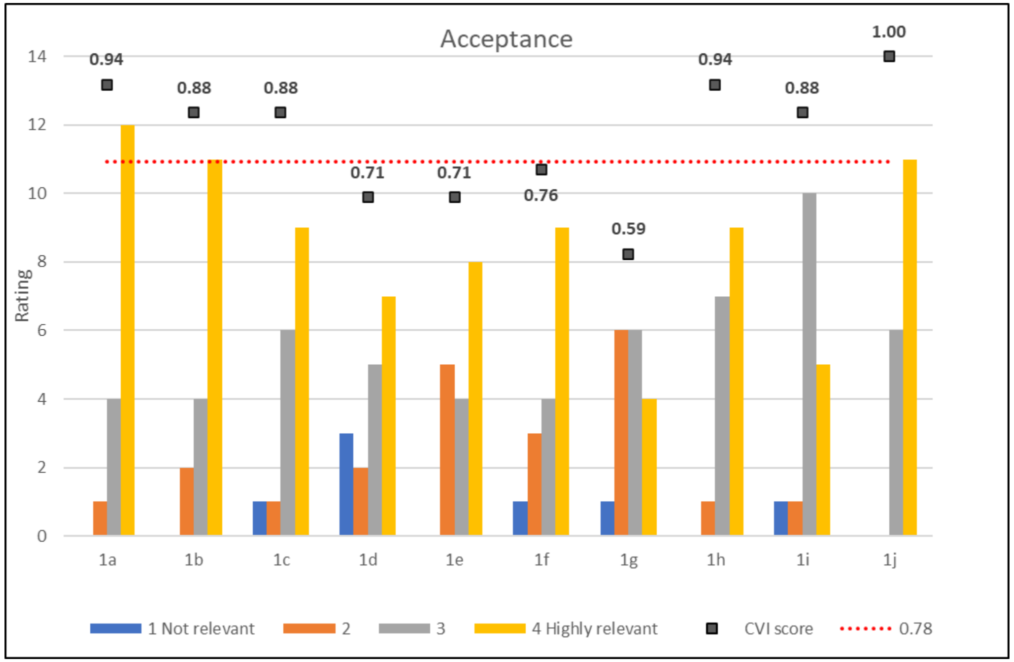
Theme definition and items
Acceptance How does a patient's level of acceptance of their illness affect their current self-managing behaviours and fears relating to illness. Linked to personality, situation and illness narrative.
Communication Comfortable interactions between patients and clinical staff and doctors that enable information sharing, decision making and the opportunity to reassure patients. Communication should be regular, conducted respectfully in terms of patient's beliefs and values, and without barriers to understanding.
Control Does the patient have a sense of control over their illness that is sufficient for them to be involved in the management of it if they wish? How much control does a patient want in the management of their kidney disease, how much do they feel able to control symptoms and illness and are they able to let go of the things they can't control.
Coping Strategies Emotion and problem focussed engagement strategies that patients use to manage their illness in everyday life. Where patients establish routines and plan ahead to support their self-management.
Hope Absence of hopelessness. Provision of clinical care that respects and maintains patients' goals and wishes. The patient has a sense of purpose, of being loved, a sense of life's achievements and some anticipation of the future.
Illness perceptions (self/others) and identity How people make sense of their illness and see themselves may be influenced by their beliefs about illness origin. They are informed by patient's lay understanding of their kidney disease, experience, and information from others. This will be reflected in coping behaviours and negative illness perceptions are linked to a reduced willingness to engage in self-management activities. Behaviours to manage others' perceptions of illness should form a sub-category. Identity refers to the degree to which illness is integrated into one's identity and as with illness perceptions, is related to physical symptoms.
Impact on family The degree to which family members support a patient in their day to day to self-management behaviours. This is likely to be cognitive/emotional as well as practical support. The impact of this support on those caring and on the patient i.e., increased family conflict, feelings of being a burden, or where support is perceived as negative and may affect the patient's ability to self-manage.
Information/knowledge If/when/how patients seek information and how they use that information to self-manage day to day. Whether the patient has the ability to process information is likely to impact on how it is used to self-manage. Information may be sought for reassurance or to make decisions about managing.

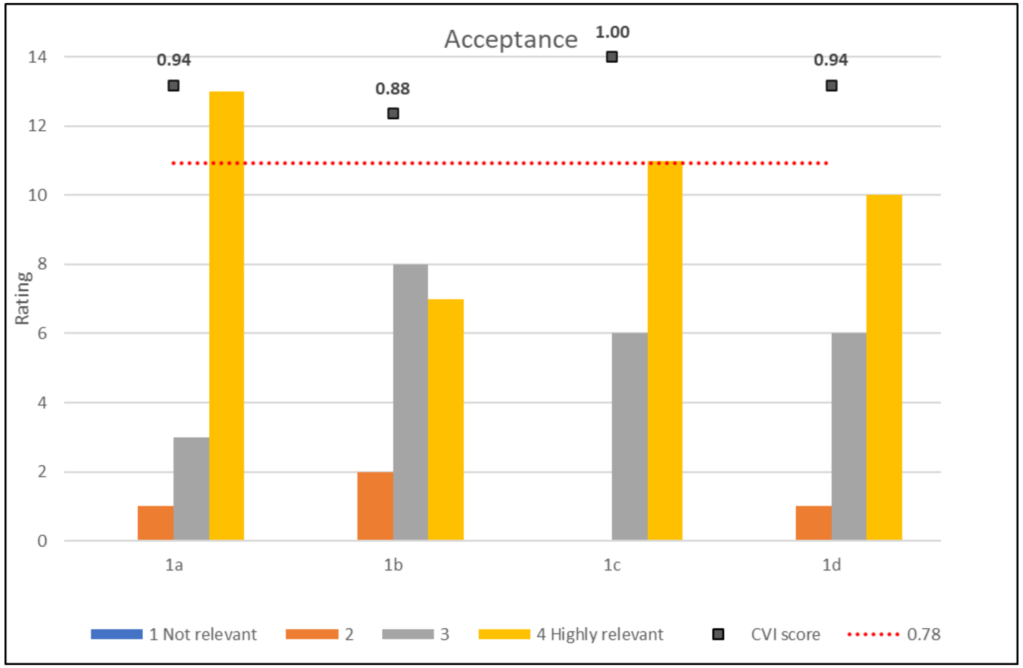
Managing day to day Managing psychological responses to illness as well as practical aspects of managing their illness within the context of their relationships, goals and own values, and life as usual. Specifically, managing symptoms (particularly fatigue), emotions, self-care tasks, multimorbidity, changes in routine, adherence to medication, fluids, and diet. What is done to achieve or maintain a level of normality.
Meaningful Life The behaviours that patients demonstrate that help them achieve a sense of balance in self-managing their kidney disease and living a meaningful life for them. How the illness has been integrated into the context of their life in a way that enables them to still experience purpose and meaning.
Multimorbidity The extent to which multimorbidity complicates the self-management of kidney disease, particularly when multiple providers are involved, and treatment recommendations may conflict. For the patient, how does it impact on day-to-day priority setting and the capacity to engage with self-management.
Social support Behaviours that indicate the patient is not isolated and seeks social connectedness in some way.
Support (multidisciplinary team) Support offered by clinical staff to promote and support self-management that goes beyond information sharing and medical support of dialysis to assessment of progress, goal setting and problem-solving support. Patient's perception of the quality and availability of support. Whether the patient is being treated with respect and as individuals with their own experiences of kidney disease and goals and values for life.
Symptoms The number of (physical and/or emotional) symptoms and degree of severity experienced by the patient and how these impact on self-managing behaviours. The strategies that patients use to cope with or prevent symptoms.
Treatment Decisions The level of perceived involvement a patient has in making informed treatment decisions and how this aligns with the involvement they want. Whether the healthcare staff provide the necessary information and supportive attitude for patients to make informed decisions. Whether patients seek support from family/friends or patients to make decisions. Behaviours related to prior experiences of decision making, current and future decisions. Ascertain style of decision making active, collaborative, passive (Durrand, 2016).

APPENDIX I Behaviours in Haemodialysis Scale (BHDS), developed by Curtin et al., 2004.

Question	**I-CVI**
Domain 1 - Suggestions to providers: How often have you ever:	
1. Asked for change in treatment based on information you learned on your own?	0.78
2. Told staff or doctor you wanted something changed about your treatment or care?	0.83
3. Asked staff or doctor to do something differently – thought there was a better way?	0.78
Domain 2 - Self-care during HD How often have you ever:	
4. Cleaned / prepared your access site for needle placement?	0.88
5. Weighed yourself?	0.75
6. Helped decide where the needles should be placed?	0.94
7. Helped decide the blood flow rate?	0.76
8. Helped decide how much fluid should be taken off?	0.94
9. Watched the care you received to make sure everything was done right?	0.76
10. Stayed awake (when you would rather sleep) to make sure treatment was going okay?	0.29
Domain 3 - Information seeking How often have you ever:	
11. Looked for additional kidney diet information?	0.94
12. Asked family, friends, or dialysis patients for information re: kidney disease and its treatment?	0.78
13. Asked questions regarding something you read regarding kidney disease and its treatment?	0.78
Domain 4 - Use of alternate therapies How often have you ever:	
14. Tried an alternative treatment (such as yoga, acupuncture, magnets or hypnosis)?	0.56
15. Experimented with treatments other than those prescribed by your doctor?	0.50
Domain 5 - Selective symptom management How often have you ever:	
16. Kept problems or symptoms to yourself so as not to bother staff or your doctor?	0.78
17. Handled problems or symptoms yourself so that you wouldn't have to talk about them?	0.94
18. Put up with problems or symptoms because you thought that nothing could be done about it?	0.78
19. Decided which problems to report to doctor / nurse and which to handle on your own?	1.00
20. Tried out different ways to handle problems or symptoms?	1.00
Domain 6 - Assertive self-advocacy How often have you ever:	
21. Spoke up to caregiver because you thought they were doing something wrong?	0.94
22. Confronted staff in order to get better care?	0.67
23. Consulted a higher authority to officially complain regarding an issue or problem?	0.39
Domain – 7 Impression management How often have you ever:	
24. Tried to get staff or your doctor to think well of you, in order to get better care?	0.33
25. Hid true thoughts because you feared staff might be angry and take it out on you later?	0.44
26. Acted more cheerful than you felt so staff would give you good care?	0.33
Domain 8 - Shared responsibility in care How often have you ever:	
27. Talked regarding a treatment or medicine you learned about, hoping the information might work for you?	0.94
28. Learned more about the dialysis machine, dialyser reuse or other technical topics?	0.94
29. Checked settings on the dialysis machine to make sure they were the same as usual?	0.94
30. Looked for information or talked with a pharmacist about your medications?	0.94
31. Adjusted your phosphate binder dose to the size of your meal?	0.94
32. Asked questions and made decisions about your care with staff or your doctor?	1.00
33. Pointed out to your doctor that some part of your treatment was not working?	0.94
34. Took responsibility for parts of your care or treatment?	1.00

APPENDIX J I-CVI data from two rounds of rating across all themes, where 1 = not relevant and 4 = highly relevant.

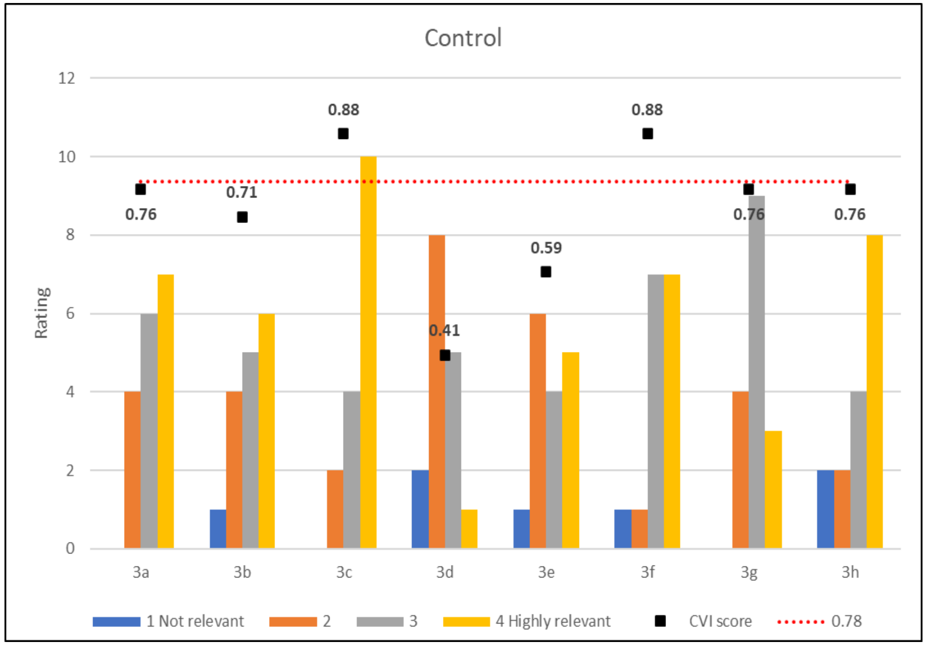


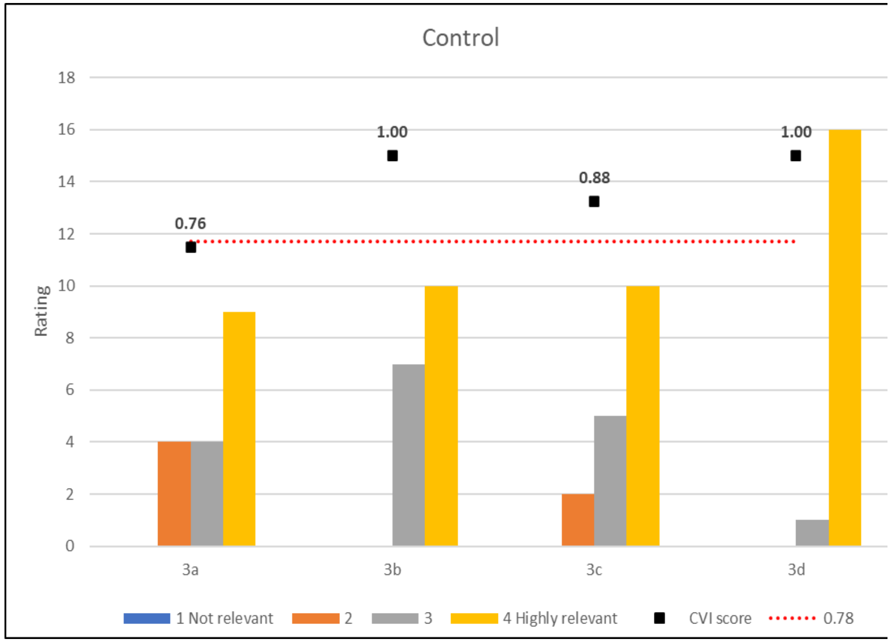


Key:

Item 1a – I've learnt to live with my kidney disease.
Item 1b – I have come to terms with the long-term nature of my kidney problem.
Item 1c – I accept the dialysis machine as part of my life now.
Item 1d– There have been occasions when I have told staff I wanted something changed about my treatment.
Item 1e – I live my life in a way that fits with who I am as much as possible.
Item 1f – I am angry about my kidney disease.
Item 1g – I have accepted my illness will not be cured.
Item 1h - Despite the dialysis I live as normal a life as possible.
Item 1i - I have accepted my kidney disease and adjusted.
Item 1j - I can face the challenges of living with kidney disease.

Item 1a – I have come to accept the long-term nature of my kidney problem.
Item 1b – I am angry about kidney disease.
Item 1c - Despite the dialysis I try to live as normal a life as possible.
Item 1d - I can face the challenges of living with kidney disease.

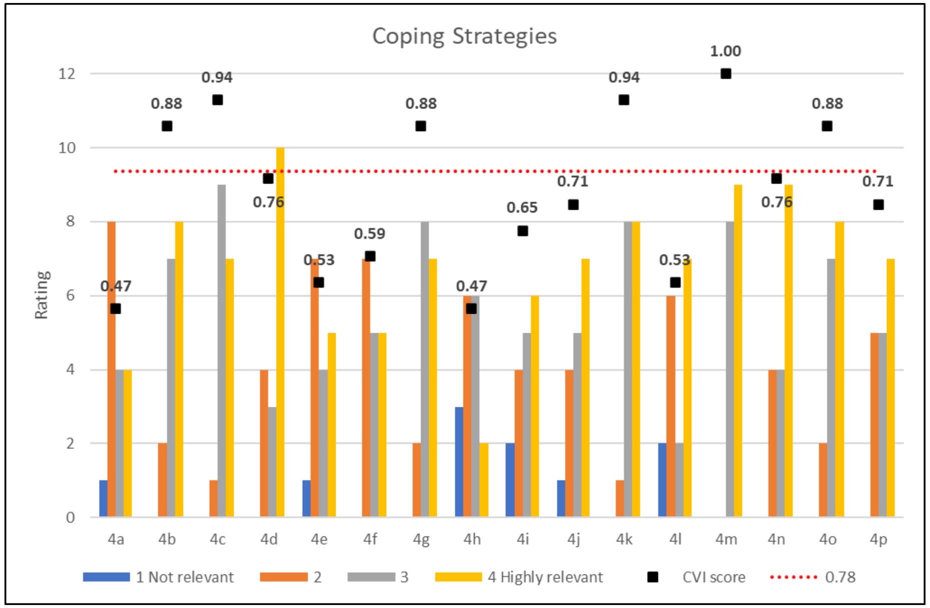




Key:

Item 3a – I can do the things I want to do.
Item 3b – At this time, I feel that my kidney disease is under control.
Item 3c - Since starting dialysis, I feel less able to control many of the important things in my life.
Item 3d - I do not dwell on things that I can't do anything about.
Item 3e - I am directly responsible for my condition getting better or worse.
Item 3f – I have at least some control over my dialysis treatment.
Item 3g - I have at least some control over the symptoms I experience.
Item 3h - Day to day I generally have a degree of control that allows me to function in a way that’s acceptable to me.

Item 3a - Since starting dialysis, I feel less able to control many of the important things in my life.
Item 3b – I feel I have enough control over my dialysis treatment.
Item 3c – I feel I have some control over my kidney disease symptoms.
Item 3d (new) – I play a large role in managing my illness.



Item 4a – When I encounter a problem with my health, I seek the help, information or support I need to deal with it.

Item 4b – I have put in place routines that help me to cope with my kidney disease.

Item 4c – I use my test results to help me decide what I eat and drink.

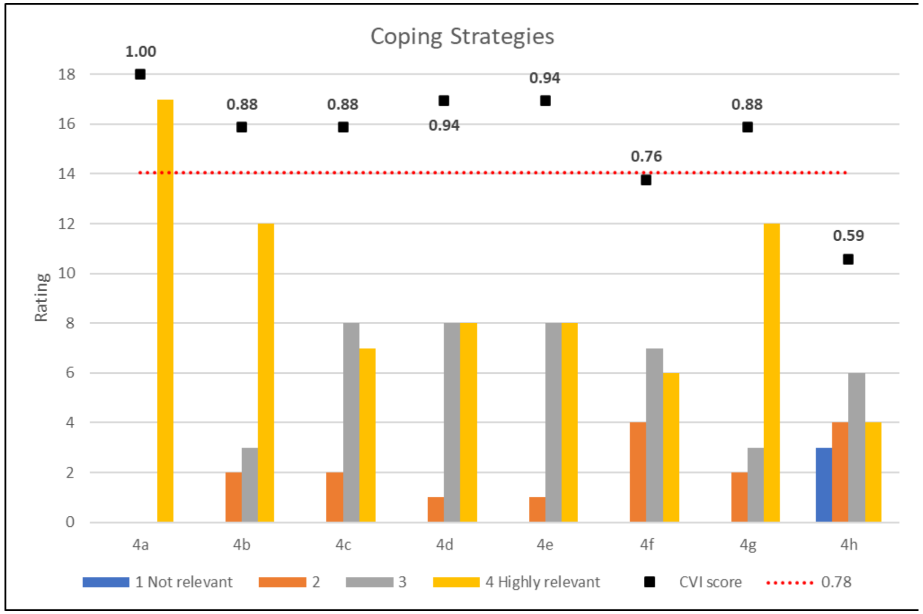
Item 4d – I [often] feel [that] I cannot cope with all the things I need to do.

Item 4e – I find it difficult to look after myself the way I would like to.

Item 4f – [Most of the time] I feel positive despite the ups and downs.

Item 4g (new) – [At times], I feel overwhelmed by my illness(es)

Item 4h (new) – Sometimes I eat the food I like even though I know I shouldn’t. Item 4p - I have learnt what makes some of my symptoms worse so I can avoid these things if I choose.



Item 4a – When I encounter a problem with my health, I seek the help, information or support I need to deal with it.

Item 4b – I have put in place routines that help me to cope with my kidney disease.

Item 4c - I use my test results to help me decide what I eat and drink.

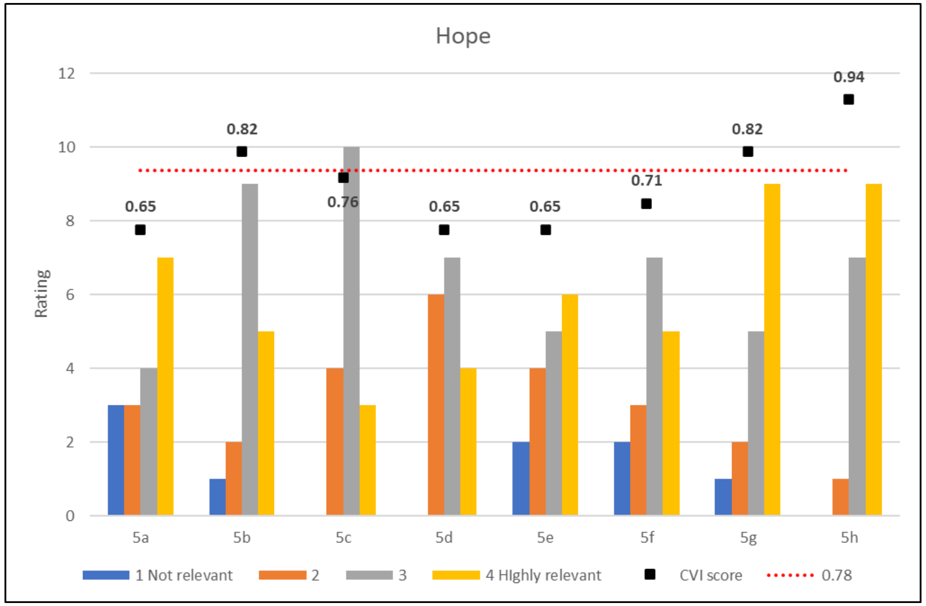
Item 4d - I [often] feel [that] I cannot cope with all the things I need to do.

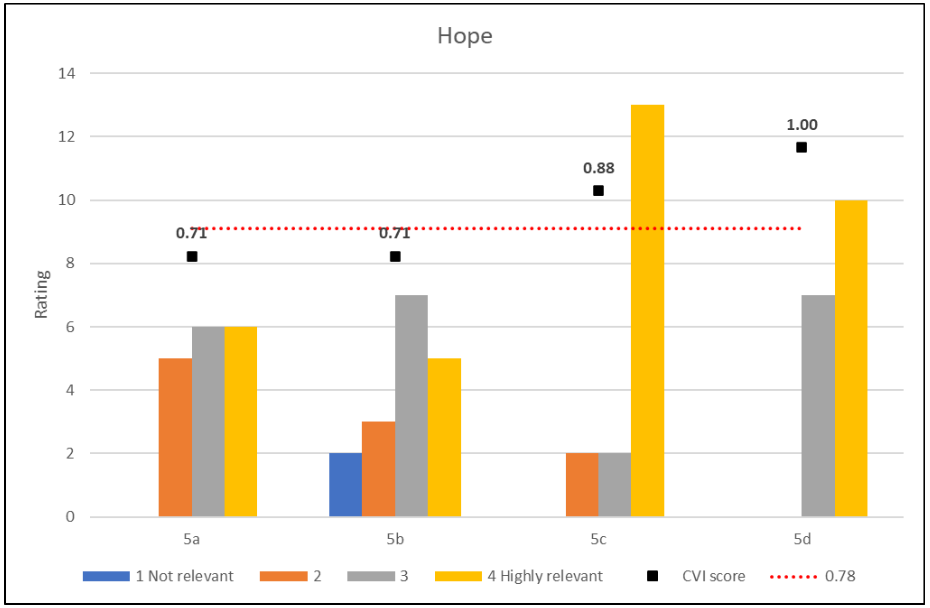
Item 4e - I find it difficult to look after myself the way I would like to.

Item 4f - [Most of the time] I feel positive despite the ups and downs.

Item 4g (new) - [At times], I feel overwhelmed by my illness(es)

Item 4h (new) - Sometimes I eat the food I like even though I know I shouldn't.

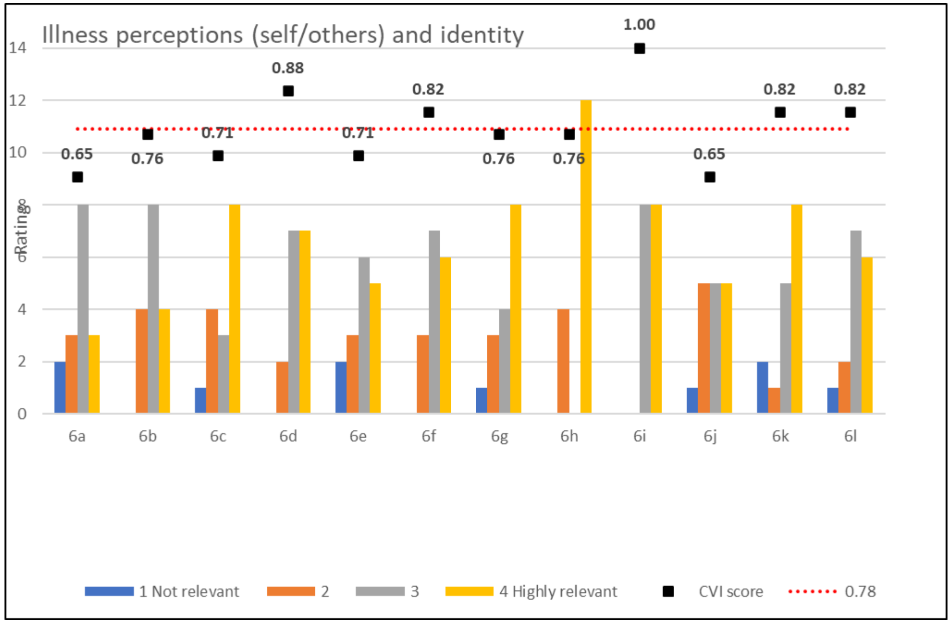




Key:

Item 5a - On the whole, I am responding well to treatment.
Item 5b – The care I receive is in line with my wishes.
Item 5c - It is harder for me to achieve my goals now.
Item 5d – I often think about what might happen with my illness in the future.
Item 5e - I have someone who makes me feel needed.
Item 5f - I often feel lonely.
Item 5g - I've been giving up the attempt to cope.
Item 5h - I have good things to look forward to.

Item 5a – The care I receive from my renal team is in line with my wishes.
Item 5b - Now that I am on haemodialysis it is harder for me to achieve my goals.
Item 5c – I have given up trying to cope with my kidney disease.
Item 5d - I have good things to look forward to.



Key:

Item 6a - The cause of my disease is a mystery to me.

Item 6b – One the whole, I understand the causes of my kidney disease.

Item 6c - Most of the symptoms I experience are directly related to my kidney disease.

Item 6d – I have got my head round the fact that I will always need treatment for my kidney problem.

Item 6e - I have hidden my illness from people in a social situations.

Item 6f - Sometimes I do not go to family or social events involving food and/or alcohol as I don't want others to know about my health problems.

Item 6g - The impact of haemodialysis on my life has been significant to me.

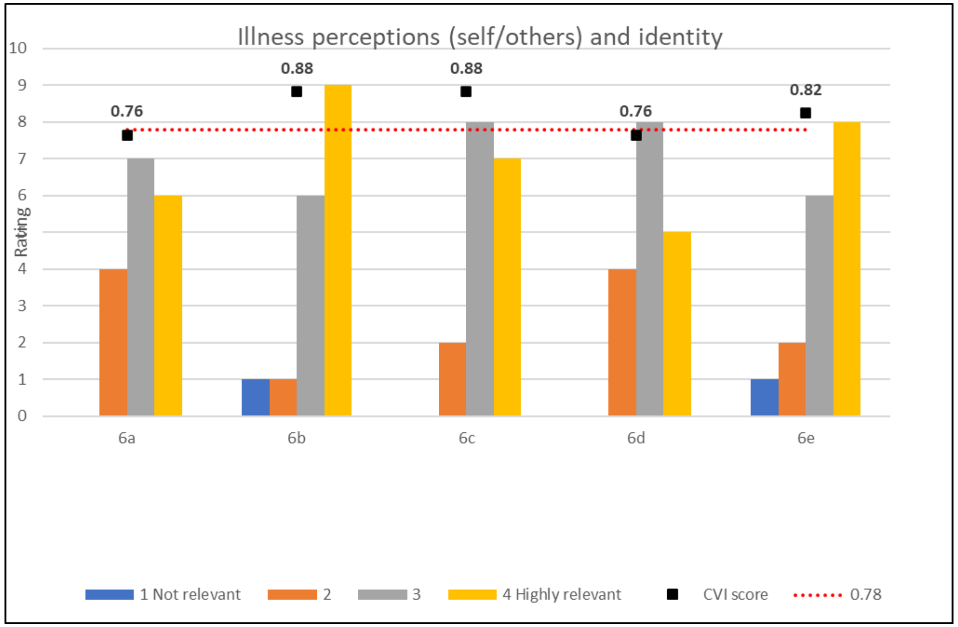
Item 6h - I play a large role in managing my illness.

Item 6i – At times, I feel overwhelmed by my illness.

Item 6j - When I think about myself, I think of my illness.

Item 6k - My illness has changed how I see myself.

Item 6l - My illness dominates my sense of self.



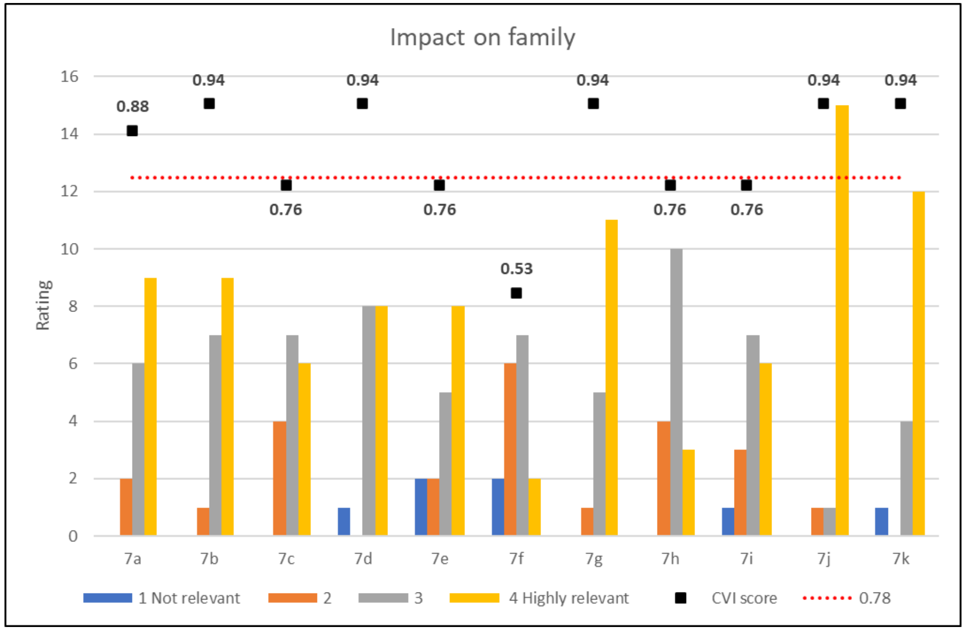
Item 6a - One the whole, I understand the causes of my kidney disease.

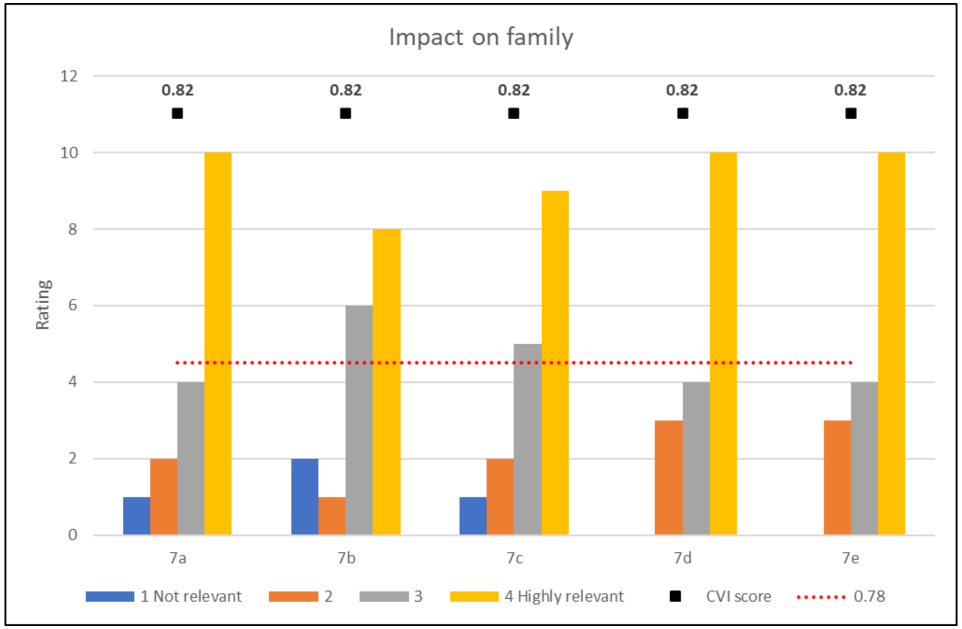
Item 6b – I believe that I will always need treatment for my kidney disease.

Item 6c - I sometimes avoid social situations [where there will be food and drink] as I don't want others to know about my kidney problems

Item 6d – Haemodialysis has had a significant impact on my life.

Item 6e – My kidney disease has changed how I see myself.

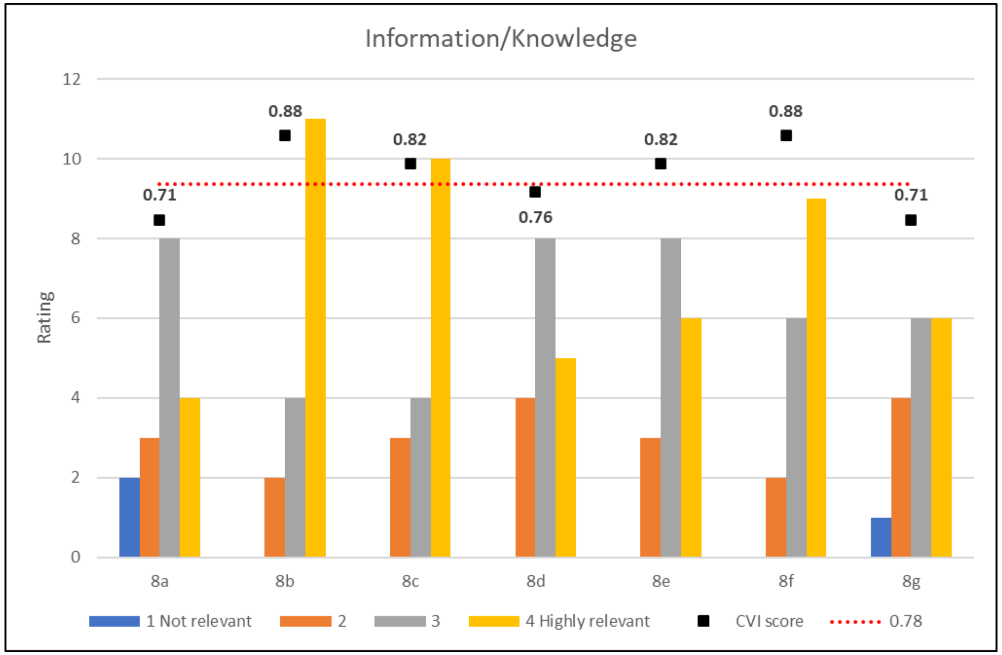


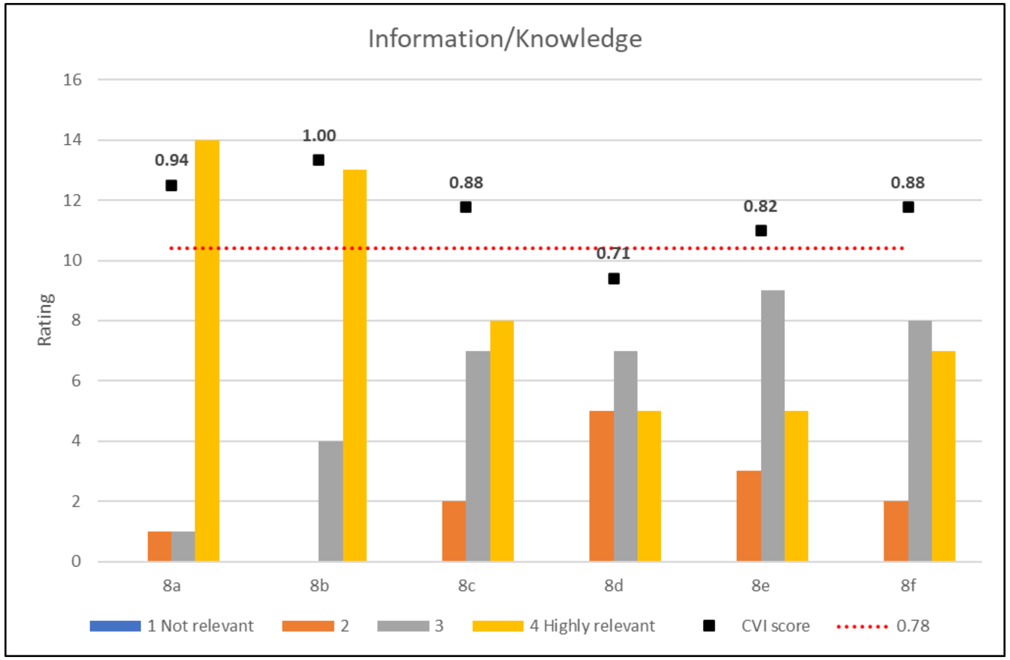


Key:

Item 7a – I have all the practical support I need to manage day to day.
Item 7b – My illness causes difficulties for those who are close to me.
Item 7c - My family and/or partner are often worried or anxious about me.
Item 7d - I have trouble meeting the needs of my family.
Item 7e - I feel I have to keep on going for my family.
Item 7f - My husband/wife/partner is unwilling to adjust their own diet to accommodate mine
Item 7g - I have shortened my dialysis time due to family or work commitments.
Item 7h - Sometimes I feel over protected or receive unwanted help from a family member, friend or partner.
Item 7i – Some emotions I have cause problems for my family.
Item 7j – I feel like a burden on my family.
Item 7k - My illness and/or its treatment interferes with my relationships.

Item 7a – My illness causes difficulties for those who are close to me.
Item 7b - I feel I have to keep on going for my family.
Item 7c (new) - There have been times when I have shortened my dialysis time due to family or work commitments.
Item 7d – I feel like a burden on my family.
Item 7e - My illness and/or its treatment interferes with my relationships.

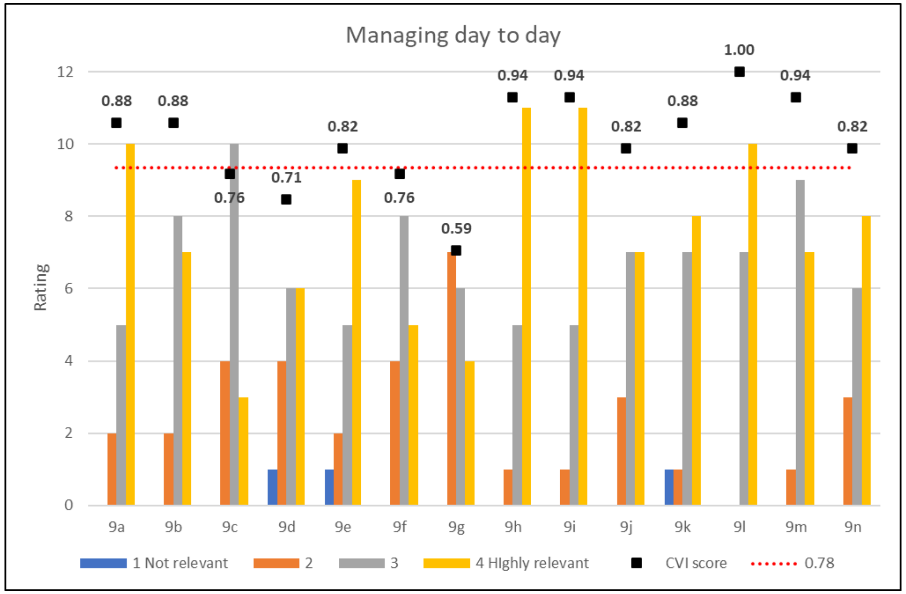




Key:

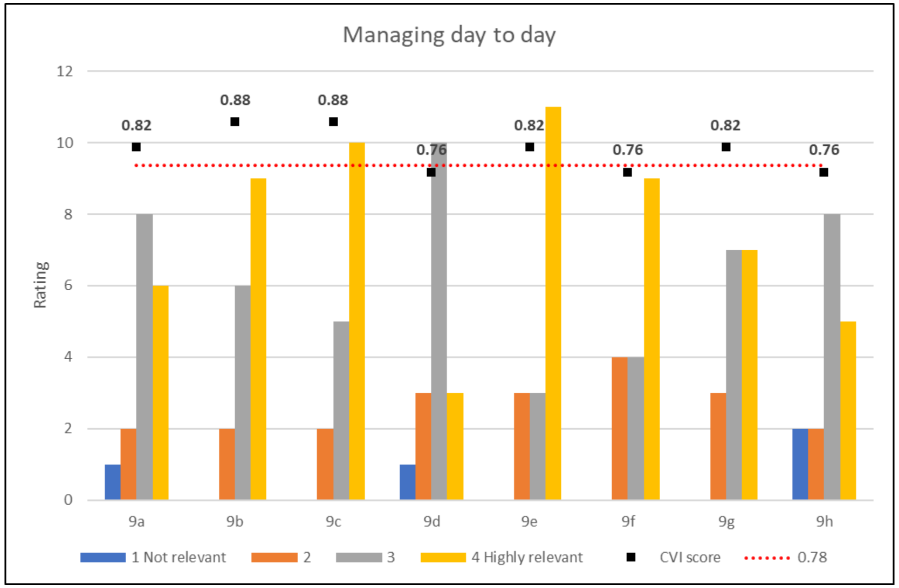
Item 8a – Past experience helps me to do deal with problems related to my kidney disease now.
Item 8b – When I encounter a problem, I seek the help or information I need to deal with it
Item 8c - I have enough knowledge about my disease to solve day to day problems related to it.
Item 8d - I seek information about my kidney disease for reassurance.
Item 8e - I have all the information about my illness and care available to me if I want it.
Item 8f - At this time, I feel that I have a good understanding of how my illness will progress.
Item 8g - I am the sort of person who likes to be prepared and plan ahead.

Item 8a – When I encounter a problem related to my kidney disease, I seek the help or information I need to deal with it.
Item 8b - I know enough about my kidney disease to solve day to day problems related to it.
Item 8c - I feel that I have a good understanding of how my illness will progress.
Item 8d (new) – I have looked for additional kidney diet information.
Item 8e (new) - I look for information or talk with a pharmacist about my medications.
Item 8f (new) - I've tried to learn more about the dialysis machine and other technical topics.

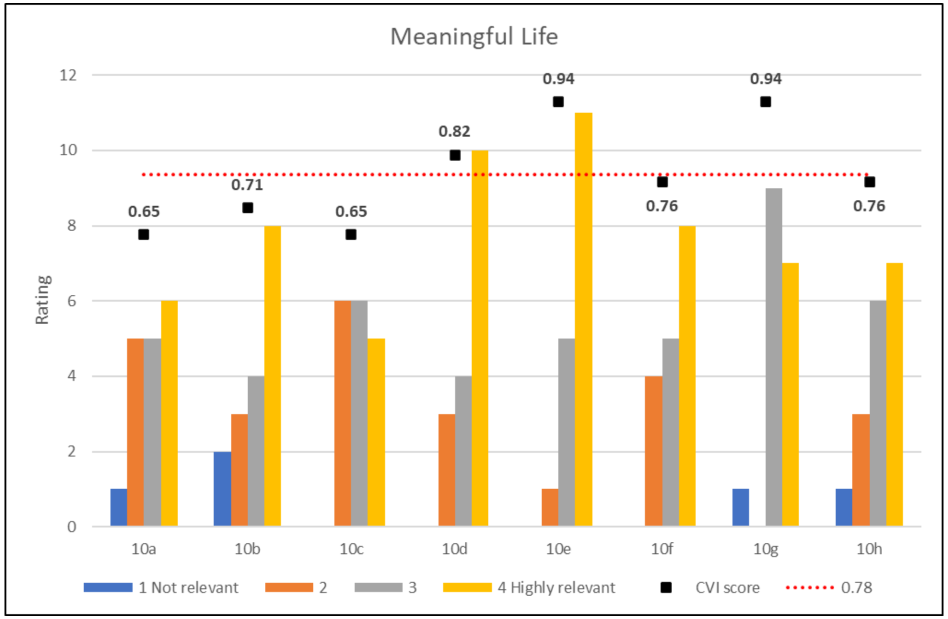


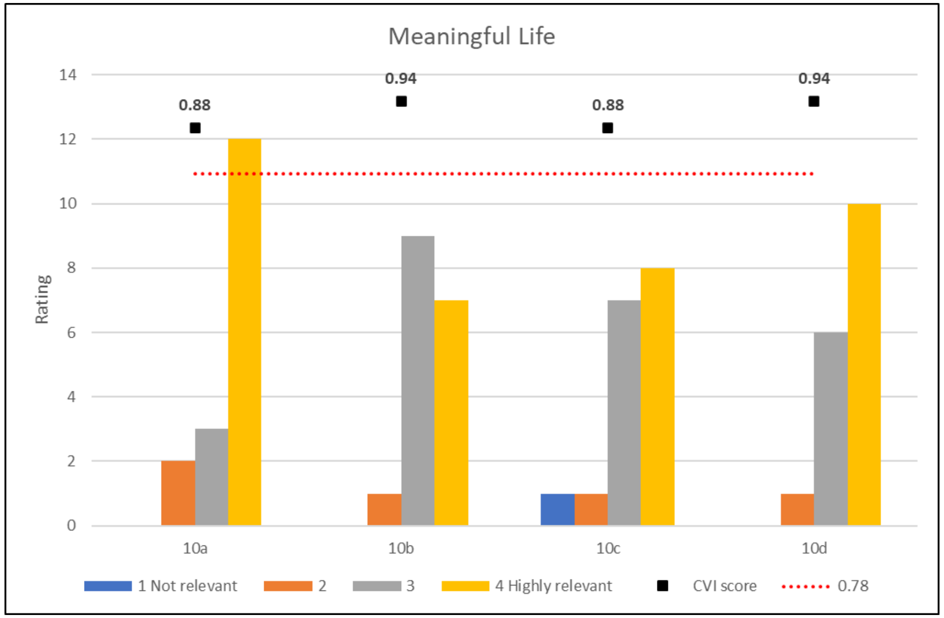
Key:

Item 9a - My kidney disease interferes too much with my life.
Item 9b – I get the support I need to manage my health and healthcare.
Item 9c - Much of the way I deal with my condition is dependent on other people.
Item 9d - I feel disengaged from my kidney care.
Item 9e - Managing my illness day to day requires a lot of effort.
Item 9f - My husband/wife/partner gives me advice and encouragement to help me manage day to day things related to my kidney disease, like diet and fluid intake.
Item 9g - My husband/wife/partner provides hands on help with tasks like preparing the right kind of diet and monitoring my fluid intake.
Item 9h - I monitor my diet so that I can make changes to my intake if necessary.
Item 9i – I monitor my fluids so that I can make changes to my intake if necessary.
Item 9j – I often experience disruption to my daily routine that prevents me taking my medication.
Item 9k - It matters to me that I take my medication.
Item 9l – One way or another I can manage most of the day-to-day tasks such as washing, dressing, jobs around the house.
Item 9m - My illness and/or treatment prevents me from doing as much exercise as I would like.
Item 9n - I am able to maintain independent living as much as I would like.



Item 9a - My kidney disease interferes too much with my life.
Item 9b – I get the support I need to manage my health and healthcare.
Item 9c - There is someone in my life whose advice and encouragement helps me manage my kidney disease day to day.
Item 9d - I have all the practical support I need to manage day to day.
Item 9e - I keep a careful watch on what I eat and drink so that I can make changes if necessary.
Item 9f - Often things can get in the way and cause me to miss taking my medication.
Item 9g – One way or another I can manage most of the day-to-day tasks such as washing, dressing, jobs around the house.
Item 9h - My illness and/or treatment prevents me from doing as much exercise as I would like.even though I know I shouldn't.

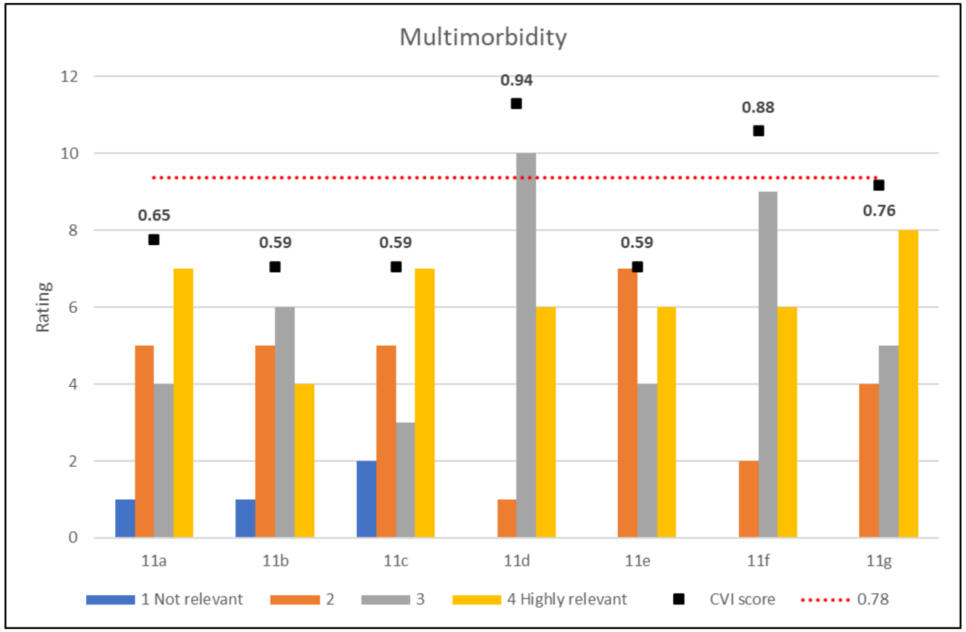


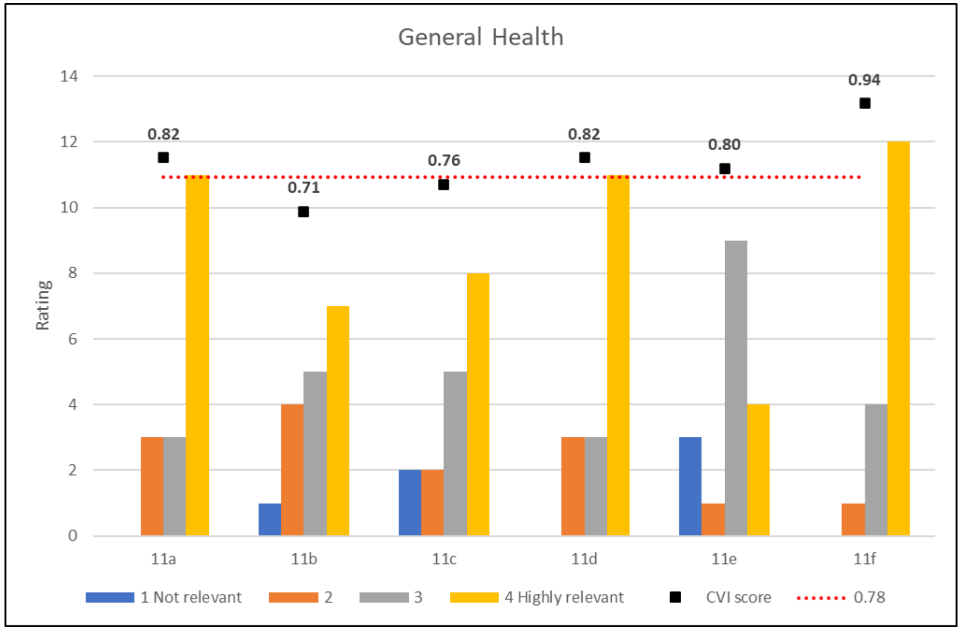


Key:

Item 10a - I have sought information about the possibility of travel (e.g., holidays) on dialysis.
Item 10b – I have had a holiday in the last year.
Item 10c - I would like to go on holiday sometimes and my kidney diseases prevents me from doing that.
Item 10d - I have a good balance between the demands of my illness and what I want to do with my life.
Item 10e - I have purpose and meaning in my life.
Item 10f - Mostly, I am still able to do the things I used to enjoy before dialysis.
Item 10g – I have activities and hobbies that keep me busy.
Item 10h - I take part in fewer social activities than I would like due to my illness and/or dialysis treatment.

Item 10a - I have a good balance between the demands of my illness and what I want to do with my life.
Item 10b - I am still able to do the things I used to enjoy before I had to start on dialysis.
Item 10c – I have activities and hobbies that keep me busy.
Item 10d - My kidney disease prevents me from taking part in social activities as much as I would like.





Key:

Item 11a - The burden of my medical conditions has changed the way I engage in looking after myself.

Item 11b – At this time, my kidney disease is not the illness that causes greatest bother.

Item 11c - When thinking about my health, the kidney disease takes priority.

Item 11d - Dialysis sometimes makes it difficult for me to access treatment for other conditions.

Item 11e - The renal staff are aware of my other health problems, beyond my kidney disease.

Item 11f - I feel the renal staff have a good understanding of all aspects of my health, including conditions unrelated to my kidney disease.

Item 11g – When I receive any medical care by another healthcare provider outside of the renal unit, I am confident this information is communicated to the renal team.

Item 11a - Being on dialysis makes it difficult for me to access treatment or attend appointments for my other health problems.

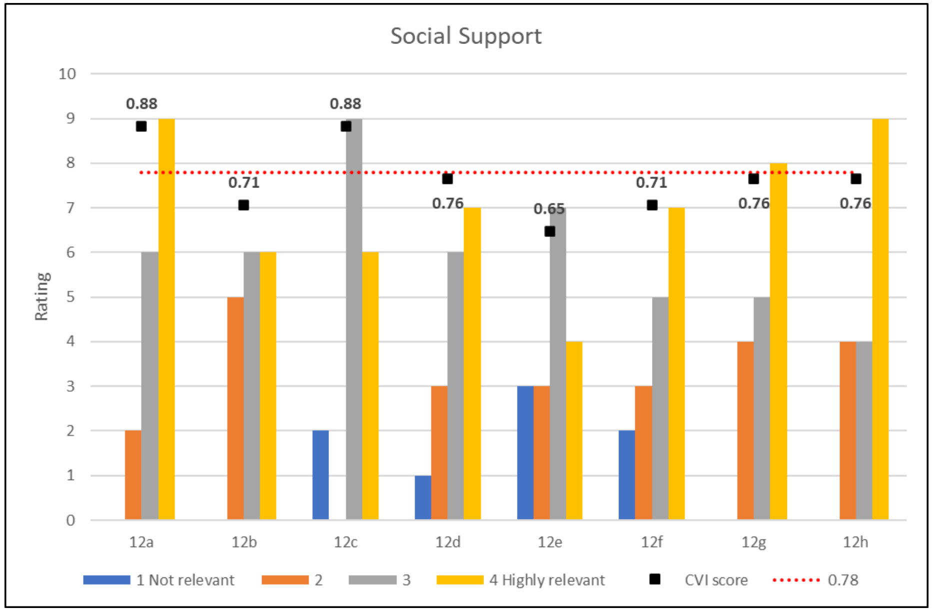
Item 11b- The renal staff have a good understanding of all my health conditions, not just my kidney disease.

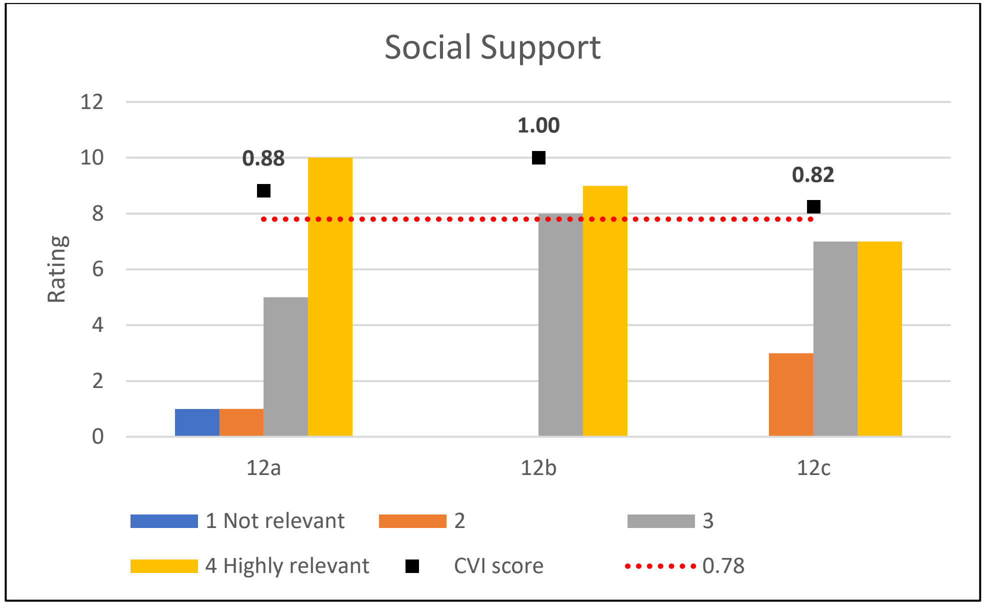
Item 11c (new) - I am confident that there is good communication between all the specialists I see.

Item 11d (new) - I often get conflicting advice from the different specialists I need to see.

Item 11e (formerly within support, MDT domain) - I am confident in the advice by GP gives me about my kidney disease.

Item 11f (new) – I have other health issues as well as my kidney disease and I find it difficult to cope with them all.

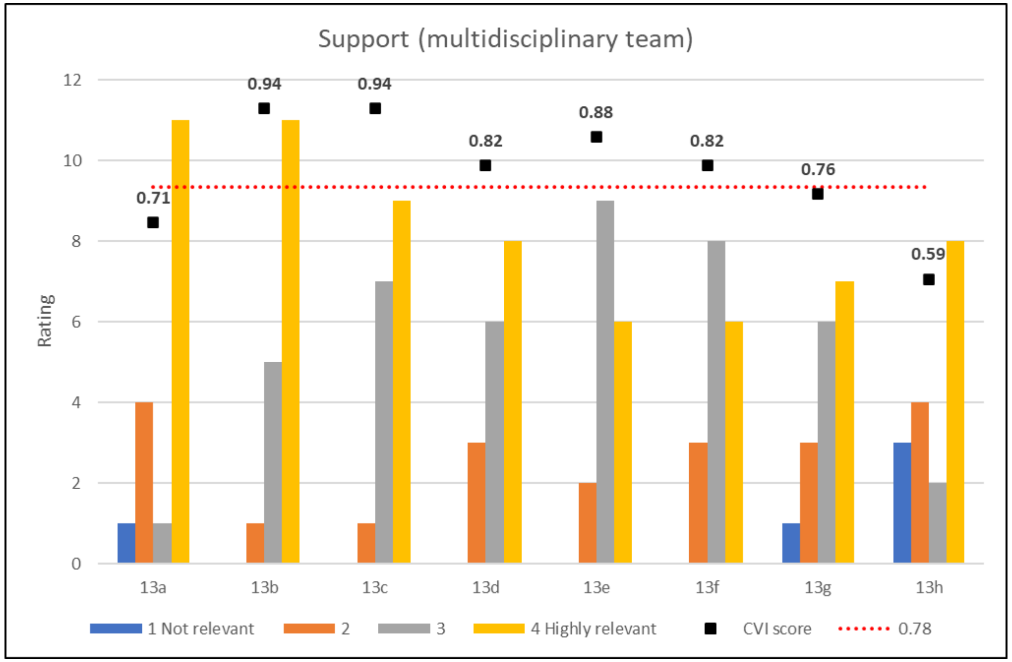


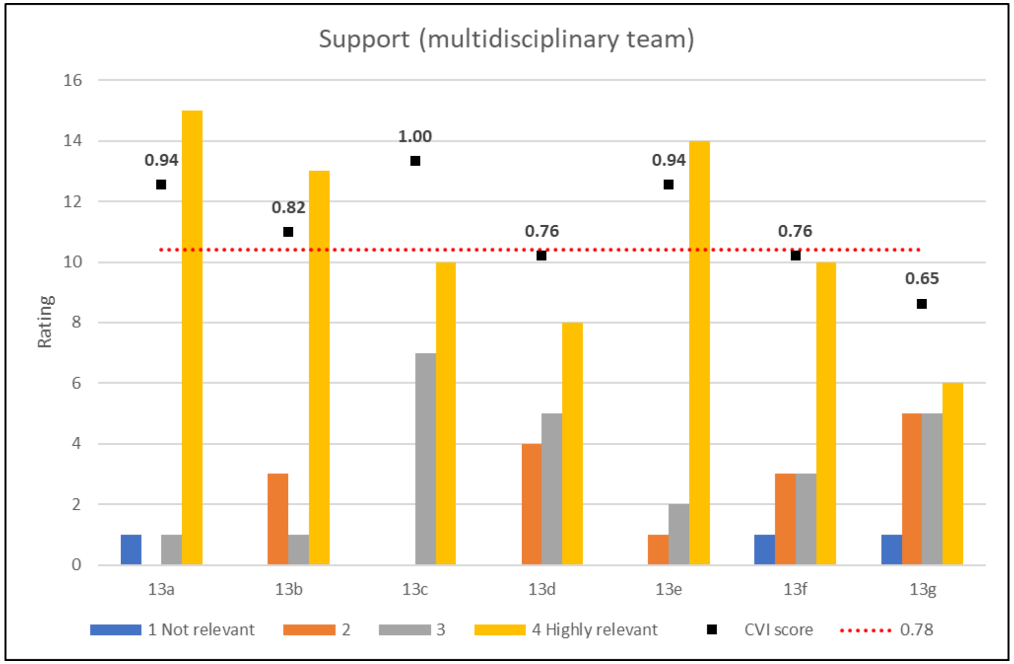


Key:

Item 12a - I ask family or friends for help when I am feeling frustrated or overwhelmed.
Item 12b – There is at least one friend or family member who gives me a nudge in the right direction with doing the right thing for my kidney disease.
Item 12c - I feel more disconnected from others now than before I started dialysis.
Item 12d - I have someone who will listen to me when I need to talk.
Item 12e - I am still able to help others sometimes.
Item 12f - I spend as much time with friends as I would like.
Item 12g – I have trouble doing all the family activities that I feel I should/that are important to me.
Item 12h – I try to avoid feeling lonely by seeking company from friends, family and/or other patients.

Item 12a - I feel more isolated than I did before I started dialysis.
Item 12b - I have someone who will listen to me when I need to talk.
Item 12fc- I seek the company of friends, family and/or other patients.

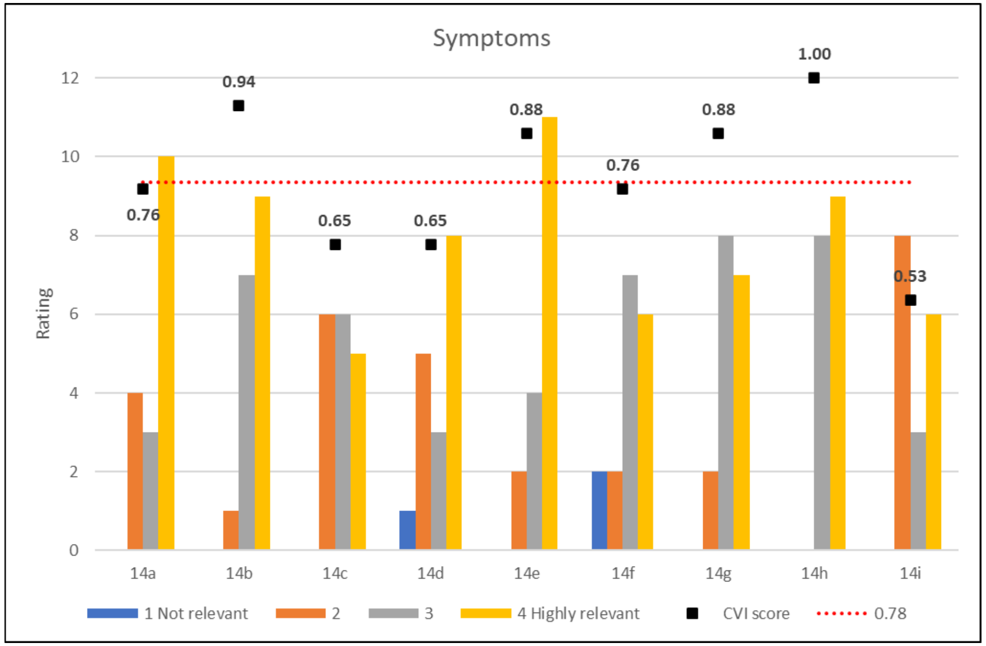




Key:

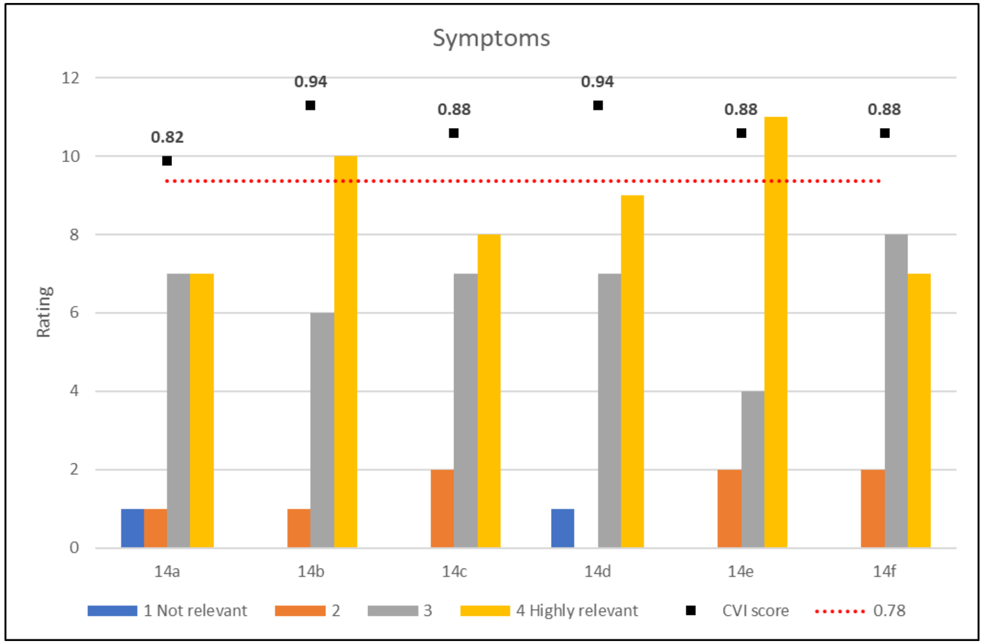
Item 13a - On balance, all things considered, I am satisfied with my dialysis treatment.
Item 13b – The renal team encourage me to be as independent as possible.
Item 13c - The relationship I have with the renal team generally supports my engagement with my care.
Item 13d - I feel that staff review my health and discuss any changes with me as often as I would like.
Item 13e - The renal team assist me in setting and achieving goals for myself.
Item 13f - There is always someone I can ask to support me on the dialysis machine.
Item 13g – I feel safe on the dialysis machine.
Item 13h - I am confident in my GP's knowledge and understanding of my kidney disease.

Item 13a – The renal team encourage me to be involved in my own care.
Item 13b – The renal team regularly review my health and discuss any changes with me.
Item 13c - The renal team support me with setting and achieving my goals.
Item 13d - There is always someone I can ask to support me when I'm on dialysis.
Item 13e (new) - I take responsibility for parts of my care or treatment that might otherwise be performed by renal staff.
Item 13f – I feel safe when I'm on the dialysis machine.
Item 13g (new) - I feel that I am treated differently compared with other patients.

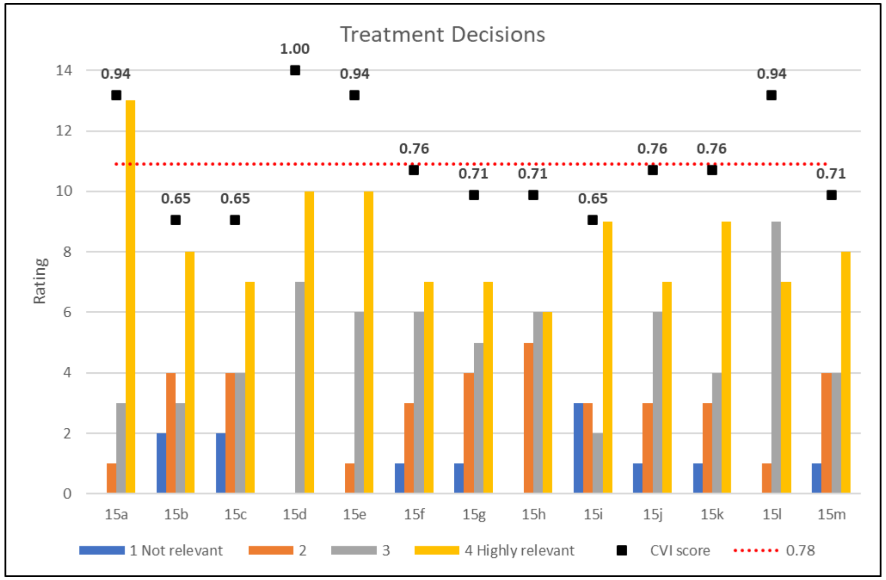


Key:

Item 14a - Most of the time I find one or more symptom overwhelming.
Item 14b – I often experience symptoms that interfere with the way I would like to live my life day to day.
Item 14c - I try to improve my sleep quality with activity or good sleep routines.
Item 14d - The pain I experience is not managed well.
Item 14e - Sometimes my feelings of distress are so intense they completely take over.
Item 14f - Generally, I feel more anxious now than I did before starting haemodialysis.
Item 14g – I often feel anxious or worried about my illness and/or treatment.
Item 14h - The level of tiredness I experience has a big impact on my ability to participate in life in the way I would like.
Item 14i - I reduce the number of things I do on the days I feel tired.



Item 14a –Symptoms often interfere with the way I would like to live my everyday life.
Item 14b - Sometimes my feelings of distress are overwhelming.
Item 14c – I often feel anxious or worried about the impact my kidney disease/treatment has on my life.
Item 14d – Tiredness stops me getting on with life the way I would like.
Item 14e (new) - I decide which problems to report to doctor / nurse and which to handle on my own.
Item 14f (new) - I have tried out different ways to handle problems or symptoms.



Key:

Item 15a - As much as I would like to be, I am involved in decisions about my care.

Item 15b – Everything I can decide, I will decide.

Item 15c - I trust the doctor to offer the right treatment choices for me.

Item 15d - Generally, I feel that all treatment options are presented to me by the renal team when I need to make a treatment decision.

Item 15e - When discussing treatment or management options I feel that what matters to me is considered by the renal team.

Item 15f - I try to avoid making treatment decisions myself.

Item 15g – I understood the side-effects and impact of dialysis on day to day life before I began treatment.

Item 15h - Before I started dialysis, I talked to other patients already on dialysis.

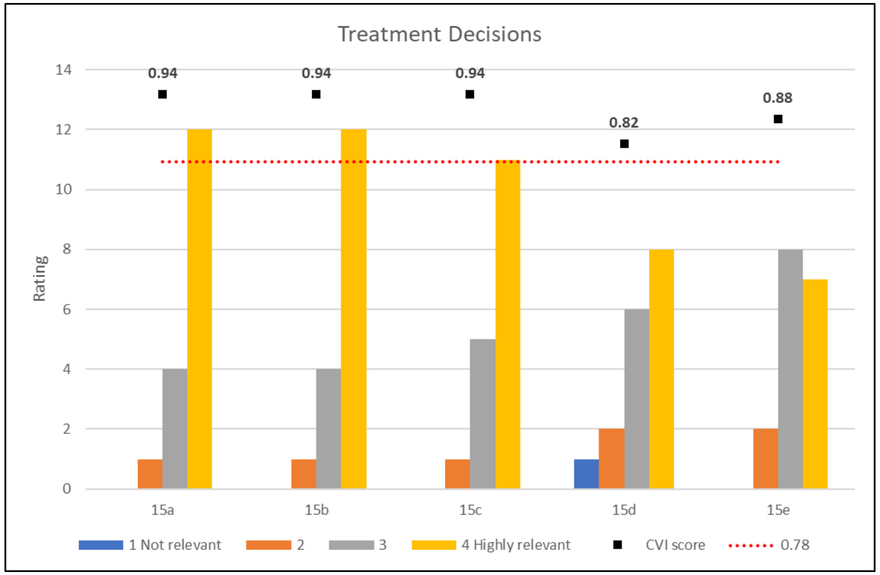
Item 15i - I regret the decision to start dialysis treatment.

Item 15j - When the decision was made to go on to dialysis, I was very unwell which had an impact on my ability to make the decision.

Item 15k - When the decision was made to go on to dialysis, I was emotionally distressed which had an impact on my ability to make the decision.

Item 15l - When I need to make a treatment decision, I talk it over with friends or family or other patients.

Item 15m - I make my own decision about which medicines to take.



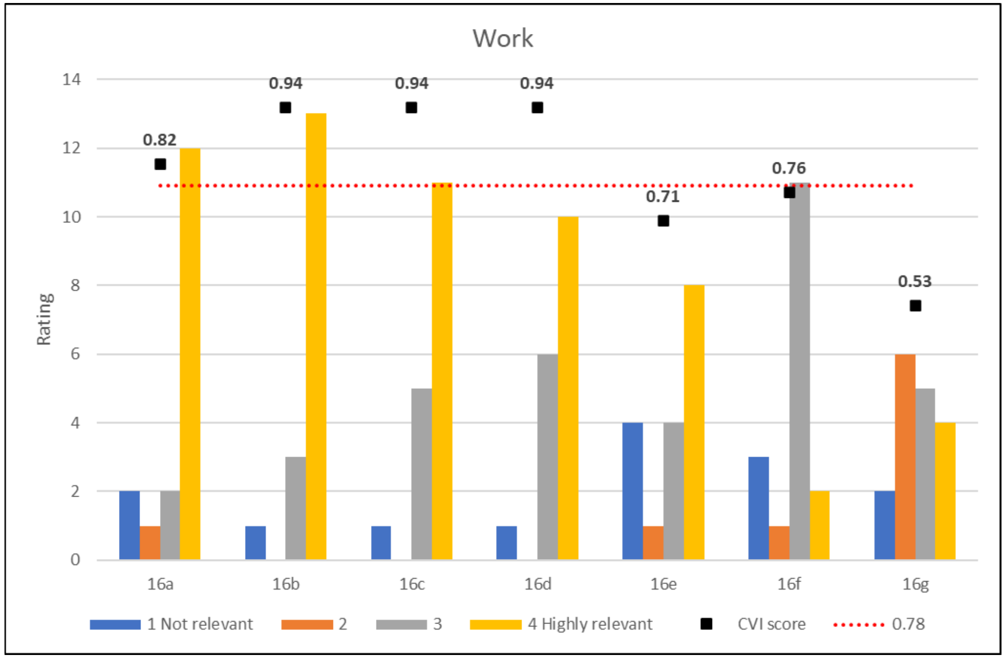
Item 15a - I am as involved in decisions about my care as much as I want to be.

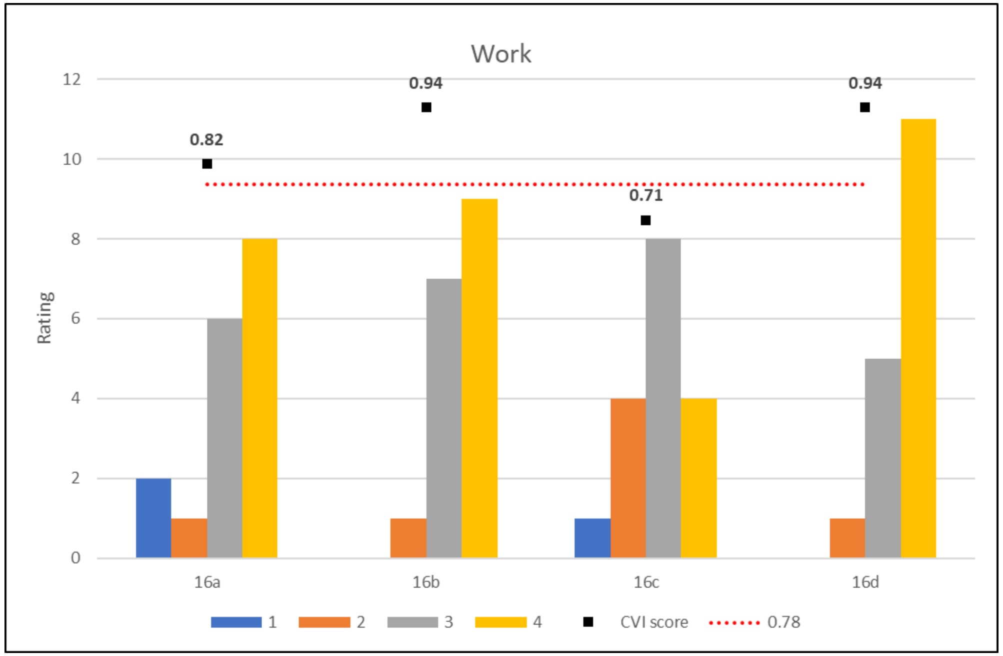
Item 15b - When discussing treatment or management options I feel that my views are fully considered by the renal team.

Item 15c - I try to avoid making treatment decisions myself.

Item 15d - I feel I wasn't as involved in the decision to start dialysis as I would have liked [because I was too distressed, or unwell]

Item 15e - When I need to make a treatment decision, I talk it over with someone I am close to.

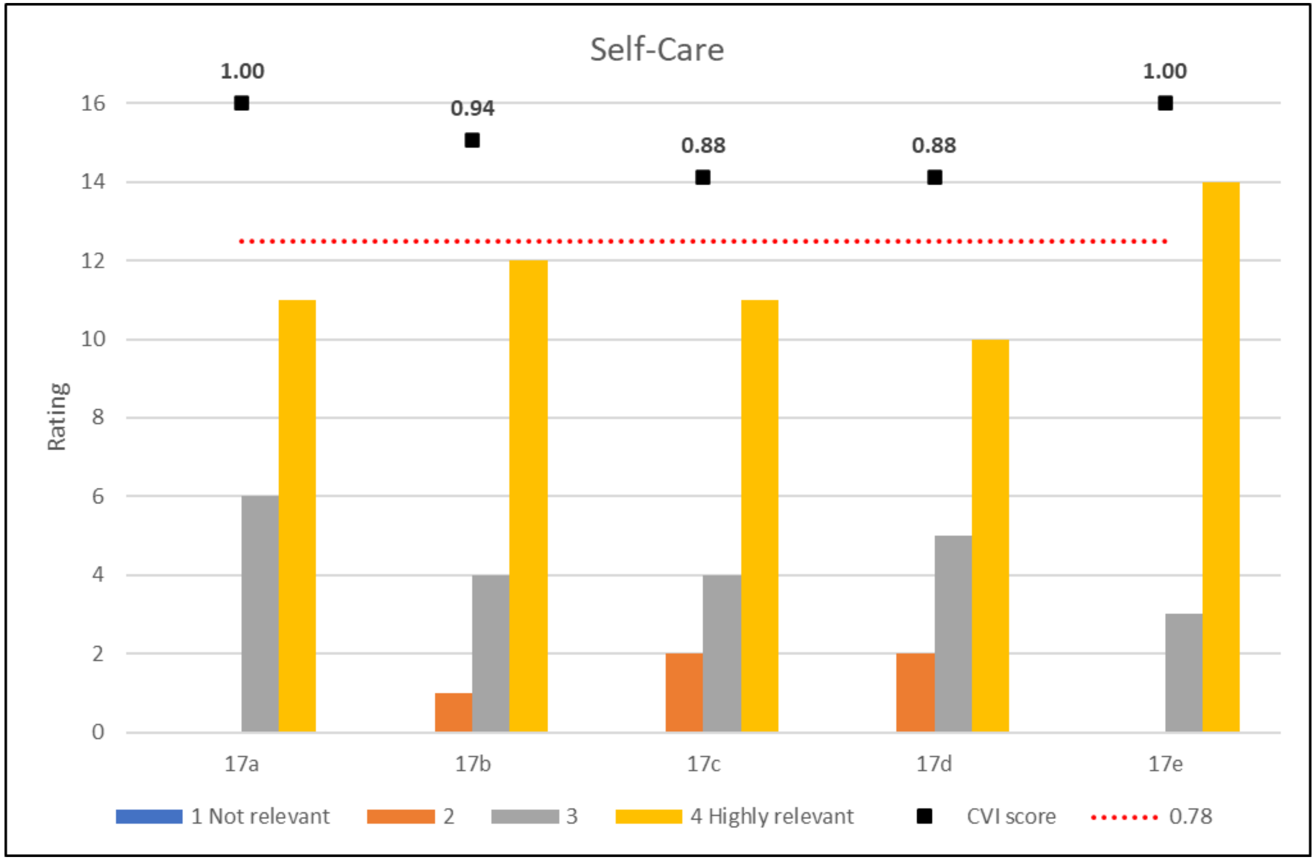




Key:

Item 16a - I am in paid employment.
Item 16b – My health prevents me from working.
Item 16c - My ability to do paid work is really affected by my health.
Item 16d - Dialysis treatment makes work difficult.
Item 16e - My family would be unable to manage if I could not work.
Item 16f - I think that people would/do discriminate against me because of my illness.
Item 16g – I avoid talking about my kidney problems with people I work with.

Item 16a - I am in paid employment.
Item 16b - Haemodialysis treatment makes keeping working difficult.
Item 16c - I think that people would/do discriminate against me because of my illness.
Item 16d - My ability to do paid work is really affected by my health.



Key:

Item 17a - I help decide where the needles should be placed.
Item 17b - I help decide how much fluid should be taken off.
Item 17c - I adjust my phosphate binder dose to the size of my meal.
Item 17d - I check settings on the dialysis machine to make sure they are the same as usual.
Item 17e - I feel confident doing the dialysis myself.

APPENDIX K Items removed post I-CVI round 2, prior to cognitive pre-testing, based on decisions by research team.

Items	Key changes	Reason
There have been occasions when I have told staff I wanted something changed about my treatment or care.	Removed despite I-CVI score .88.	Content covered by 'The renal team regularly review my health and discuss any changes with me' AND 'When discussing treatment options, I feel that my views are considered by the renal team".
I use my test results to help me decide what I eat and drink.	Removed despite I-CVI score 0.88.	Some duplication with 'I keep a careful watch on what I eat and drink so that I can make changes if necessary'
I am confident that there is good communication between all the specialists I see.	Question retained despite I-CVI score 0.76.	Research team view it as extremely relevant considering importance of holistic treatment and MDT.
I have a good balance between the demands of my illness and what I want to do with my life.	Removed despite I-CVI score 0.88.	Content covered by 'My kidney disease interferes too much with my life'.
I often feel anxious or worried about the impact my kidney disease/treatment has on my life	Removed despite I-CVI score 0.88.	Q14b about distress is enough to cover the anxiety aspect of Content covered by 'Some days my feelings of distress are overwhelming' Plus, worry is a relatively generic "mild" state.

APPENDIX L Word changes post I-CVI round 2, based on decisions by research team and comments made by consensus panel.

Original wording	**Revised wording**	**Comments from consensus panel**
I have come to accept the long-term nature of my kidney problem.	I have come to accept the life-long nature of my kidney problem	I know long-term is always used but it's actually life-long?
Despite the dialysis I try to live as normal a life as possible	Despite being on dialysis I try to live as normal a life as possible.	The phrase 'the dialysis' seems strange and I wonder if this needs to be re-worded. E.g. 'being on dialysis'?
I feel I have enough control over my dialysis treatment	I feel I have control over my dialysis treatment. Anchors altered to reflect degree 'no control'/'enough control'	Overlap with the previous question 'Since starting dialysis, I feel less able to control the important things in my life'.
I feel I have some control over my kidney disease symptoms	I feel I have control over my kidney disease symptoms.	As for above 'no control'/'some control'
I play a large role in managing my illness	I have an important role in managing my illness.	not sure how clear the term 'large role' is. Suggest: 'I take responsibility for managing some aspects of my illness'
I [often] feel [that] I cannot cope with all the things I need to do.	I feel that I cannot cope with all the things I need to do.	The brackets are confusing, I would not use often, it doesn't need to be often for it to be important or worthy of discussion -maybe sometimes is better?
[At times], I feel overwhelmed by my illness(es)	I feel overwhelmed by my kidney disease.	I think it should specifically be asking about kidney disease- it's very hard to answer a question about many diseases, as a person might be overwhelmed by some and not others.
Being on dialysis makes it difficult for me to access treatment or attend appointments for my other health problems	Being on dialysis makes it difficult for me to get the care I need for my other health problems.	Could we take out 'access treatment or' and it mean the same thing? Add sometimes?
I often get conflicting advice from the different specialists I need to see.	I get conflicting advice from the different specialists I see.	shouldn't it be more about all the 'healthcare professionals' as are GPs defined as specialists? What about diabetes nurse specialists etc.
I sometimes avoid social situations [where there will be food and drink] as I don't want others to know about my kidney problems	I avoid social situations [where there will be food and drink] as I don't want others to know about my kidney problems.	Use of "food and drink" too directive. May be other reasons, exclude.

My kidney disease has changed how I see myself	I see myself more negatively since the kidney disease.	Research team felt this should be more specific.
I feel I have to keep on going for my family	The main reason I keep going is for my family and/or people close to me.	family and people close to me? Some people may not have close family but may have close friends
There have been times when I have shortened my dialysis time due to family or work commitments	I have shortened my dialysis time due to family or work commitments.	Research team felt this could be more concise without losing meaning
I feel like a burden on my family	Sometimes I feel like a burden on my family.	Might be upsetting for the patient to answer.
I feel that I have a good understanding of how my illness will progress	I understand how my illness will progress.	Research team felt this could be more concise without losing meaning.
I look for information or talk with a pharmacist about my medications.	I understand what my medications are for.	Split sentence, why pharmacist in particular?
I've tried to learn more about the dialysis machine and other technical topics.	I've tried to learn more about my dialysis.	Suggested 'technical issues related to my dialysis treatment'. Research team decided to simplify.
My kidney disease interferes too much with my life	My kidney disease interferes with my life. Anchors altered to reflect 'too much'/'not at all'	It does for all kidney patients.
There is someone in my life whose advice and encouragement helps me manage my kidney disease day to day.	There is someone in my life whose advice and/or encouragement helps me manage my kidney disease day to day.	Amendment made by research team, may not be both advice and encouragement.
One way or another I can manage most of the day-to-day tasks such as washing, dressing, jobs around the house.	One way or another I can manage most of the things I need to do day-to-day.	Research team felt this could be more concise without losing meaning.
I am still able to do the things I used to enjoy before I had to start on dialysis.	There are things that I miss that I used to enjoy before I had to start on dialysis.	Change made by research team, they felt changing the emphasis improves the question.
My kidney disease prevents me from taking part in social activities as much as I would like.	My kidney disease prevents me from taking part in social activities	Research team felt this could be more concise without losing meaning.

I take responsibility for parts of my care or treatment that might otherwise be performed by renal staff.	I take responsibility for parts of my care that might otherwise be done by renal staff.	Research team felt language could be simplified.
Symptoms often interfere with the way I would like to live my everyday life.	My symptoms interfere with the way I would like to live my everyday life. Anchors altered to reflect 'Hardly ever'/'often'	I would begin with MY symptoms.
Sometimes my feelings of distress are overwhelming	Some days my feelings of distress are overwhelming.	Research team felt this question should be more specific.
Tiredness stops me from getting on with life the way I would like.	Tiredness stops me from getting on with life.	Research team felt this could be more concise without losing meaning.
I decide which problems to report to doctor / nurse and which to handle on my own	I know which problems or symptoms to consult the renal team about.	Maybe always say care team/renal team, or are you specifically interested in doctor and nurse? Suggested wording "I decide which problems I discuss with the renal team and which to handle myself"
When discussing treatment or management options I feel that my views are fully considered by the renal team.	When discussing treatment options, I feel that my views are considered by the renal team.	Be consistent for care team and renal team. Research team felt this could be more concise without losing meaning.
I feel I wasn't as involved in the decision to start dialysis as I would have liked [because I was too distressed, or unwell]	I feel I wasn't as involved in the decision to start dialysis as I would have liked.	I wonder why you have added the section in brackets - it makes it more difficult to answer the question
When I need to make a treatment decision, I talk it over with someone I am close to.	When I need to make a treatment decision, I talk it over with someone I trust.	Medical, Family, Friend? Suggested wording "When I need to make a treatment decision, I can talk it over with someone I trust"
Haemodialysis treatment makes keeping working difficult	Haemodialysis treatment makes working difficult.	Question phrase isn't completely clear to read - Being on dialysis makes it difficult to work (paid employment) OR My haemodialysis treatment makes it difficult to keep working.
My ability to do paid work is really affected by my health.	My ability to work is really affected by my heath.	Do you want to specify kidney disease? "My ability to work is affected by my haemodialysis treatment"

APPENDIX M Cognitive pre-testing topic guide.

Self-management behaviour scale

July 2019

Introduction

1. Confirm participant has seen patient information sheet and answer any questions.
2. Introduce self – background. Thank participant for agreeing to be part of the study.
3. Background to study so far – some patients may have been involved in phase one. We have developed a set of patient-centred questions and would like to know whether these questions are meaningful to patients and fit for purpose? Identify common problems with any questions and reduce vagueness or uncertainty in meaning.
4. Structure – The testing will take up to an hour.
5. Take written consent, reconfirm permission for audio once recording has begun.
6. Write patient ID onto copy of questionnaire and give to respondent. Check whether they would like interviewer to read questions to them as they follow on their own paper copy or need any assistance in marking their response to the questions.

Patient background

- Please tell me a little about yourself - (if respondent was involved in phase 1 reflect back 2-3 key things you remember about them) - your kidney disease, your family and work life, any interests or hobbies and anything about your treatment or kidney care that you'd like to share.

Self-management behaviour scale

- Explain the purpose of collecting the demographic data and ask them to read the questions and comment.
    - Specifically, do we need to ask about employment and ethnicity in such detail?
    - Sense-check pill and medication burden questions. Is the wording, right?
    - Any other comments.

- Ask them to read the introduction to the main questionnaire.
    - What did you understand from it?
    - Is anything missing?
    - Does anything need rewording?

- Go through specific sets of questions, vary the order to ensure adequate coverage.

  Sampling plan

    - 1-21 (acceptance, communication, control, coping, gen health, hope)
    - 22-29 (illness perceptions, impact on family)
    - 30-45 (info & knowledge, managing, meaningful life, social support)
    - 46-49 (support MDT) – focus particularly on response options
    - 50-53 (symptoms) - have we got the wording of these Q's right?

    - 54-58 (decision making)
    - 59-63 (self-care) – focus particularly on response options
    - 64-66 (work)

- In terms of response options specifically
    - Always/Never appropriate? (Q12-15, 30, 45, 53, specifically)
    - Completely true/Not at all true valid? (Q24-26, 29, 44, 57)
    - Would it be valid to use Strongly disagree/Strongly agree throughout?

- Are there questions which patients find particularly sensitive or distressing (perhaps Q14, 20, 28, 32, 43, 51).

Method

- A sampling plan will be used (see above). Each patient will be given sets of questions rather than asked to respond to the entire scale. This avoids undue respondent burden (Irwin et al., 2010) but ensures all questions are tested by 3 or more patients across the sample (n=12).
- The cognitive interview will use a combination of verbal probing and think aloud. This will allow clarification and refinement of questionnaire items, as well as examining the thought processes involved in answering the questions.
- Participants must verbalize their thoughts and understanding as they read each survey question aloud and then attempt to answer the question as they understand it. The interviewer will ask them to also mark the relevant answer on the paper questionnaire for reference.

  Comprehension, memory retrieval, judgement and response mapping (Hay et al., 2014):

    - Do you understand what you are being asked?
    - Can you recall the information to answer the question? And/or what information are you using to answer this question?
    - Can you make the judgement about where to mark the scale?

  Other possible probes:
    - Is this question meaningful to you? Do you think it may be meaningful to other dialysis patients?
    - Do you think this question would be better asked in a different way?
    - Do the response categories fit the question?
    - How do you feel answering this question?
    - Do you see any problems with this question?
    - How do you make the decision about where to the circle on the 7-point scale?
    - Should not applicable or don't know be an option for each question?
    - Where the patient indicates there are issues, it is important to ensure the interviewer ascertains -

        - Why is the question problematic?
        - How could we improve the wording?
        - Should the question be eliminated?

- Interviewer must note body language, questions raised and generate a checklist of problems and comment next to each item.

- Talk about the response the respondent has provided.
    - If the respondent can't respond to a question, find out why.

- Ask about response options and time frames where relevant.
- Ask about thoughts on ordering of questions.
- Ask about whether each question should be retained or deleted.

- Where participants seem to have few issues, after each set of questions ask the patient to consider the questions overall:

    - Did you have difficulty answering anything on this page?
    - Were there any questions you had difficulty answering?
    - Do you think the response options fit the question?

Home dialysis patients

For patients that do dialysis at home, there are some other specific questions.

- All of these patients must look at the questions about self-care (Q59-63).
    - Are these questions applicable for you?
    - Are they worded correctly?
    - Are there any questions about self-care you think have been missed that are important to you?
- Of the other questions they look at, do any of them feel less relevant to them as home-dialysis patients?

Development

- To inform future development of the scale all participants will be asked:

    - Do you think asking these types of questions to dialysis patients is –
        - Acceptable?
        - Useful?
        - Could help guide how patients are treated and cared for?

    - How do you think your care team might use the information provided by patients in this kind of question?

    - How should we include patients in continuing to develop this set of questions?

End of interview

1. Is there anything else the participant would like to say that hasn't been covered?
2. Are there any questions they would like to ask?
3. Remind them that they can contact you if they have any questions, and where they can seek support if talking about any of the issues was difficult (details on Patient Information Sheet).
4. Thank the participant for their time.

APPENDIX N Cognitive pre-testing free text coding frame.

Clarity of meaning, does the respondent understand what they are being asked?

Do they know where to mark the scale? Hesitations in response.

Specific comments on wording, response categories or tone.

Issues – where the question problematic, why? Should the question be eliminated?

If the respondent can’t respond to a question, why?

Acceptability, appropriateness, and potential distress caused by any of the questions.

APPENDIX O Final word changes based on cognitive pre-testing.

Original wording	Comments	Revised wording
In conversations about my care, I feel I'm treated as a whole person rather than someone with an illness.	One patient said they answered this in terms of people generally rather than in relation to clinical teams.	When I talk to the renal team about my care I'm treated as a whole person rather than someone with an illness.
Sometimes I feel like a burden on my family	Sometimes is a description of frequency, scoring showed a tendency for respondents to circle 4 (potentially as a neutral response) or 7. Perhaps because it may be uncomfortable to think of oneself as a burden.	I worry that I am a burden on my family
I have put in place routines that help me to cope with my kidney disease.	Two patients emphasised the importance of routines "basically day-to-day, life isn't it?" and "You have to have routines". Another patient though, seemed unclear about the meaning of the question and answered in terms of exercise routines.	I've organised my daily routines to help me cope with my kidney disease.
I've tried to learn more about my dialysis.	This question was viewed as ambiguous. Tried but not succeeded?	I'm interested in learning more about my dialysis. Response options also changed to reflect change in item wording. Not at all/very actively to strongly disagree/strongly agree.
I try to avoid making treatment decisions myself.	One patient scored this in the middle of the scale but described a view that was closer to strongly agree. Perhaps indicating this might be better framed more positively to mitigate against response bias.	I prefer not to make treatment decisions myself.
I feel I have control over my kidney disease symptoms.	Most patients interviewed talked about symptoms related to other conditions.	I feel I have control over my symptoms.
I believe that I will always need treatment for my kidney disease.	The meaning was unclear for one patient, it was felt more specific wording was required.	I believe that to stay well, I will always need some kind of treatment for my kidney disease.

I have given up trying to cope with my kidney disease.	Four respondents commented directly on this item all expressing a similar sentiment "If you've given up you'd may as well lie down and die". Another said "I think whether this question is answered honestly will depend on the person". In response, the wording was softened.	I find it hard to cope with my kidney disease.
feel that I cannot cope with all the things I need to do. **Always/never**	Change response categories (too extreme) should be about frequency e.g. 'Sometimes'. Unlikely any person with or without CKD always feels able to cope.	Often/never.
I feel I have control over my dialysis treatment. **I feel I have control over my kidney disease symptoms.** **No control/Enough**	Both of these questions were omitted by one respondent, but the responses showed variation across the scale indicating relevance. Perceived control is an important factor in self-management so both questions were retained but repetition of the use of control was removed from the response anchor.	None/Enough
I feel overwhelmed by my kidney disease.	This is a strong statement and 4/7 respondents that reviewed this item commented on the word "overwhelmed". One equated it with feeling "sorry for yourself" and another struggled with the question despite further explanation of the meaning.	I sometimes feel overwhelmed by my kidney disease. The original response option was incorporated into the question so the response changed from sometimes/always to strongly agree/strongly disagree.

APPENDIX P RESPONSE DISTRIBUTION OF SIX DROPPED ITEMS POST COGNITIVE TESTING.

Item - omitted	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	R11
There is someone in my life whose advice and/or encouragement helps me manage my kidney disease day to day.	4		1			7	7	7	7	7	1
I keep a careful watch on what I eat and drink so that I can make changes if necessary.	4		6			7	4	1	5	6	N/A
I seek the company of friends, family and/or other patients.	7		2			2	7	7	DK		-
The renal team support me with setting and achieving my goals.		N/A		-	-				-		-
When I need to make a treatment decision, I talk it over with someone I trust.	6		6	4		7	1	1	2	1	
I feel confident doing the dialysis myself.		7		1	N/A	1			1	1	

APPENDIX Q 60-item scale used for data collection in main survey.

Study Number:
Patient ID Number:

Chronic Kidney Disease Self-Management Behaviour Scale

This questionnaire asks you questions about your kidney disease and dialysis treatment, and how it impacts your life and wellbeing. We are interested in how patients manage day to day and in the kind of support they may receive. We hope that this questionnaire will be introduced into clinical practice as a way of supporting patients better.

We are still designing the questionnaire and the information you provide will help us improve it and reduce the number of questions to those that matter most.

Things may change over time, but these questions are about you now.

Please answer every question by circling a response on a scale of 1 to 7.

Note that the response categories vary so it is important to read each question carefully. If you think the question is not applicable (N/A) to you or you don't know the answer (DK), please mark the most appropriate of these responses.

1. **I'm able to ask a doctor for more information if I don't understand what he or she said.**

Never — Every time — N/A — DK

1	2	3	4	5	6	7	○	○

2. **I am confident I can talk to somebody in the renal team about my care if I need to.**

Not at all confident — Very confident — N/A — DK

1	2	3	4	5	6	7	○	○

3. When I talk to the renal team about my care I'm treated as a whole person rather than someone with an illness.

Never Every time N/A DK

1	2	3	4	5	6	7

○ ○

4. I have someone who will listen to me when I need to talk.

Not at all true Completely true N/A DK

1	2	3	4	5	6	7

○ ○

5. I feel I have control over my symptoms.

None Some N/A DK

1	2	3	4	5	6	7

○ ○

6. The renal team review my health and discuss any changes with me.

Hardly ever Enough N/A DK

1	2	3	4	5	6	7

○ ○

7. I can face the challenges of living with my kidney disease.

Strongly disagree Strongly agree N/A DK

1	2	3	4	5	6	7

○ ○

8. I feel more isolated than I did before I started dialysis.

Strongly agree Strongly disagree N/A DK

1	2	3	4	5	6	7

○ ○

9. I feel confident doing the dialysis myself.

Strongly disagree Strongly agree N/A DK

1	2	3	4	5		6	7

○ ○

10. My symptoms interfere with the way I would like to live my everyday life.

Never						Always	N/A	DK
1	2	3	4	5	6	7	○	○

11. I worry that I'm a burden on my family.

Sometimes						Never	N/A	DK
1	2	3	4	5	6	7	○	○

12. I understand how my illness is likely to progress.

Strongly Disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

13. Day to day I can manage most of the things I need to do.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

14. I find it hard to cope with my kidney disease.

Completely						Not at all	N/A	DK
1	2	3	4	5	6	7	○	○

15. I get the support I need to manage my health and treatment.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

16. Being on dialysis makes it difficult for me to get the care I need for my other health problems.

Often						Never	N/A	DK
1	2	3	4	5	6	7	○	○

17. The main reason I keep going is for my family and/or people close to me.

Strongly agree					Strongly disagree			N/A	DK
1	2	3	4		5	6	7	○	○

18. I adjust my phosphate binder dose to the size of my meal.

Never						Always	N/A	DK
1	2	3	4	5	6	7	○	○

19. I feel I have control over my dialysis treatment.

None						Enough	N/A	DK
1	2	3	4	5	6	7	○	○

20. I believe that to stay well, I will always need some kind of treatment for my kidney disease.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

21. My kidney disease interferes with my life.

Too much						Not at all	N/A	DK
1	2	3	4	5	6	7	○	○

22. I have activities and interests that keep me busy.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

23. I know enough about my kidney disease to deal with day to day problems related to it.

Not at all true						Completely true	N/A	DK
1	2	3	4	5	6	7	○	○

24. I would like to be more involved in decisions about my care.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

25. I have other health issues as well as my kidney disease and I find it difficult to cope with them all.

Very difficult						Not at all difficult	N/A	DK
1	2	3	4	5	6	7	○	○

26. I check settings on the dialysis machine to make sure they are the same as usual.

Never						Always	N/A	DK
1	2	3	4	5	6	7	○	○

27. There are things that I miss that I used to enjoy before I had to start on dialysis.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

28. I am angry about my kidney disease.

Very angry						Not angry at all	N/A	DK
1	2	3	4	5	6	7	○	○

29. I find it difficult to look after myself the way I would like to.

Always						Never	N/A	DK
1	2	3	4	5	6	7	○	○

30. My kidney disease prevents me from taking part in social activities.

Strongly disagree Strongly agree N/A DK

1	2	3	4	5	6	7

○ ○

31. I prefer not to make treatment decisions myself.

Strongly agree Strongly disagree N/A DK

1	2	3	4	5	6	7

○ ○

32. I'm interested in learning more about my dialysis.

Strongly disagree Strongly agree N/A DK

1	2	3	4	5	6	7

○ ○

33. I wasn't as involved in the decision to start dialysis as I would have liked.

Completely true Not at all true N/A DK

1	2	3	4	5	6	7

○ ○

34. I understand what my medications are for.

Strongly Disagree Strongly agree N/A
DK

1	2	3	4	5	6	7

○ ○

35. I know which problems or symptoms to consult the renal team about.

Hardly ever Most times N/A DK

1	2	3	4	5	6	7

○ ○

36. I get conflicting advice from the different specialists I see.

Often Never N/A DK

1	2	3	4	5	6	7

○ ○

37. I’ve organised my daily routines to help me cope with my kidney disease.

Not at all						Some	N/A	DK
1	2	3	4	5	6	7	○	○

38. Some days I feel distressed.

Hardly ever						Often	N/A	DK
1	2	3	4	5	6	7	○	○

39. I am confident in the advice my GP gives me about my kidney disease.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

40. I sometimes feel overwhelmed by my kidney disease.

Strongly agree						Strongly disagree	N/A	DK
1	2	3	4	5	6	7	○	○

41. I have good things to look forward to.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

42. I help decide how much fluid should be taken off.

Never						Always	N/A	DK
1	2	3	4	5	6	7	○	○

43. Despite being on dialysis I try to live as normal a life as possible.

Strongly disagree						Strongly agree	N/A	DK
1	2	3	4	5	6	7	○	○

44. I am confident that there is good communication between all the specialists I see.

Not confident						Very confident	N/A	DK
1	2	3	4	5	6	7	○	○

45. I take responsibility for parts of my treatment that might otherwise be done by the renal team.

Hardly ever						Often	N/A	DK
1	2	3	4	5	6	7	○	○

46. I have shortened my dialysis time due to family or other commitments.

At times						Never	N/A	DK
1	2	3	4	5	6	7	○	○

47. I see myself more negatively since I've had kidney disease.

Strongly agree						Strongly disagree	N/A	DK
1	2	3	4	5	6	7	○	○

48. My illness and/or its treatment interferes with my relationships.

Completely true						Not at all true	N/A	DK
1	2	3	4	5	6	7	○	○

49. I have come to accept the life-long nature of my kidney problem.

Do not accept at all						Completely accepted	N/A	DK
1	2	3	4	5	6	7	○	○

50. I avoid social situations where there will be food and drink, as I don’t want others to know about my kidney problems.

Often						Never	N/A	DK
1	2	3	4	5	6	7	○	○

51. I feel that I cannot cope with all the things I need to do.

Often						Never	N/A	DK
1	2	3	4	5	6	7	○	○

52. The renal team encourage me to be involved in my own care.

Never						Always	N/A	DK
1	2	3	4	5	6	7	○	○

53. Tiredness stops me from getting on with life.

Hardly ever						Often	N/A	DK
1	2	3	4	5	6	7	○	○

54. When discussing treatment options, my views are considered by the renal team.

Hardly ever						Often	N/A	DK
1	2	3	4	5	6	7	○	○

55. My illness causes difficulties for those who are close to me.

Completely true						Not at all true	N/A	DK
1	2	3	4	5	6	7	○	○

56. I help decide where the needles should be placed.

Never						Always	N/A	DK
1	2	3	4	5	6	7	○	○

57. When I have a health-related problem, I seek the help or information I need.

Never — Always

1	2	3	4	5	6	7	N/A ○	DK ○

58. I have an important role in managing my illness.

Strongly disagree — Strongly agree

1	2	3	4	5	6	7	N/A ○	DK ○

For the following two questions, if you don't work use the N/A option:

59. Haemodialysis treatment makes working difficult.

Extrememly difficult — Not at all difficult

1	2	3	4	5	6	7	N/A ○	DK ○

60. My ability to work is affected by my heath.

Very much — Not at all

1	2	3	4	5	6	7	N/A ○	DK ○

APPENDIX R REC favourable opinion and approval for scale and other measures.

NHS
Health Research Authority

East Midlands - Leicester South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

27 September 2019

Helen Munro Wild
Research Fellow
Health Research Methods Unit, The Centre for Health Services and Clinical Research (CHSCR)
The University of Hertfordshire
College Lane, Hatfied, Hertfordshire
AL10 9AB

Dear Helen Munro Wild,

Study title:	**Development of a self-management behaviour scale for people with Chronic Kidney Disease (CKD) on haemodialysis in the UK**
REC reference:	**17/EM/0451**
Protocol number:	**N/A**
Amendment number:	**1.3**
Amendment date:	**14 August 2019**
IRAS project ID:	**221766**

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.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Non-validated questionnaire [SelfManagementBehaviourScale_Aug2019_Final_1.1]	1.1	12 August 2019
Non-validated questionnaire [SelfManagementDemographicsAug2019_Final_v1.2]	1.2	14 August 2019
Notice of Substantial Amendment (non-CTIMP)	1.3	14 August 2019
Research protocol or project proposal [Protocol_IRAS_221766_v1.5_14082019]	1.5	14 August 2019
Research protocol or project proposal [Protocol_IRAS_221766_v1.5_14082019 (with highlights)]	1.5	14 August 2019

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

17/EM/0451:	**Please quote this number on all correspondence**

Yours sincerely,

p.p.

Mr John Aldridge Chair

E-mail: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net

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

Copy to:	*Professor Ken Farrington, East and North Hertfordshire NHS Trust* *Prof Phillip Smith*

East Midlands - Leicester South Research Ethics Committee Attendance at

Sub-Committee of the REC meeting on 26 September 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr John Aldridge (Chair)	Retired Senior Lecturer in Nursing	Yes	
Mrs Jeanne-Anne Charly	Retired State Registered Nurse/Teacher	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Kate Loven	Approvals Administrator (minutes)

From: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net [mailto:noreply@harp.org.uk]
Sent: 01 October 2019 14:35
To: FARRINGTON, Ken (EAST AND NORTH HERTFORDSHIRE NHS TRUST) <ken.farrington@nhs.net>; SMITH, Phillip (EAST AND NORTH HERTFORDSHIRE NHS TRUST) <phillip.smith5@nhs.net>
Subject: IRAS Project ID 221766. HRA Approval for the Amendment

Dear Professor Farrington,

IRAS Project ID:	221766
Short Study Title:	Development of a self-management behaviour scale for people with CKD
Amendment No./Sponsor Ref:	1.3
Amendment Date:	14 August 2019
Amendment Type:	Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the conditions outlined in your categorisation email.

Kind regards

Ann Parry

Health Research Authority

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

APPENDIX S Topic guide for pre-implementation focus groups and interviews.

1	Welcome, introduction and background *Outline structure:* Concept of self-management; How is it currently assessed (if at all)?; Views on the scale and utility; Barriers and facilitators to implementation within renal centres.
2	Concept of self-management
Aim	Introduce a broader concept of self-management, using quotes and presenting the 26-item scale to ensure group have a good understanding of why the term needs to be more than adherence and needling. Establish if staff accept broader conceptualisation. Q1 What do you understand by the term ‘Self-management’? - *Do you prefer – or use - another term?* - *How do your colleagues/organisation view SM [directed at clinical staff]?* **To patients***: Have you completed questionnaires about self-management as part of your care? Tell me your experience of this?* Q2 How do you currently assess self-management and patient need? - *Are there particular healthcare professionals in your team who tend to assess SM?* - *What is your experience of these assessments [ask both staff and patients]?* PRESENT QUOTES *I’m going to show you a couple of quotes [1 + 2]…* **How personal circumstance may affect treatment adherence.** **Quote 1**: '…it could be the fact that actually somebody going for treatment is not a problem, they can handle that. It's fine. It's actually […] the transport when they go home or it's the stuff that's going on at home. And it's the family. There's money issues, there's work issues, and those are all the things which can knock the confidence down […] until you know what they are, and you can then clearly direct them in other ways to help them to solve those issues. […] .[Male, White British, 60s] **Quote 2:** […] I think there's only so much sometimes they can deal with in their life. There's only so much they can take on, so if they have a lot of other stuff going on in their personal life, it can sometimes feel overwhelming to do anything else related to their medical care. Whereas […] if you [are] aware of those things, sometimes you can't solve them, but you can work with them and […] help move people towards self management a little bit better. [Senior HD Nurse] **To patients first**: *Is this experience something you relate to?* Then open up to **rest of group**: *What do you think?* *I’m going to show you another couple of quotes (3 + 4)…*

	Clinical communication and Peer support **Quote 3**: ‘A lot of clinicians know what they are doing but I don’t think that they have the time to explain it to me, to patients, possibly the consultant, lack of time, lack of patient to […] doctor ratio, consultant ratio, but it’s important that the consultant also […] explains it in simple English… They shouldn’t feel cross when patients ask questions about their health because they’re doing a service and they have to explain things...’ [Male, Black British, 45 years] **Quote 4:** ‘…I was just nervous, because I didn't know [about dialysis]. And then I had […] an open day […] we had like the doctors and dieticians, the nurses all talking to us about it, and telling us exactly what's happening. And then they took us around to meet the patients, and then I could see, actually see what they had to do. And we talked to the patients, and I think it - for me, it really helped me, and put me more at ease, because I knew what to expect then’. [Male, Black British/Caribbean, 56 years] **To patients first**: *What about these quotes, Is this something you relate to?* Then open up to **rest of group**: *What do you think?* *I’m going to show you a final quote (5)…* Managing condition outside the hospital **Quote 5:** ‘Remember that for this self management, treatment is only a third of what we're talking about. You've got the other two thirds, which are the days of your life when you're outside of the hospital, they all impact massively on yourself and how you self manage, and that could be whether you're a builder and you've got various jobs that you've got, you have to do, or you work at a university […] All these things impact self management’. [Male, White British, 60s] **To patients first**: *Is this experience something you relate to?* Then open up to **rest of group**: *What do you think?* PRESENT SCALE ***What are your first impressions of the scale?*** - *Are there questions that seem particularly important to ask? Prioritise* [less important/don’t see the purpose?]
3 Aim	Using the scale in clinical practice How to use the scale to support patients with self-management This scale has been designed to calculate an overall score, but it’s also possible to look at individual domain scores for managing, communication and self-care. Low scores on individual items can provide very specific information about where support may be necessary and give staff a starting point for conversations with patients. PRESENT PATIENT LEVEL DATA [Provide explanation]

We think the scale is important in three ways:

1. It provides a systematic way to measure engagement in self-management and highlight potential gaps in support.
2. The choices patients make are embedded in family, community and social circumstances. Use of this scale may help patients feel more understood.
3. Use of this scale could change perceptions of self-management, and improve patient care

Q5 ***To staff****: Would you use this scale with patients in your renal service?*

- ***To patients****: How would you feel about completing a survey covering the topics featured in the scale?*

To Staff:
Q6 Would this scale help support staff in approaching patients?

Q7 Have you used the PAM? [Are you aware of it/Perceived issues with it?]

- *We think this scale could compliment use of PAM. What do you think?*

4

Aim

Implementation:

This scale was devised to highlight areas where patients need support. What steps need to be taken to implement the scale? Which staff are best placed to deliver it?

To Staff:
Q8 What services do you offer to help support patients? *[psychologists, counsellors, social workers]?*

To Patients:
Q9 *Have you been offered support beyond routine clinical care? Why were you offered this support?* [Quality, frequency, satisfaction with support].

Potential of scale; This scale is intended to…

- *Give a more holistic assessment of patient's circumstances* (because scale facilitates a more in-depth conversation, covering topics not routinely talked about)
- *To give clinicians more information to support patients better* [and build relationships with patients which strengthen over time]
- *To access services/additional support more efficiently* [for patients but also relevant to renal services who may want to argue for more funding and resource].

Q10 Which staff are best placed to use the scale with patients? Is there a role for peer support?

- What do you see as the benefits of using this scale in routine clinical practice?

Q11 What kind of support would you need to implement this scale [if a patient is willing to be supported]

- Do you anticipate any challenges with implementation in your service?

	Q12 This scale has been developed for established haemodialysis patients but could be adapted to be used at different points on the patient pathway. What do you think about that? [Acknowledge SH reservations if they arise: tick box exercise; patients giving ‘right’ answers; staff burden; staff unconvinced of benefits, want to do everything for patients; patient frustration if no action taken; physical difficulties with completion; language barriers/cognitive decline; Healthcare staff would already identify struggling patients] **Administration:** Q12 *In what format should the scale be administered?* [intended to be self-report]. - *Paper copy? Electronically? Linked to patient’s other records?* - *Any concerns about self-reporting?* **How to present information:** Q13 We presented the scale results to you as a traffic light system - is this useful? Is there other information you would need before approaching a patient? - [If not addressed previously]*, are threshold scores useful? Easy to interpret?* Q14 What key information would you need to see in a guidance document on how to implement the scale? ***To patients:*** Q15 *How would you want the information you provide to be used?* - *What would you expect to happenmight the expectation be [for patients] once the scale has been completed.* -
5	**Final comments, thank you and close.** *Thank participants and close – recognise that a great deal has been covered – thank all for their contribution. Check whether anyone would like to add anything that hasn’t been discussed? Any last questions or comments before the discussion is closed?* *Reiterate that participants can get in touch with the research team if they have anything further, they’d like to contribute or any further questions they’d like to address.* END

APPENDIX T Plain English summary of the scale development process and findings.

Understanding what self-managing means for people undergoing haemodialysis

Summary for Patients and Participants

Funding: British Renal Society/Kidney Care UK

Sponsor: East and North Herts NHS Trust

Participating centres:

East and North Herts NHS Trust, Stevenage Royal Free Hospital, London

Queen Elizabeth Hospital, Birmingham

Study Team:

Chief Investigator – Professor Ken Farrington, Head of Centre for Health Services and Clinical Research, University of Hertfordshire & Consultant Nephrologist, Lister Hospital

Study Coordinator – Ms Helen Munro Wild, University of Hertfordshire

Collaborators:

Dr David Wellsted, University of Hertfordshire

Dr Janine Hawkins, University of Hertfordshire

Professor Andrew Davenport, UCL Department of Nephrology, Royal Free

Hospital Professor Paul Cockwell, Department of Nephrology, Queen Elizabeth

Hospital Ken Lawson, Lister Hospital

Background

Patients generally do better when they are involved in their own healthcare. 'Self- management' is a term used to describe how patients manage their own care and well-being, both when receiving treatment but also in their day-to-day lives. Healthcare teams supporting renal patients often focus on behaviours related to diet, fluid intake and the dialysis itself when thinking about self-management.

This study aimed to look at what self-management means for haemodialysis patients, in and out of the clinical setting. From conversations with patients, we began to develop a questionnaire for measuring self-management based on how patients relate to their kidney disease and its treatment.

Aim

The study had four phases and involved almost 400 patients. The aim was to develop a questionnaire to help understand how patients engage with their own care to maintain their own health and wellbeing. We hope the final questionnaire will be used by healthcare staff to help identify the support that patients need to overcome the barriers to this engagement.

Design

Three hospitals were involved; the Lister in Stevenage, the Royal Free in London and the Queen Elizabeth in Birmingham. Twenty-seven patients from these hospitals were interviewed about their experiences of living with renal disease and being on haemodialysis. The knowledge gained was used to identify a number of areas related to self-management.

Then a group of people with different experience of renal disease (patients, carers, doctors, nurses, charity workers) came together to look at the areas identified by patients and consider how to frame questions to address the main issues raised. A large number of questions was produced which were reviewed to produce a final list of 60 questions.

A further group of 11 patients were then asked to consider the content of the questions, how they were worded, and how patients being presented with these questions would view them.

The final questionnaire was then completed by 363 patients. The responses obtained were used in a statistical process to group clusters of questions together to reveal the important themes related to self-management. This also allowed the number of questions to be reduced to a manageable size.

Findings

The final questionnaire contained 26 questions. Three main themes were found - managing day to day, communication, and clinical care. Within these themes there were questions which explored the difficulties managing multiple health conditions, having hobbies and interests, communication with the renal team, and decisions about diet and fluid management. Other questions enquired about mental health and wellbeing and clinical aspects of renal disease and its treatment.

Quote: "They just know daddy's going to dialyse, I'll be back in four hours or five hours, that's fine. The days that I have the energy for us to, you know, do stuff, I'll do it, and the days that I'm unable to respond to what they're wanting to do, they understand".

Quote: "Fatigue, just mind-numbingly, body-aching exhaustion".

Theme: Managing day to day

Question: My symptoms interfere with the way I would like to live my everyday life

(Never/Always)

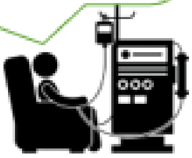
Quote: "I am up at about 06:30 in the morning on dialysis days. I take medication. I prepare my fistula for being needled with some cream and put a bandage on it. And then I drive here most times, and if my wife needs the car then I'll get a car, or she'll take me".

Theme: Clinical care

Question: I have an important role in managing my illness

(Strongly disagree/Strongly agree)

Quote: "I'm actually probably more social now than I was, because I've got more time to be. A couple of my friends wouldn't worry about the machine, so I've said, look, you've got me, I'm captured, have another cup of coffee".



Theme: Communication

Question: I have someone who will listen to me when I need to talk

(Not at all true/Completely true)

Implications

We now need to look at the best way to use this questionnaire in clinical practice. We will engage with groups of patients and clinicians to consider how it might be used, and how we can address any potential barriers. This will help us develop guidance for clinical staff and researchers in the use the questionnaire. We hope that its use will help broaden the way we think about self-management to include important social and emotional aspects and will help to identify the support that problems in these areas may require.

Thank you

We would like to say **thank you** to all who participated in the study. We are most grateful. We hope you will take pride in your contribution to this research and that you found involvement to be a positive experience.

If you have any questions about this study, you can contact us. Address: HMRU, Health Research Building | University of Hertfordshire | AL10 9AB| Email: ken.farrington@nhs.net