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Development of an acceptable, safe and feasible physical activity intervention for haemodialysis patients.

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Abstract

It is well documented that haemodialysis patients have low physical activity (PA) levels compared to their healthy counterparts. Increasing PA has been shown to increase some areas of quality of life and improve physical function. Utilising the Medical Research Council (MRC) methodology for developing complex interventions, I developed and intervention and measurement methods that aimed to increase PA levels in haemodialysis patients.

Stage 1 of this research program used qualitative and quantitative methods to investigate the motivators and barriers towards PA in this population to inform the exercise intervention and investigated the acceptability and utility of wearable sensors as a measure of physical activity and a prompting tool for interviewing. One hundred and one participants were approached, and 98 participants (23 female) completed self-report PA questionnaires. A subset of 20 participants (9 female) went on to wear accelerometers and wearable devices to capture one week's worth of activity on both dialysis and non-dialysis days and take part in semi-structured interviews.

Participants described a desire to be more active but said that the burden and associated symptoms of dialysis were barriers towards achieving a physically active lifestyle. Motivators and cues to action identified by participants included a health care professional to support them with PA, and exercise programmes to be accessible on dialysis days. The use of wearable cameras was found to be an acceptable method of quantifying activity levels in this population which may be used in future research. Overall findings from stage 1 were used to inform stage 2 to co-design a safe, acceptable and sustainable PA intervention with patients and staff, and to provide education to engage patients and improve health outcomes.

In stage 2, the feasibility study, participants were given a 10-minute instructor-led training on how to perform chair-based exercises (CBE), up to three times a week for six weeks pre-dialysis. Participants were encouraged to continue exercises at home and functional mobility assessments taken at baseline, month three and six. These included Timed-up-and Go, 10 metre walk test, hand rip and a battery of quality of life questionnaires. Sixteen participants were recruited, one withdrew, one was transplanted, and one had insufficient data. Of the

thirteen participants, six completed the study and the remaining seven missed final functional mobility tests due to the commencement of the Covid-19 pandemic lockdown in March 2020. Participant feedback indicated that CBE is an acceptable method of exercise. For some participants confidence and motivation increased during the intervention and they engaged in more PA on non-dialysis days. Mobility assessments improved over the six-month period. Further exploration of CBE in a larger scale study would be important for future work, not just in the renal setting but in wider healthcare settings such as nursing homes.

Outcomes from this thesis

The work contained in this thesis, unless indicated by acknowledgment or reference to published literature is the work of the author. The following publications contain, in part, findings from the thesis or relevant findings discussed in the thesis that are the work of the author and collaborators.

Publications and Presentations:

Sutherland S, Penfold R, Doherty A, et al. (2019) A cross-sectional study exploring levels of physical activity and motivators and barriers towards physical activity in haemodialysis patients to inform intervention development. *Disability and rehabilitation*: 1-7.

Nawab K, Storey B, Doherty A, Harper C, Staplin N, Gajendragadkar P, **Sutherland S**, Pugh C, Baigent C, Landray MJ, Herrington WG.(2017) Feasibility of using wearable devices to record arrhythmias and physical activity in patients on dialysis. BHF-CRE Symposium September 2017.

Sutherland S, Penfold R, Doherty A et al (2017) Exploring baseline activity levels and health beliefs surrounding physical activity in haemodialysis patients: a mixed-methods cross sectional study. *British Renal Society Conference* Nottingham UK.

Nawab, K, Storey, B, Staplin, N, Walmsley, R, Haynes, R, **Sutherland, S**, Crosbie, S, Pugh, C, Harper, C, Landray, M, Doherty, A. & Herrington, W. 2020. Accelerometer-measured physical activity and functional behaviours among people on dialysis. *Clinical kidney Journal*, 1-9. https://doi.org/10.1093/ckj/sfaa045

Outcomes from study to date:

There have been several positive outcomes since the start of this study. The pilot work completed to assess the feasibility and acceptability of the wearable cameras and accelerometers in the haemodialysis group has allowed further studies to measure PA as part of study objectives (Nawab et al., 2020). The additional dialysis codes I added to the Compendium of Physical Activity (Chapter 4) to code the wearable cameras for this thesis have been used as a resource for future projects including Nawab et al's (2020) study.

Based on a modification of the British Heart Foundation programme, the 10-minute exercises developed by myself and the Clinical Exercise and Rehabilitation Unit (CLEAR) at Oxford chair-based Brookes University was found to be sufficient length of time to increase heart rate and rate of perceived exertion. Furthermore, while participant numbers are small, the 6 week intervention period also improved Timed up and Go and 10 metre walk tests (Chapters 6 and 7).

The chair-based exercise programme devised for this study was adapted for a further study; Oxfordshire Sedentariness, Obesity and Cardiometabolic Risk in Adolescents – A trial of exercise in schools (OxSocrates) (Chapter 7).

During the COVID-19 pandemic at the start of 2020, a 10-minute exercise video was developed based on the exercises developed for the feasibility study. The video is available on the CLEAR Trust webpage and on YouTube and discussed more in detail in Chapter 6.

Chair-Based Exercise Programme: http://cleartrust.org.uk/ or https://www.youtube.com/watch?v=EJgZygWBKaE

Chair-Based Exercises Stage 1: https://www.youtube.com/watch?v=ZToQJom6fOk

Chair-Based Exercises Stage 2: https://www.youtube.com/watch?v=83QIUkCdJ24

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A few years ago it was written by the wonderful and witty Dr David Meredith that it was my turn to take on a PhD after working for several years on other doctoral projects. So, thank you, it was my turn indeed and five years later I have done just that.

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Abbreviations

AAS	Adjusted Activity Score
ACR	Albumin:Creatinine Ratio
ACSM	American College of Sports Medicine
ADL	Activities of Daily Living
ADPKD	Autosomal Dominant Polycystic Kidney Disease
AKI	Acute Kidney Injury
ARPKD	Autosomal Recessive Polycystic Kidney Disease
BCW	Behaviour Change Wheel
BHF	British Heart Foundation
CBE	Chair-Based Exercises
CHF	Chronic Heart Failure
COM-B	Capability Opportunity Motivation Behaviour System
CKD	Chronic Kidney Disease
CLEAR	Clinical Exercise and Rehabilitation Research Unit
CSRI	Client Service Receipt Inventory
CVD	Cardiovascular Disease
DoH	Department of Health
DPEBBS	Dialysis Patient Perceived Exercise Barriers and Benefits Scale
GPPAQ	General Practice Physical Activity Questionnaire
eGFR	estimated Glomerular Filtration Rate
EQ-5D-3L	Euro-Quality of Life 5 Dimensions Questionnaire
ESA	Erythropoiesis-Stimulating Agent
ESRD	End Stage Renal Disease
FITT	Frequency, Intensity, Time and Type
GBD	Global Burden of Disease
GCP	Good Clinical Practice
GN	Glomerulonephritis
HAP	Human Activity Profile Questionnaire

HBM	Health Belief Model
HD	Haemodialysis
HHD	Home Haemodialysis
HIIT	High Intensity Interval Training
IDH	Intradialytic Hypotension
IgA	Immunoglobulin A Nephropathy
IPOS	Integrated Palliative Outcome Score
KRUK	Kidney Research UK
MAS	Maximal Activity Score
MEMs	Micro-Electromechanical System
MET	Metabolic Equivalent of Task
MI	Motivational Interviewing
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
NHSBT	National Health Service Blood and Transplant
OEP	Otago Exercise Programme
PA	Physical Activity
PD	Peritoneal Dialysis
PPI	Patient and Public Involvement
QI	Quality Improvement
RA	Renal Association
RRT	Renal Replacement Therapy
SBP	Systolic Blood Pressure
SCT	Social Cognitive Theory
SDT	Self-Determination Theory
TPB	Theory of Planned Behaviour
TP-CKD	Transforming Participation in Chronic Kidney Disease
TRA	Theory of Reasoned Action
TTM	Transtheoretical Model
TUG	Timed Up and GO

Tx	Transplant
UKRR	United Kingdom Renal Registry
VM	Vector Magnitude
WHO	World Health Organisation

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Chapter 1

Introduction to Chronic Kidney Disease and Haemodialysis

1.1 Overview

Chronic Kidney Disease (CKD) brings an array of associated lifestyle changes for patients who require haemodialysis (HD) as a life sustaining therapy. HD is the most common mode of therapy compared to peritoneal dialysis (PD) and kidney transplant and is the preferred treatment to improve quality of life. This chapter will outline the causes and prevalence of chronic kidney disease and the effects haemodialysis has on quality of life. The impact of chronic kidney disease on the National Health Service (NHS) will also be discussed.

1.2 Causes of CKD

1.2.1 Glomerulonephritis

Glomerulonephritis (GN) is the most identifiable cause of renal disease accounting for 19.7% of the renal population in the UK in 2017 (UKRR, 2019). Glomerulonephritis is used to refer to several kidney diseases that injure the glomeruli and glomerular basement membrane in the kidney causing a reduction in urinary filtration and excretion; however, inflammation of the glomeruli is mainly autoimmune related (Vinen and Oliveira, 2003). Acute GN can be caused by Goodpasture's syndrome or lupus and several infections such as strep throat (Mathieson, 2007). Chronic GN is more commonly seen in men and runs in families although the cause is generally not identified (Mathieson, 2007). There are several types of GN, including minimal change disease, immunoglobulin A (IgA) nephropathy and membranous GN, each with its own progressive pathway to renal disease (Mathieson, 2005, Mathieson, 2007, Vinen and Oliveira, 2003).

1.2.2 Diabetes

In 2017, diabetes was the second most common cause of renal failure in the UK accounting for 17.8% of diagnosed renal disease cases (UKRR, 2019) and in 2019, 4.7 million people in the UK were diagnosed with diabetes (Diabetes-UK, 2019). In the UK, 40% of patients with diabetes are at risk of kidney disease (KRUK, 2020) due to progressive damage to blood vessels within the kidneys and thickening of the glomerular basement membrane (Anders et al., 2018). This causes a lack of kidney filtration increasing water and salt retention, leading to weight gain. Accumulation of protein and waste material causes emptying of the bladder to be problematic. Pressure from the bladder causes back-flow to the kidneys initiating injury and changes in vascular infrastructure, ultimately leading to diabetic nephropathy (Tervaert et al., 2010).

1.2.3 Hypertension

Diagnosis of hypertension is the fifth commonest cause of CKD in the UK and more common in men (UKRR, 2019). The incidence of patients with hypertension as their primary renal diagnosis is 6.3% of the renal replacement population (UKRR, 2019). Hypertension, blood pressure with a systolic of 140 mmHg or more and a diastolic of 80 mmHg or more (NHS, 2020) damages the kidney vasculature by increasing intraglomerular pressure leading to decreased glomerular filtration. Protein filtration increases due to damaged glomeruli and proteinuria develops (Keane and Eknoyan, 1999). With an ageing population, hypertension also increases the risk of cardiovascular disease (CVD) and with 30 - 45% of populations across European countries (Pereira et al., 2009) the risk of associated risk factors such as stoke is increasing (Feigin et al., 2016, Kjeldsen, 2018) Modifications in lifestyle, such as maintaining a healthy diet and regular exercise can decrease and maintain systolic blood pressures (NHS, 2020, Pescatello et al., 2004).

1.2.4 Cardiovascular disease (CVD)

Cardiovascular disease is the most common non communicable disease and accounts for over 17 million deaths each year (Crespo et al., 2019, WHO, 2018b). In the UK approximately 7.4 million people are living with a heart condition and these contribute to almost 27% of all UK deaths, 44,000 of these deaths are premature (BHF, 2020a) and CVD is the leading cause of death contributing to 31% of deaths globally (WHO, 2017). The main risk factors include poor or inadequate diets and physical inactivity leading to elevated blood glucose levels and hypertension (WHO, 2018a). Cardiac disease (22.7%) is the leading cause of death in the renal population across all ages (UKRR, 2019) and is independent of other factors such as diabetes or hypertension (Gargiulo et al., 2015). Complications caused by additional risk factors contribute to the cardiovascular burden, causing arterial stiffness and cardiovascular morbidity (Gargiulo et al., 2015). There are several pathophysiological and haemodynamic associations between the heart and kidney, such as atherosclerosis of both heart and kidney and bone mineral changes in the kidney leading to changes in cardiac function (Rangaswami et al., 2019). Due to the complex synergy between the heart and kidney disease, the term cardio-renal syndrome encompasses acute and chronic changes in cardio-renal dysfunction (Rangaswami et al., 2019). CVD costs the NHS £9 billion every year and costs to the UK economy are estimated to be around £19 billion due to premature death (BHF, 2020a).

1.2.5 Heredity

Hereditary diseases include polycystic kidney disease (PKD), metabolic diseases and immune glomerulonephritis (Bergmann, 2015). PKD is one of the most commonly inherited diseases, where fluid-filled cysts on the kidneys are present (Bergmann et al., 2018). Autosomal dominant polycystic kidney disease is identified in adulthood and affects 1 in 1000 people, approximately 12 million worldwide. It is caused by a mutation in the *PKHD1* gene from one parent passed on to the child (PKDC, 2018a). Autosomal recessive polycystic kidney disease (ARPKD) is rarer but more severe. ARPKD is diagnosed in early infancy or childhood (Bergmann et al., 2018) and caused by mutation in the *PKHD1* gene from both parents (PKDC, 2018b, Torres et al., 2007).

1.2.6 Acute Kidney Injury

Acute kidney injury (AKI) causes a reduction in urine output and an increase in serum creatinine levels (KDIGO, 2012) and appears in up to 15 % of hospital admissions (Al-Jaghbeer et al., 2018). AKI is a complex syndrome often caused by numerous underlying conditions making it difficult to diagnose and treat efficiently (Ronco et al., 2019). Causes of AKI include dehydration, sepsis, CVD or vasculitis (Bienholz et al., 2015, NHS, 2019). However, if AKI is not treated in a timely manner, further complications could arise leading to acidosis and loss of kidney function requiring haemodialysis (Ronco et al., 2019).

1.3 CKD Classification

There are five classifications to CKD and these are determined by blood tests which include urea, albumin and creatinine (albumin:creatinine ratio or ACR) and estimated glomerular filtration rate (eGFR). Glomerular Filtration Rate (GFR) is a key indicator and an estimate of kidney function. Adults with an eGFR of over 60mls/min/1.72m^2 (body surface area) are considered to have normal renal function; however this may not be appropriate for their age and may need follow up (RA, 2020a). Levels of eGFR and the level of protein in the urine will determine the CKD classification (RA, 2020a) (Appendix 1). Patients with an eGFR less than

$60ml/min/1.72m^2$ are classed as having CKD Grade 3. As reduced kidney function progresses and eGFR is less than 15 $mls/min/1.72m^2$, patients are in kidney failure (Grade 5), and symptoms experienced can include tiredness, swollen ankles, shortness of breath, and nausea.

1.4 Renal Replacement Therapy

Renal replacement therapy (RRT) describes the provision of artificial kidney filtering. Peritoneal dialysis (PD), Haemodialysis (HD), Home Haemodialysis (HHD) and Transplantation (Tx) all fall under the umbrella of RRT (Figure 1.1). Whilst there is no cure for kidney failure, transplantation is the most desired form of RRT. However, finding a suitable organ is not always easy. In 2017, the median age for incident patients starting RRT in the United Kingdom (UK) was 63.7 years (UKRR, 2019) (Figure 1.2) compared to 64.1 years in 2007 (UKRR, 2008). Currently, the most common form of RRT is haemodialysis with more men (61.1%) than women (38.9%) starting RRT (UKRR, 2019). This demographic is represented at Oxford Kidney Unit where 65% of patients on dialysis are males and 35% females, with a median age of 60 years.

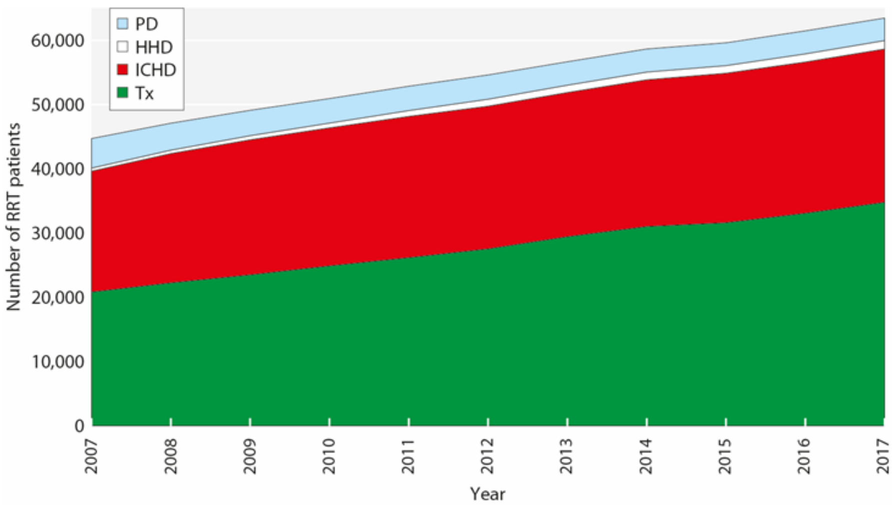


Figure 1.1: Growth in prevalent patients by treatment modality at the end of each year 2007–2017
Taken from 21st UK Renal Association, Renal Registry Report, 2019

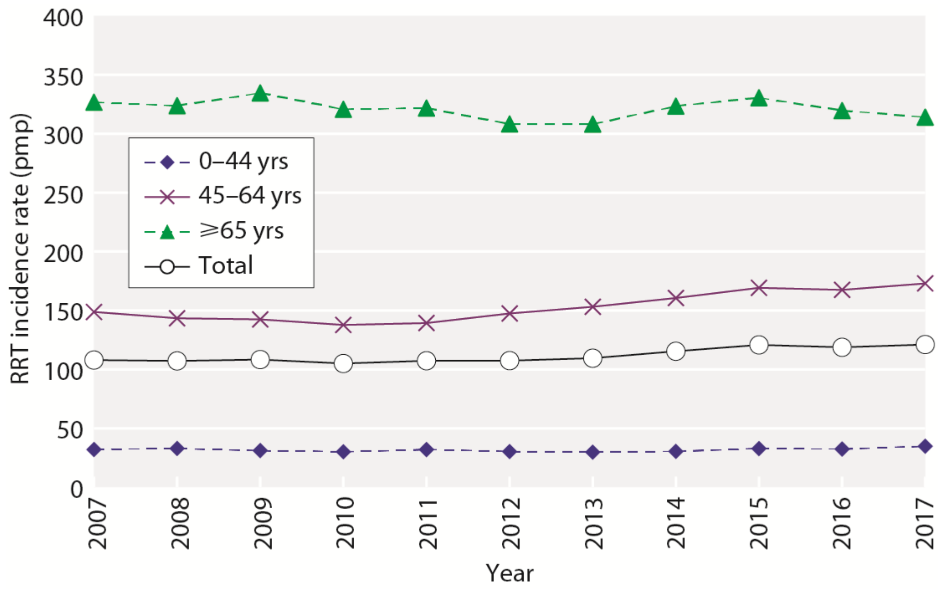
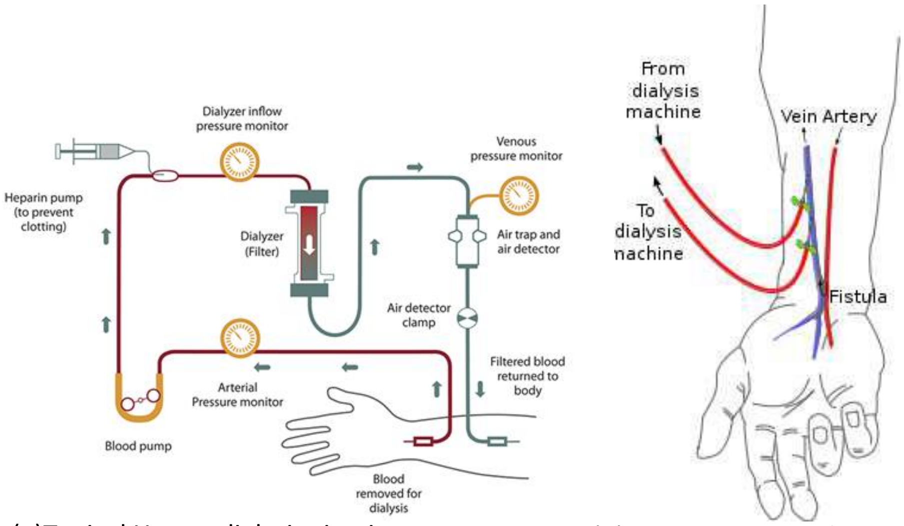


Figure 1.2 RRT incidence rates between 2007 and 2017
Taken from 21st UK Renal Association, Renal Registry Report, 2019

1.5 Haemodialysis

Haemodialysis is an essential maintenance treatment for many patients with end stage renal disease (ESRD), and is usually conducted in-hospital three times a week as per Renal Association (RA) guidelines (RA, 2019). Each session lasts approximately 4 hours. Patients are attached to a dialysis machine via a surgically created fistula or Tesio line and their blood is filtered and cleaned extra-corporeally to remove toxins and additional extra-cellular fluid (Levy et al., 2016) (Figure 1.3). Two main functions of the kidney; toxin clearance and fluid balance are performed through the process of dialysis. Diffusion clears waste products from the blood, and ultrafiltration removes the excess water from the blood (Levy et al., 2016) to achieve the desired patient dry weight each session. The median age of patients on haemodialysis is 66.8 years (UKRR, 2019) and currently fewer than 30,000 patients are on dialysis in the UK (UKRR, 2019). However, while 2560 kidney transplants were performed in the UK between January 2018-2019 (NHSBT, 2019), over 5000 patients are on the transplant waiting list (NHSBT, 2019) with a waiting time of 2 and half years or more (NHSBT, 2017).



(a)Typical Haemodialysis circuit (b) Arterio-venous fistula

Figure 1.3**:** Schematic haemodialysis circuit and diagram of an Arterio-venous Fistula
Taken from: https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis and http://www.thefullwiki.org/Hemodialysis

Typical set up of a haemodialysis machine is shown (a). The vascular anatomy of a radial fistula is shown in (b). The arterial (outflow) needle is inserted distal to the venous (inflow) needle. This prevents recirculation of filtered blood. The blood from the patient is removed at a prescribed rate by the blood pump of the haemodialysis machine which generates a negative pressure within the arterial line (measured by the arterial pressure monitor). To prevent blood clotting in the dialyser, an anticoagulant is administered at the start of the treatment. Blood passes in an opposing direction to the dialysate solution within the dialyser. Before filtered blood is returned to the patient through the venous line, air is checked via the air detector.

1.6 Impact of end stage kidney disease

End stage kidney disease itself impacts heavily in patients. Patients have lower health related quality of life (HRQoL) in both CKD 5 pre dialysis and those on CKD 5 on haemodialysis. There is little difference in QoL after one year of commencing haemodialysis (Broers et al., 2018). Patients face an array of psychosocial and physical stressors and a recent systematic review by Hansen et al. (2021) found that stressors include depression, anxiety, financial concerns, reduced quality of life and adjustment to illness. Depression and anxiety progress over the course of the illness (Goh and Griva, 2018) and pain also negatively impacts QoL and is associated more with the elderly and those on low incomes (Samoudi et al., 2021). End stage kidney disease does not only affect patients but also their partners and families as well. Sadness, resentment and loss within their relationship are some of the feelings experienced by patient's partners (White and Grenyer, 1999). Due to the associated burden renal disease, fatigue is experienced by both patients and families which impacts on QoL (White and Grenyer, 1999) and physical activity can play a role in improving HRQoL in patients (Broers et al., 2018) and family members.

1.6 Impact on quality of life

The associated co-morbidities of CKD and long term haemodialysis impact on general quality of life and increase the risk of mortality (WHO, 2018b). Mortality rates in haemodialysis patients are eight times higher compared to the general population (de Jager et al., 2009).
HD patients have a higher incidence of depression, malnutrition (Goodkin et al., 2003) and hospitalisation (Thong et al., 2008) due to the number of lifestyle changes that patients have to modify such as diet, fluid intake and treatment regimen. The restrictions of haemodialysis impact on psycho-social aspects and physical functioning (Finnegan-John and Thomas, 2012) and thus reduced activity levels in HD patients are well documented (Johansen et al., 2000, Kurella Tamura et al., 2009). Other factors that impact on quality of life for patients is early retirement or requiring to stop work due to the demands of haemodialysis and reduced time with family (Partsiopoulou et al., 2017). In a qualitative study by (Jones et al., 2018), the rigorous 12 to 14 hours per week of treatment limits holiday plans and forgoing job opportunities potentially leading to financial difficulties. In England, the economic burden differs for different stages of CKD and genders. It is estimated that men with stage 2, stage 3 with albuminuria and CKD stage 4/5 and associated health related quality of life economic costs is approximately £103,735, £83,399 and £125,335 respectively compared to £143,582, £70,288 and £203,804 in females (Nguyen et al., 2018). These costs are estimated to increases by 2025 (Nguyen et al., 2018). Despite the financial burden on the NHS, renal failure brings an array of associated symptoms that impact the quality of life in renal patients. Below are a summary of the main symptoms.

1.6.1 Fatigue

Fatigue has been widely reported as a debilitating symptom for dialysis patients, and while the reasons for this are not well known, this impacts on their day to day lifestyles (Artom et al., 2014). Fatigue is described as experiencing sensations ranging from tiredness to exhaustion limiting normal day to day capacity (Ream and Richardson, 1996). Frequency, distress, quality and intensity have been classed as dimensions of fatigue and individuals experience fatigue differently (Joshwa and Campbell, 2017). Patients in all stages of CKD have described fatigue as the most distressing symptom (Almutary et al., 2013)

There are several fatigue assessment tools such as fatigue severity scale, multidimensional inventory-20 and functional assessment of chronic illness therapy fatigue (FACIT-F) among others (Joshwa and Campbell, 2017). However, reliability of these assessments remain limited due to lack of validity within the CKD population (Joshwa and Campbell, 2017). Methods to help fatigue include administering erythropoiesis stimulating agents (ESA) to correct anaemia by producing more red blood cells. Anaemia is one of the most cited causes of fatigue, not just in renal dialysis but in other conditions (Ossareh et al., 2003). Other physiological factors that contribute to fatigue include pruritus, co-morbidities, depression, chronic inflammation, as well as post dialysis fatigue (PDF). Fatigue has been linked to depression through raised inflammatory cytokines (Bossola et al., 2015) which can cause an increase sleep disorders such as restless leg syndrome and sleep apnoea (Joshwa et al., 2012). Additionally, poor dialysis adequacy is associated with fatigue (Dadgari et al., 2015). HD is an invasive treatment and the recovery time after dialysis can take up to 3 hours after each session (Alvarez et al., 2019, Artom et al., 2014, Sklar et al., 1996) and it has been suggested physical activity may alleviate PDF symptoms (Gordon et al., 2011).

1.6.2 Pain

Pain is a widely cited symptom for patients with CKD and for those on haemodialysis. Changes in serum phosphate, calcium and para-thyroid hormone (PTH) levels can cause chronic kidney disease-mineral bone disease (CKD-MBD) due to the reduced or abnormal rates in bone turnover, formation of micro restructuring and remodelling of bone, and increased calcification in tissue (Hou et al., 2018). These mineral changes can lead to increased fracture risk and dietary changes, phosphate lowering treatments and vitamin D medications are required to maintain safe calcium and PTH levels (Wheeler and Winkelmayer, 2017). Despite these treatments, 40-60% of patients receiving dialysis report the incidence of pain (Pham et al., 2017).

1.6.3. Intradialytic Hypotension

A sudden drop in blood pressure during haemodialysis, also known as intradialytic hypotension (IDH) are more common in dialysis patients with diabetes and are also associated with the aging process (Shi et al., 2010) and decreased left ventricular function (Miach et al., 1981, Punzengruber and Wallner, 1989). IDH can be caused by inadequate dry target weight, reduced cardiac function and hypovolaemia during dialysis (Daugirdas, 2001) and occurs in up to 30% of dialysis sessions which can lead to long term complications and mortality (Shoji et al., 2004). Intradialytic hypotension may lead to cerebral ischaemia, which occurs frequently in haemodialysis patients and is not easily predicted from blood pressure (MacEwen et al., 2017). Meredith et al. (2015) found that dizziness and cramp in patients were strongly associated with systolic blood pressures (SBP), more so than nausea, and symptoms were under-reported in patients with low blood pressure.

1.7 Impact of CKD on the NHS

With the NHS experiencing challenges due to financial pressures to continue delivering an optimum standard of care. To maintain good practice, Quality Improvement (QI) strategies have been implemented to support the NHS process in improving quality service to reduce costs, and identify patients at risk of end stage renal disease (TKF, 2020). In 2012, more than 1.8 million people in England alone were diagnosed with CKD, but it is estimated that there are up to 3 million undiagnosed cases (Kerr, 2012). The estimated costs for all patients receiving HD and PD amount to £504 million and the total cost attributable to CKD was approximately £1.45 billion in 2009-10 (Kerr et al., 2012). Strategies to prevent CKD, such as changes in lifestyle, could reduce medical and societal costs in the long term (Vanholder et al., 2017), and better collaboration between the NHS and other UK Government departments to implement these strategies is vital. Poor diet, smoking and lack of physical activity are linked to the progression of non-communicable long term diseases such as diabetes, cardiovascular disease and CKD (Vanholder et al., 2017, WHO, 2018b) and preventative strategies to improve health can significantly reduce risk factors (WHO, 2018a).

1.8 Desirable outcome for interventions

When implementing any new intervention or pathway, a careful review of the potential benefits to stakeholders should be considered. These include patients, their families, clinicians, national commissioners and policy makers. Routine biomarkers such as serum phosphate and calcium are regularly reported in trials but have little association in improving quality of life improvement (Palmer et al., 2011). A recent Standardised Outcomes in Nephrology-HD (SONG-HD) Delphi study which involved patients and clinicians sought to identify core outcomes to improve patient quality of life (Evangelidis et al., 2017). SONG-HD Delphi study found that patients reported outcomes of wellbeing, ability to travel and dialysis free time were important whereas health professionals ranked mortality, hospitalisation and drops in blood pressure as key outcomes. However, both groups identified that vascular access, fatigue, cardiovascular and mortality as the top priority outcomes that will potentially improve trial outcomes. From these four core outcomes, outcome measures are being established so that research is relevant to this population group (Evangelidis et al., 2017, Ju et al., 2020, O'Lone et al., 2020). Outcomes applied to any study should directly benefit renal patients and caregivers to improve their quality of life and decrease mortality.

1.9 Improving patient outcomes

The lack of physical activity in renal patients (Aucella et al., 2015, Johansen et al., 2000), and the population in general is well documented (DoH, 2019). There are still challenges to promote, facilitate and embed physical activity programs for renal patients in hospital in-centre haemodialysis units to reduce dialysis associated symptoms, increase muscle strength and improve patient outcomes. Chapter 2 will discuss the UK physical activity guidelines and describe current strategies to improve renal patients’ physical activity levels, wellbeing and functional mobility.

Chapter 2

Physical activity and haemodialysis

2.1 Overview

Current evidence suggests that individuals receiving maintenance haemodialysis frequently do not participate in regular physical activity (PA) and attempts to promote PA participation have been undertaken. This chapter will explore the current PA recommendations and the physical and mental benefits that PA brings, current strategies to promote PA and the current methods to increase PA opportunities within the haemodialysis (HD) clinical setting. The motivation for this research and outcomes derived from this study will be discussed at the end of the chapter.

2.2 Defining PA and UK recommendations

The World Health Organization (WHO) defines PA as any body movement produced by the skeletal muscles to perform tasks which result in energy expenditure (WHO, 2018a). PA encompasses a wide array of activities including exercise, outdoor games, household chores and recreational activities (WHO, 2018a). Adverse health consequences have been associated with a sedentary lifestyle; the UK Department of Health (DoH) therefore recommends that physical activities such as brisk walking and cycling should be incorporated into the daily routine (DoH, 2019). The WHO estimates that one in four adults are currently inactive globally with three to four hours of leisure time spent in sedentary positions (WHO, 2018a). This is thought to contribute to the growing burden of non-communicable diseases including cardiovascular diseases and diabetes (WHO, 2018a). These non-communicable diseases are in turn contributing to increased CKD prevalence, morbidity and mortality (Jager et al., 2003, Lüscher, 2015, WHO, 2018b).

Current UK Department of Health (DoH, 2019) recommendations for adults and older adults advocate that 150 minutes of moderate activity per week or 75 minutes of vigorous activity is beneficial to maintain physical and mental health. These recommendations apply to all patient groups and not just healthy people. Time spent sitting on sofas watching television or using computers should be minimised. However, despite these recommendations, many of the UK population continue to be inactive and do not meet these recommendations (DoH, 2011, DoH, 2019). Patients on dialysis have self-reported low levels of activity. Up to 45% of dialysis patients may not engage in any exercise at all (Avesani et al., 2012) and exercise levels can vary across countries (Tentori et al., 2010). A recent observational study identified the prevalence of inactivity in renal patients increased with disease progression (Wilkinson et al., 2021). Physical activity and function were assessed in 5,258 CKD and transplanted patients across the UK using the General Practice Physical Activity Questionnaire (GPPAQ) and Duke Activity Status Index (DASI) and those with CKD grades 1-2 were the most active compared to those at CKD stage 5 and on dialysis. Patients who were transplanted were also found to be active and walking was the most preferred activity across all CKD stages (Wilkinson et al., 2021).

The underlying reasons for HD patient's low PA level is multi-faceted. Associated HD symptoms include fatigue, shortness of breath and weakness contribute to the disinclination to engage in PA (Delgado and Johansen, 2012). In a more recent study, the barriers remain similar and that fatigue is the widely cited symptom to not participate in PA (Moorman et al., 2019). Even if the provision of an exercise program may be available in a dialysis unit, the opportunity to participate in exercise on a non-dialysis day may not be achievable due to lack of transportation or distance to a specific venue (Kontos et al., 2007). Other factors that limit the uptake of PA in dialysis patients are fear of falling, exercise knowledge and finding the time to exercise (Jayaseelan et al., 2018).

2.3 Exercise for health

The International Classification of Functioning, Disability and Health (ICF) model, based on the biopsychosocial model for disability, provides a classification of disease health and various health states across different countries and ethnic groups (WHO, 2001). The ICF is designed to provide a basis for understanding health related conditions and changes in functioning, including body functions, activities, participation and health status. Health related ICF domains include changes in body structure, ability and performance of PA in a person's standard or social environment and the capability of performing PA in their own environment (WHO, 2001). However, the original ICF developed core sets and practical tools for 12 diseases to support health care professionals understand their patients with physical functioning in clinical practice. Practical tools for Diabetes Mellitus and musculoskeletal conditions are available within the ICF and despite new conditions being added, renal disease is not one of them. The core components of the ICF collectively look at the positive abilities at patient level and therefore elements from other key diseases such as diabetes could be utilised. With this in mind, applications of the ICF on an individual level, as well as institutional or societal, can assess participant's current level of functioning and evaluate which treatment or treatments would benefit their functioning (WHO, 2001).

2.4 Benefits of Physical Activity

PA promotes health and wellbeing in the general population by improving cognitive function and self-esteem and decreasing depression and risk of cardiovascular disease. Maintaining physical activity in adult life also reduces the risk of hypertension, maintains bone health and maintains muscular and cardiovascular fitness (WHO, 2018a). Randomised Controlled Trials (RCTs) have shown that PA provides many physical and mental health benefits in the CKD population, with improved fitness, walking capacity, cardiovascular dimensions, nutritional parameters and quality of life; indeed, national guidelines now consider PA to be a cornerstone of disease management (Chan et al., 2019, Heiwe and Jacobson, 2011, K/DOQI-Workgroup, 2005, RA, 2019). CKD patients have lower levels of PA than age-matched controls; this is particularly marked for older patients and those on renal replacement therapy (Delgado and Johansen, 2012, Jayaseelan et al., 2018, Johansen et al., 2000, Kontos et al., 2007).

2.4.1 Physical activity and cognitive function

The number of patients diagnosed with cognitive diseases such as dementia is increasing and the WHO estimates that the existing figure of 50 million people with dementia worldwide (WHO, 2020c). PA has been found to reduce the cognitive decline of dementia, especially aerobic exercise when combined with pharmacological support (Groot et al., 2016). However, current research by Sabia et al. (2017) as part of a 28 year follow up in the Whitehall II cohort study, asserts that PA has no causal effect on reducing cognitive decline. In a study by MacEwen et al. (2017), 23.5% of the 638 dialysis sessions in 58 patients had episodes of cerebral ischemia which were captured using near-infrared spectroscopy (NIRS). To assess cognitive function, Trails Test B (TTB) and the modified mini-mental state test (3MS) were used at baseline and at month 12. The TTB score deteriorated with a median increased time of 7.5 seconds whereas transplanted patients scores had improved (MacEwen et al., 2017). More studies are needed to understand the exact benefits of PA on the mechanism of the brain in the ageing process (Gallaway et al., 2017) and cognitive decline.

2.4.2 Physical activity and mental health

Research on physical exercise continually suggests benefits to mental health (Mikkelsen et al., 2017). The naturally occurring steroid hormone cortisol, secreted by the adrenal gland, plays a key role in stress response. Cortisol levels increase when faced with fight or flight situations or continual stressful situations can lead to a negative impact on the body and impact on mental health disorders (McEwen and Gianaros, 2010). Increasing physiological stress levels due to a critical illness, for example, increases the amount of circulating cortisol in the blood stream. This is due to a reduction of cortisol-binding globulin proteins and stimulation of the hypothalamic-pituitary-adrenal axis (Téblick et al., 2019). A study involving healthy men found that the effects of low level exercise can reduce the amount of circulating cortisol levels compared to high intensity exercise (Hill et al., 2008). Even during unforeseen situations such as pandemics, PA is associated with better mental health in the general population (Jacob et al., 2020). PA has also been found to promote better sleep (Baron et al., 2013, Lowe et al., 2019), improve self-esteem (Gilani and Feizabad, 2019) and reduce depression (Schuch et al., 2016).

2.4.2 PA and cardiovascular disease

In a systematic review by Murtagh et al. (2015) an increase in walking regimens can improve blood pressure (Brandon and Elliott-Lloyd, 2006), aerobic capacity (Murphy et al., 2007) and body mass (Aldred and Rohalu, 2011) to prevent cardiovascular disease.

Physical activity shares a complex relationship with obesity which is also a further risk factor of CVD as approximately 39% of adults across the world are overweight (WHO, 2020). The severity of obesity increases the risks of CVD, hypertension and diabetes (Bastien et al., 2014, Lavie et al., 2016). In 2015, 63% of adults in England were classed as obese with NHS treatment costs at £6.1 billion and costs projected to increase to over £9 billion by 2050 (PHE, 2017). In the renal population, obesity has been increasing and there is a strong association between obesity and incidence of CKD, more so in women than in men (Wang et al., 2008).

However, there is evidence of the ‘obesity paradox’ where Body Mass Index (BMI) is associated with a better survival in HD patients (Vashistha et al., 2014). Obesity therefore should be managed prior to onset of CKD and more research is needed in to the pathogenesis of obesity in CKD patients (Rhee et al., 2016). The uptake of physical activity is a cost effective method to reduce the incidence of heart disease by approximately 35% (BHF, 2020a).

2.4.3 Physical Activity and diabetes

PA of 150 minutes of moderate activity is associated with lower incidence of type II diabetes (Smith et al., 2016). Studies have shown that PA improves glycaemic control (Umpierre et al., 2011), blood pressure (Colberg et al., 2016, Gordon et al., 2009), cholesterol (Balducci et al., 2012) and slows the progression of peripheral neuropathy (Balducci et al., 2006). Both aerobic and resistance exercise are beneficial although supervised exercise programs have been found to be more effective in glycaemic control (Umpierre et al., 2011). Obesity again is one of the main causes of diabetes and a modifiable risk factor. PA has been found to decrease mortality in patients with CKD and diabetes (Tikkanen-Dolenc et al., 2017).

Diabetes accounts for 9% of the total NHS annual budget and costs £8.8 billion to support patients (PHE, 2018). To alleviate the ongoing burden, the NHS Diabetes Prevention Programme (NHS DPP) was launched in 2015 to provide patients with diabetes and those at risk of diabetes coping strategies and interventions to improve health and wellbeing and increase physical activity (PHE, 2018).

2.5 Current strategies to promote physical activity

Previous studies have sought to characterise the most effective forms of exercise for CKD patients (Greenwood et al., 2012, Heiwe and Jacobson, 2011, Orcy et al., 2012). Cardiovascular, resistance, and supervised or unsupervised exercises programmes were found to improve walking capacity, resting blood pressures and quality of life, with length of sessions varying from 20-110 minutes (Heiwe and Jacobson, 2011). However, research into renal rehabilitation seems relatively lower compared to other key areas such as stroke, due to numerous reasons including lack of professional knowledge, established renal exercise programmes and funding (Bennett et al., 2017).

Current Renal Association (RA) guidelines acknowledge that PA levels in dialysis patients is low. The association recommends that any type of intradialytic exercise be implemented in all units and delivered by a trained staff member (RA, 2019).

2.5.1 Exercise referral schemes

Exercise referral schemes involve GPs and practice nurses referring patients to schemes that facilitate supervised exercise programmes in suitable locations within the community, such as leisure centres (DoH, 2001). Guidelines published in 2014 for exercise referral schemes highlighted that primary care practitioners should only refer patients who are inactive and have existing health concerns rather than patients who are inactive and healthy (NICE, 2014). Referral schemes that promote structured exercise programmes for certain health conditions include patients recovering from myocardial infarction, stroke, chronic fatigue syndrome and chronic heart failure (CHF) amongst others (NICE, 2014). Currently there are no NICE rehabilitation guidelines for renal failure patients. In the United States however, anyone wishing to start an exercise programme must undergo an exercise pre-participation health screen, for example using the Physical Activity Readiness Questionnaire (PAR-Q) as described by the American College of Sports Medicine (ACSM). However new screening for professionals includes a cardiovascular risk profile to see if an exercise test is needed before any exercise takes place (Magal and Riebe, 2016). This is to assess any individuals who may be at risk of a sudden cardiac event during exercise (Magal and Riebe, 2016, Riebe et al., 2015). However, pre-screening may hinder the uptake of any activity with unnecessary cardiac and exercise tests (Riebe et al., 2015) and exercise prescriptions and programmes should be designed specifically to avoid unnecessary cardiovascular events (Magal and Riebe, 2016).

2.5.2 Supervised Physical Activity

To improve exercise adherence, structured exercise programmes have been found to be successful in the clinical setting by providing patients guided supervision (Mudge et al., 2018, Torres et al., 2019). The benefit of a sports exercise trainer or a 'wellbeing trainer' delivering face to face meetings has proven to be successful in past studies (Annesi and Unruh, 2007). Known as the 'Coach Approach', 6 sessions are delivered over a 6-month period. Within the contact time, motivational interviewing and tailored feedback are given to participants who are new to an exercise program (Annesi, 2003, Annesi and Unruh, 2007). The aim of the Coach

Approach is supporting the learner to establish and maintain a habit of exercise. One of the key approaches in delivering the Coach Approach is incorporating tenets of the social cognitive model. The model is a threefold relationship between environment, person and behaviour, and individuals receive support value by connecting behaviour (Bandura et al., 1999). An additional benefit of supervised PA is that feedback can be given during a PA session. Tailored or effective feedback is seen as a sequential process in delivering facilitative feedback in several forms such as verbal, written or numerical to support and nurture positive development (Archer, 2010). Tailored interventions have been used in healthcare to assist patients with smoking cessations and weight loss (Kreuter et al., 1999, Unrod et al., 2007). Tailored feedback has also been seen to improve physical activity compared to patients receiving generic information (Vries et al., 2008). A study by Achterkamp et al. (2018) found that tailored feedback should be given to participants depending on the level of self-efficacy and that participants with higher self-efficacy had higher activity levels.

2.6 Strategies to increase physical activity in haemodialysis patients

Physical activity has been shown to have specific benefits in the HD population, including reduced cramp, improving muscle function and reducing cardio-instability (Greenwood et al., 2014).

Activity levels in haemodialysis patients are low and have been well documented (Johansen et al., 2000, Zelle et al., 2017). Years of research have sought to improve quality of life, symptom burden and overall fitness of patients through exercise programmes (Heiwe and Jacobson, 2014). There have been numerous studies exploring aerobic exercises, resistance exercises and combined resistance and aerobic exercise programmes in haemodialysis patients (Hargrove et al., 2021, Heiwe and Jacobson, 2011).

Aerobic exercise is activity that increases heart and respiratory rates (Hargrove et al., 2021). Haemodialysis symptom burden, such as restless legs and depression improved with intradialytic cycling for 45 minutes, three times a week for six months (Giannaki et al., 2013). However, in a review by Young et al. (2018), aerobic exercise in the form of intradialytic cycling still provides inadequate evidence to suggest that exercise improves physical function and quality of life, whereas a previous review suggested otherwise (Sheng et al., 2014). A more recent review of 15 randomised controlled trials assessing aerobic exercise and haemodialysis symptoms, found improvements in dialysis related symptoms such as restless legs syndrome and fatigue (Hargrove et al., 2021). The duration of the intervention also has an impact on outcomes as interventions of at least 6 months have more patient benefit compared to intervention less than 12 weeks in duration (Bohm et al., 2019).

Resistance training in haemodialysis has been shown to improve skeletal muscles strength (Cheema et al., 2014) and that muscle volume can be increased over a 12 week resistance exercise programme (Kirkman et al., 2014). However, there are differences between load, frequency, intensity and duration of resistance exercises study protocols to reduce hypertrophy and improve strength and power (Gollie et al., 2018). It is therefore difficult to prescribe a suitable resistance exercise programme and external load, for example; dumbbells (Cheema et al., 2007) or resistance bands (Song and Sohng, 2012) which may make it difficult to determine what is the most valuable component to improve patient strength.

A review by Scapini et al. (2019) found that combined exercise programmes are a better exercise modality for haemodialysis patients to improve aerobic capacity and blood pressure compared to aerobic exercise alone. Aerobic exercise was found to improve aerobic capacity and not improve blood pressure whereas resistance training did not have a positive effect on blood pressure or aerobic capacity. A study by Huang et al. (2020) provides further evidence of a 24 week intradialytic cycling programme which included both aerobic and resistance components which improved blood pressure and physical fitness. However, follow up post 24 weeks does not indicate whether the intervention continued to take effect (Huang et al., 2020) and sustaining an intervention after the study period continues to be a challenge. In a different study, HD patients were found to have low exercise tolerance associated with blood pressure instability (Yabe et al., 2020); however, intradialytic exercise can improve intradialytic hypotension (IDH) and physical health (Rhee et al., 2019).

Due to varying study designs of exercise intensity, duration and location, more randomised controlled studies are required to explore these factors and to understand outcomes and implications. Detailed design and implementation of an intervention is also required, and can help development of robust, suitable and meaningful exercise programmes that provide patient benefit (Hargrove et al., 2021).

Barriers to increasing PA in this population include cost of trial design (Moorman et al., 2019) and application of intervention in the long term. Furthermore, clinical staff, nurses in particular feel they lack confidence or have time to motivate patients to engage in exercise (Regolisti et al., 2018) however, they are in the best place to motivate, encourage and educate patients about the benefits of PA (Jhamb et al., 2016).

2.6.1 Intradialytic cycling

One method to engage and embed structured PA in the dialysis setting is through cycling on dialysis (intra-dialytic); however, this is only available in a very small number of dialysis units across the United Kingdom (Greenwood et al., 2012). Research to date has focused on the benefits of intra-dialytic exercise (Heiwe and Jacobson, 2011) with studies showing associated benefits in both exercise tolerance (Groussard et al., 2015) and physiological parameters (Jung and Park, 2011, Reboredo et al., 2011). Storer et al. (2005) reported that 9 weeks of leg-cycling during haemodialysis improved not only cardiopulmonary fitness and endurance but also muscle strength, power, fatigability, and physical function (Storer et al., 2005). In a more recent study by Bogataj et al. (2020), sit to stand tests were significantly improved after eight and 12 weeks of functional training and ergonomic intradialytic cycling (IDC) compared to the control group of intradialytic cycling only. Furthermore, sit to stands and 6 minute walking tests improved after 12 weeks of 30 minutes of intradialytic cycling each dialysis session (Yeh et al., 2020). While evidence suggests that IDC has potential to improve patient outcomes that include increased exercise capacity, improved quality of life and physical function, the benefits of IDC remains unclear. Young et al. (2018) found that IDC remains unsupported due to insufficient reporting and varied use of outcome measures in the 13 studies included in their systematic review. Several studies demonstrated no statistical significance in improving blood pressure (Wilund et al., 2010), VO_2 Max (Moug et al., 2004) or work capacity (Parsons et al., 2004) and therefore larger randomised trials are required to provide more concrete data on the benefits of IDC (Young et al., 2018). Translating research-guided PA programmes into routine clinical practice is challenging, requiring consideration of patients' physical and psychological motivators, preferences and barriers to exercise, and substantial costs in terms of special equipment, training and staff time (Koufaki et al., 2013).

2.6.2 Exercise prescription in haemodialysis

With the established need for exercise during haemodialysis, there has been a call for nephrologists to 'prescribe' exercise for patients (March et al., 2017). However, the issue still remains that there are no clear guidelines as to the right dose, intensity and frequency of exercise that are safe for haemodialysis patients. It is well known that the health benefits of exercise and PA are essential to wellbeing but the availability to provide intradialytic exercise for haemodialysis patients is limiting due to time and other resource constraints (Greenwood et al., 2014).

PA prescription has been found to increase PA levels (Grandes et al., 2009, Stevens et al., 2014) by 10% especially in inactive patients (Courneya et al., 2008). Despite the benefits to exercise prescription, clinicians find it difficult to prescribe due to different patient specific co-morbidities such as cardiovascular disease (CVD) and the risk factors associated with such diseases (Hansen et al., 2017). Clinicians may not have appropriate training to prescribe PA, and patients may be referred to community based programmes to receive further support in goal setting and progress (Thornton et al., 2016). Furthermore, older patients voice that they do not receive that right support and advice regarding PA (Loprinzi and Beets, 2014) despite frequency of contact (Haseler et al., 2019). However, organisations such as Moving Medicine provide a range of evidence based resources to support professionals to advise and prescribe PA on a range of long term conditions (MM, 2018).

2.6.3 Walking programmes

Walking programs have been found to improve post dialysis fatigue (Malagoni et al., 2008) and exercise rehabilitation programs have improved general physical function (Greenwood et al., 2012). Home based pedometer walking programs to achieve 10,000 steps a day during non-dialysis days compared to intra-dialytic cycling during dialysis over a 24 week period demonstrated similar improvements in lower extremity function (Bohm et al., 2014). However, the goal of 10,000 steps was not achieved and adherence rates were low (Bohm et al., 2014). Despite low adherence rates in inter-dialytic exercise programs, peak oxygen and exercise time were much improved in a long term four year exercise program compared to participants who were assigned to the intradialytic cycling (Kouidi et al., 2004). The ability to engage patients in long term exercise programs and increase adherence rates in non-dialysis days has proven difficult. Age and length on dialysis has been found to be a significant factor in adherence; those who were older and with co-morbidities were less likely to adhere to exercise programs (Williams et al., 1991).

2.7 Behaviour change

Changing PA behaviour is a complex matter and involves several levels of external influences (Buchan et al., 2012). Social and physical environments play a role in behavioural change (Glanz et al., 2008) as well as other environmental factors (Humpel et al., 2002). A systematic review and meta-analysis by Williams and French (2011) assessed intervention techniques for changing PA behaviour and found that people who were provided with information on where, how and when to access exercise in the community, were associated with an increase in PA levels and self–efficacy versus those not given this information.

In a meta-analysis by Conn et al. (2008), it was found that educational and motivational sessions were just as effective as supervised exercise sessions in changing PA behaviour in patients with chronic illnesses (Conn et al., 2008, Dishman and Buckworth, 1996). A higher effect size using intervention strategies came from educational approaches that were designed to change one PA behaviour rather than many (Conn et al., 2008, Conn et al., 2002). It has been found that frequent contacts between participant and healthcare provider can also affect behaviour change and adherence to exercise uptake (Room et al., 2017, Williamson et al., 2016). In addition, a recent systematic review indicates that provision of information and feedback facilitates improved exercise adherence in older adults (Room et al., 2017).

2.7.1 Health promotion frameworks

There has been a long tradition of documented frameworks in understanding psychological behavioural change, particularly among patients with chronic disease. Numerous behavioural change techniques which have been successful in increasing PA in younger adults may not be suitable for older adults due to reduced intention to change behaviour (French et al., 2014, Orbell and Sheeran, 1998). Frameworks include Self-Determination Theory (SDT) and the Ecological Framework. SDT is concerned with the processes which motivate individuals to start new activities such as PA or other health behaviours and to sustain them over a longer term (Ryan and Deci, 2017). Behavioural change theories are discussed in detail in Chapter 3.

2.8 Outcome measures to assess physical activity

Numerous outcome measures have been used to assess physical activity in haemodialysis patients and both objective and subjective measures have advantages and disadvantages (table 2.1). Performance physical activity tests are useful prognostic tests, are cost-effective and can be administered easily and frequently (Mendoza et al., 2015). Devices for capturing PA in renal patients, such as pedometers and accelerometers are used as they can provide additional PA information on non-dialysis days (Mendoza et al., 2015) and have correlation to subjective measures such as the Human Activity Profile (Johansen et al., 2001). Heart rate monitors have been validated to detect heart rate variability in athletes (Hernando et al., 2018) and young renal patients (Weigmann-Faßbender et al., 2020). When heart rate monitors are not available, the Borg Scale can be implemented so that the participant can indicate to the researcher their rate of perceived exertion (RPE) and changes in heart rate (Borg, 1990). There have been numerous studies that have used the Borg scale as a simple method to assess an individual's work rate and perceived physical exertion (Afshar et al., 2010, Koufaki et al., 2002, Morishita et al., 2019, Weigmann-Faßbender et al., 2020) where formal exercise testing may not be accessible. While the Borg scale has been validated in several long term conditions (Penko et al., 2017, Rosales et al., 2016), the use of the Borg scale under certain conditions may not be as reliable due to variations in types of exercise, exercise protocol (Chen et al., 2002).

Subjective measures in the form of questionnaires have been validated in the renal population. These include the HAP (Johansen et al., 2001), General Practice Physical Activity Questionnaire (Wilkinson et al., 2020) and International Physical Activity Questionnaire (da Costa Rosa et al., 2015). The HAP has a wide range of activities compared to other questionnaires and is utilised more in longitudinal studies to capture participant physical function (Johansen et al., 2001, Mendoza et al., 2015). In terms of capturing quality of life, the EQ-5D-3L has been found to be reliable in chronic kidney disease patients (Hu et al., 2012) and transplant patients (Cleemput et al., 2004) and this will be discussed in Chapter 4.

Table 2.1 List of objective and subjective outcome measures used to assess physical activity in the haemodialysis population

Objective measures	ICF domain	Advantages	Disadvantages	Reference
Functional mobility tests: e.g.				
-6 minute walk test	Aerobic capacity and enduran ce	-Functional mobility tests are easy to administer	Does not effectively provide insight to mechanisms of exercise limitation	(Kohl et al., 2012)
-sit to stand test	Leg strength Fall risk	-Inexpensive	Does not identify risk of future falls	(Segura-Ortí and Martínez-Olmos, 2011)
-timed up and go test	Leg strength Fall risk	-Minimum amount of tools		(Ortega-Pérez de Villar et al., 2018)
Hang grip strength	Measure of isometric strength of hand and forearm	-Easy to calculate -Detects change in hand strength	-Dynamometer needs to be adjusted for hand size for accurate results -Calibration of dynamometer is required for accuracy -Does not measure strength of other muscle groups	(Olvera-Soto et al., 2016, Segura-Ortí and Martínez-Olmos, 2011)
Pedometers		Can inform participant how much they are walking. Easy to use	Can be unreliable	(Nowicki et al., 2010)
Accelerometers: e.g.		Intensity of activity Sedentary time	Does not determine type of activity	(Johansen et al., 2001)
-ActiGraph		Easy to use.	Bulky/challenging for participant to wear	(Huang et al., 2021)
-Axivity		2 week wear time/waterpro of.		(Doherty et al., 2017)

		Easy to use.		
Heart rate monitors BORG scale		 Easy to use	Cannot predict sedentary time	
Subjective measures	**ICF domain**	**Advantages**	**Disadvantages**	**Reference**
Self-report Questionnaires: -Human Activity Profile -GPPAQ -IPAQ -Kidney Disease quality of life short form 36		Correlation to accelerometer /large range of activities Easy to administer Easy to administer Specifically designed for dialysis patients	Under-reporting from participant/could lead to bias	(Johansen et al., 2001) (Wilkinson et al., 2020) (da Costa Rosa et al., 2015) (Hays et al., 1997)
Physical activity diaries/logs		Participants can detail daily activities	Time consuming/recall bias	
Interviews: -Structured -Semi-structured -Unstructured		Easy to compare participant answers Selection of topics to cover Narrative approach/personalised	Strict set of questions-one size fits all Combine both structured and unstructured approach Questions not prepared/hard to compare answers	(Bristowe et al., 2015)

2.9 Reasons for undertaking on this study

I have worked with dialysis patients for over 10 years and continue to witness the challenges and restrictions haemodialysis brings, I wish to give something back to these patients. In 2014, the unit was originally going to participate in the PEDAL trial (Greenwood et al., 2021). However, our unit predominately uses hospital beds instead of dialysis chairs which was required for purpose of the PEDAL study, and apologetically decided not to participate. As a result of this and with an already established group of sports exercise medicine experts wishing to explore exercise barriers and up take in this population, an in-house study was developed based on pilot data that was already being collected (Kluzek et al., 2013).

2.10 Pilot data to inform the research

This study builds on a pilot questionnaire-based study of patients undergoing treatment at Oxford Kidney Unit in February 2013 (Kluzek et al., 2013). The aim of this pilot study was to assess current activity PA levels, awareness of national Department of Health PA recommendations and perceptions of and barriers towards exercise in a representative group of dialysis patients. Patients were given validated self-report questionnaires of PA (General Practice Physical Activity Questionnaire (GPPAQ)) along with a validated questionnaire exploring perceptions of and barriers towards exercise (Dialysis patient-perceived Exercise Benefits and Barriers Scale (DPEBBS)) (Zheng et al., 2010). This pilot work found that 78% of patients were inactive according to GPPAQ score and that the majority of DPEBBS exercise correlates were poor predictors of actual PA levels. However, PA levels for the general population were not collected for this pilot and not compared. Questionnaires may not be as sensitive to small differences in activity among individuals as device based measurements, particularly for low-intensity activity, hence this thesis builds on work by Kluzek et al. (2013) to further explore motivators and barriers towards exercise in this population. This pilot work provided the foundation of my research question: *Can identifying motivators and barriers towards PA in dialysis patients help identify a safe, feasible and acceptable intervention to increase PA levels?*

2.11 Objectives for this research

There has been very little research using qualitative and quantitative methods to capture and understand activity levels in haemodialysis patients. The first objective is to understand previous PA patterns in HD patients prior to initiation of dialysis using self-report questionnaires. Assessing the impact of any PA intervention requires comparison of health and exercise behaviours pre-and post-intervention. Several self-report questionnaires of PA levels have been validated in the general population, with evidence suggesting that the Human Activity Profile (HAP) shows the best correlation with quantitative accelerometery and physical performance measures in an end-stage renal disease cohort (Johansen et al., 2001).

The second objectives is to describe current PA patterns in HD patients on both dialysis and non-dialysis days. This will involve objective measurement devices such as accelerometers and small wearable cameras to facilitate quantitative validation of self-report data. I will also explore perceptions, symptoms, motivators and barriers which facilitate or constrain HD patients' participation in PA. The use of cameras to enhance the process of semi structured interviews allows researchers to gain a deeper understanding of patient specific motivators and barriers towards PA. Qualitative semi structured interviews have been found useful in healthcare research as they allow for ideas and interviewee responses to be explored in detail (Britten, 1999, DeJonckheere and Vaughn, 2019). The knowledge gained will be used to develop a targeted educational PA intervention that is suitable to haemodialysis patients.

The third objective is to co-develop a safe and feasible physical activity intervention with patients and relevant stakeholders. Experts in rehabilitation and exercise physiology will develop and adapt a suitable intervention as well as reviewing current literature. The fourth objective is to trial a feasible PA intervention within the clinical setting. Short, directed questions and semi-structured interviews with study participants will assess the feasibility and acceptability of the exercise programme. The data from the feasibility study will inform the suitability of a further larger randomised controlled study.

2.12 Thesis structure

The structure of this thesis is based on the updated *2000 Medical Research Council (MRC) Framework for the Development and Evaluation of RCT's for Complex Interventions to Improve Health* (Figure 1.4) (UKMRC, 2006). This document, currently being revised provides researchers with appropriate and relevant guidance on development, evaluation and implementation of interventions that aim to improve health within a clinical or non-clinical environment. Chapters 1, 2, 3 and 4 will underpin phase one of the framework and understand the theory to systematically develop a planned intervention. Chapter 6 (phase 3 of the framework) will identify and describe the components of the protocol and implementation of the intervention (feasibility study) within the clinical setting. Chapter 7 will provide preliminary results from the feasibility study. Phase 4 and Phase 5 of the framework will not be discussed in detail but will acknowledge future work and forward planning with evaluation processes in place to assess any discrepancies between observed or expected outcomes.

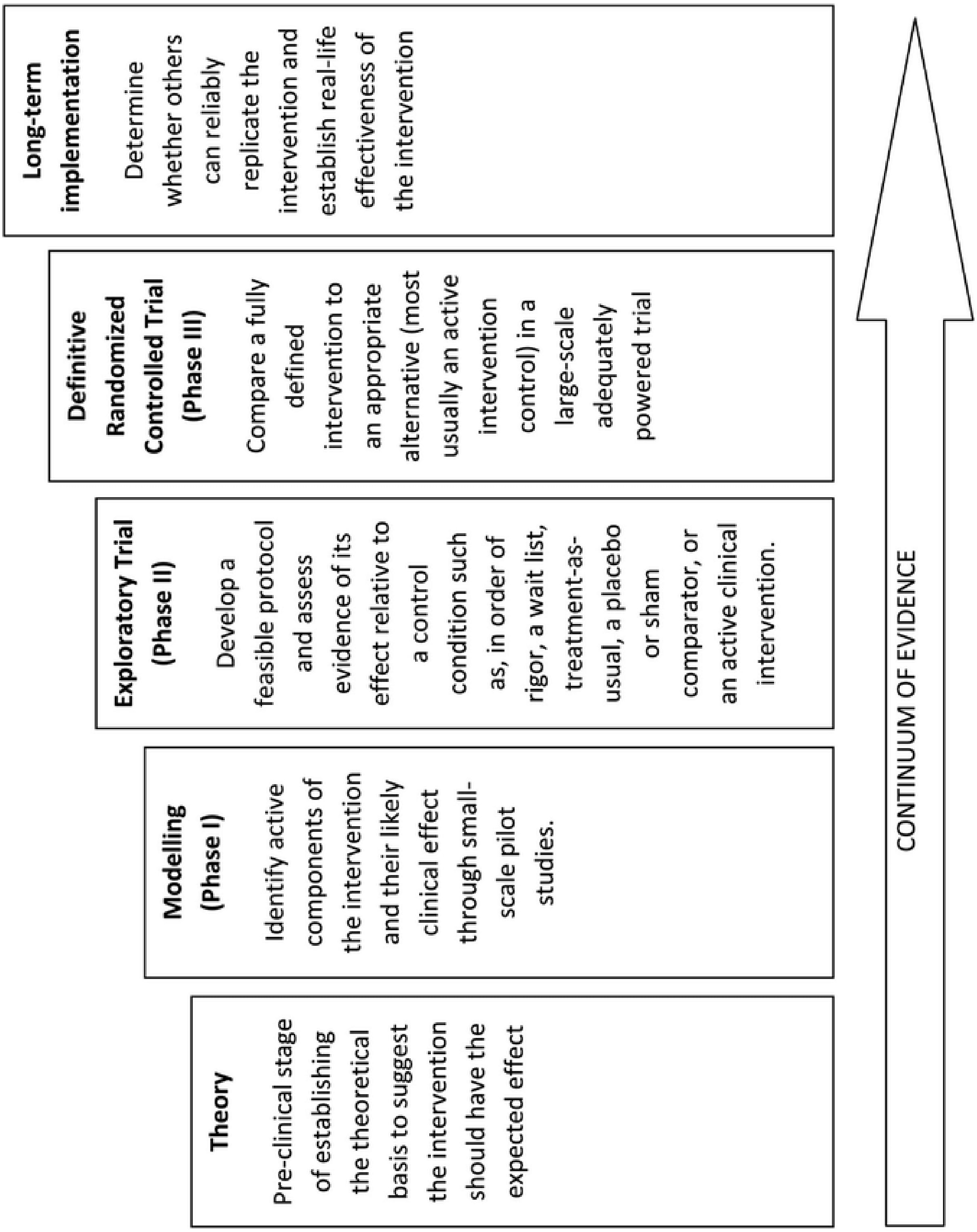


Figure 2.1 Medical Research Council Framework for trials with complex intervention

Taken from: https://mrc.ukri.org/documents/pdf/rcts-for-complex-interventions-to-improve-health/

Chapter 3

Theoretical foundations: developing the intervention to increase physical activity

3.1 Overview

Within the MRC framework (UKMRC, 2006), the development of the intervention for this study requires a review of current evidence and theories. It is often difficult to explain how an intervention causes change, and so a good understanding of existing theory is essential to underpin a complex intervention (Craig et al., 2008, O'Cathain et al., 2019). This chapter will provide an overview of the psycho-social frameworks and behavioural change techniques and interventions, which have informed the development and implementation of the intervention to increase physical activity (PA) among patients on haemodialysis.

3.2 Theory

Theory has been defined as a set of inter-related concepts or ideas intended to explain observed phenomena (Stevenson, 2010). Theories are in essence abstract in an nature and the content or topic of interest is not necessarily specified (Health and Services, 2005).

3.3 Theories of health behaviour and behaviour change

Theories of health behaviour are helpful in understanding participation in PA at all levels (Biddle and Mutrie, 2007). To enable a suitable design of an intervention to increase PA, theories provide direction and structure to achieve specific goals (Nurse and Edmondson-Jones, 2007) and are useful tools to improve current policies, strategies and health programmes (DoH, 2012, Hickson, 2015).

Numerous psychosocial theories have been developed to promote changes in behaviour to improve health. Among the most commonly used are Theory of Planned Behaviour (Ajzen, 1985), Social Cognitive Theory (Bandura, 1991, Bandura, 2004, Biddle and Nigg, 2000), the Transtheoretical Model (Prochaska and DiClemente, 1983, Prochaska et al., 2015), the Self-Determination Theory (SDT)(Ryan and Deci, 2017, Deci and Ryan, 2008) and Health Belief Model (Becker, 1974, Champion and Skinner, 2008).

3.3.1 Theory of Reasoned Action and Theory of Planned Behaviour

The Theory of Reasoned Action (TRA) (Ajzen, 1991, Fishbein and Ajzen, 1977) is useful for recognising where and how to target strategies for behaviour change (Sheppard et al., 1988). This theory suggests that 'intent' is the most important factor of behaviour, influenced by the individual's attitude and social influences towards behaviour. In its simplest form, behavioural intention is equal to individual attitudes towards performing the behaviour (e.g. benefits of PA) weighed against the impact or consequences of that behaviour (e.g. providing long term health). However, several limitations of the TRA were identified which led to the development of the Theory of Planned Behaviour (TPB) (Ajzen, 1985, Ajzen, 2011).

The Theory of Planned Behaviour includes the Theory of Reasoned Action with an added construct: perceived behaviour control. This construct looks at whether the individual or group believe they have the means to control the outcome and essentially asks if they can achieve the desired goal. The added construct has improved the TRA by modifying the 'intent' to 'action' and what the individual believes they need to do to change a certain behaviour (Crosby et al., 2013). There are several limitations with the TPB. It does not take into account individual emotion, or the opportunities and resources available to change behaviour (Ajzen, 2011).

3.3.2. Social Cognitive Theory

The basis of Social Cognitive Theory (SCT) takes into consideration the interactions between environmental, behavioural and personal influences that contribute to change and maintaining behaviour (Bandura, 2004, Bandura et al., 1999). There are six constructs to the SCT; reciprocal determinism, behavioural capacity, observational learning, reinforcements, expectations and self-efficacy. There is a strong emphasis on social influences, especially internal and external social support and how people obtain and retain behaviour. Some studies in renal settings have used SCT in understanding PA change in dialysis patients (Patterson et al., 2014). Whilst the use of SCT may be suitable for some studies, there is a limitation of the SCT as it focusses mainly on individual past experience rather than change behaviour.

3.3.3 Transtheoretical Model of Change

Unlike other theories that focus on social and biological influences, the Transtheoretical Model (TTM) (Prochaska and DiClemente, 1983, Prochaska et al., 2015) is more integrative being a biopsychosocial model. The main focus of the TMC is that there are stages of change and change process and this happens over time. The 6 key constructs or stages of the TMC include pre-contemplation (not ready), contemplation (getting ready), preparation (ready), action, maintenance and termination of behaviour change. Mainly used to aid people in smoking cessation, the stages of the TMC did not take into account that there would be numerous attempts for patients in attaining a stage, i.e. repeating the pre-contemplation and contemplation stage as the individual experience of behaviour change is variable (DiClemente et al., 2013). The TTM has been and can be applied across a wide range of behaviours including diet and physical activity (Bohm et al., 2018, Povey et al., 1999) and involves 10 principles that support the processes of change (DiClemente et al., 2013). These 10 processes of change can be matched or aligned with the TTM to allow for effective intervention. The limitations of the TTM however are that there is no mention of how long a person needs to remain at a particular stage and does not necessarily take into consideration the social context in which change occurs.

3.3.4. Self Determination Theory

SDT is concerned with the processes which motivate individuals to start new activities such as PA or other health behaviours and to sustain them over a longer term (Ryan and Deci, 2000, Ryan and Deci, 2017). This theory suggests that individuals have three basic needs: autonomy (source of one's behaviour), competence (feeling effective) and relatedness (feeling connected to communities and others). The more these needs are attained and fulfilled the more the person is able to determine their own behaviour (Ryan and Deci, 2000, Ryan and Deci, 2017). SDT in essence is the individual's relationship to motivation, both 'autonomous' and 'controlled'. Autonomous motivation synthesises the internal and external sources. This involves how and individual perceives the value of the activity and how it aligns with their own beliefs. Therefore, the motivation is more self-directed. Controlled motivation involves external regulation, where the individual's behaviour or motivation is brought out by the need for rewards or approval (Deci and Ryan, 2008).

A review of several social cognitive models found strengths and weaknesses in TRA, TPB and TTM, but found that the TRA and TPB were superior to the HBM (Coulson et al., 2016, Taylor et al., 2006). The TTM continues to be used for behaviour change, however, is limited by its applicability in terms of environmental, social, or even biological context in relation to change behaviour. The use of the TTM in some health care specialities is not better than alternative interventions and that the TTM is difficult to validate due to lack of empirical data (Taylor et al., 2006) and provides inconclusive evidence in changing physical activity behaviour (Kleis et al., 2020). Similarly with the TRA and TPB, there have been several criticisms of these theories with validity and utility (Sulat et al., 2018). The TPB in longitudinal studies is less predictive than shorter studies and that it does not help understand future behaviour change (McEachan et al., 2011). Despite these weaknesses, these theories especially the TPB continues to be used widely due to its structural and conceptual framework which can be applied to any speciality (Ajzen, 2020).

Despite being inferior to the TRA, TPB and TTM, a recent scoping review found the HBM to be a good predictor of change behaviour, however, data is varied and a meta-analysis is required (Sulat et al., 2018). The HBM, however less superior to other models, continues to be used in health research and is a useful model to discover new information that can help prompt new intervention designs (Taylor et al., 2006).

3.4 Health Belief Model

The Health Belief Model was originally developed in the early 1950s to understand why medical screening programs for tuberculosis were unsuccessful (Hochbaum, 1958). Health behaviour is about what people do to maintain health and prevent disease. After initial development, the HBM was revised to include general health motivation in order to distinguish illness behaviour and the sick-role behaviour from health behaviour (Champion and Skinner, 2008, Becker, 1974). Examples of illness behaviour in renal patients include non-adherence to medication or attendance to dialysis (Geldine et al., 2017, Janosevic et al., 2019). Depression is a major contributing factor to non-adherence in renal patients (Alosaimi et al., 2016, Tohme et al., 2017) and thus attention to behaviour change is needed (Dean and Low, 2012).

The HBM has been used extensively to predict and explain behaviour change in the health care setting and is well documented in previous reviews (Carpenter, 2010, Harrison et al., 1992, Janz and Becker, 1984, Zimmerman and Vernberg, 1994). The HBM can be used as a theoretical framework to develop programs specific to clinical areas including renal in preventing disease behaviours. These programs also provide an idea of the individual's belief of the severity of the disease. The HBM has also been used in understanding PA behaviours and understanding how PA uptake can change over time. The HBM is of value in obtaining relevant and specific information to help determine the design of suitable interventions to enable change in behaviour (Taylor et al., 2006). The HBM is therefore suitable for this study as it provides the structure to seek and understand patient's behavioural reluctance to engage in PA. The Health Belief Model also allows the mechanisms to find solutions to facilitate behaviour change.

The HBM attempts to predict health-related behaviour in terms of certain beliefs and has been used to study a wide range of health behaviors (Champion and Skinner, 2008). Motivations to undertake a health-directed change have been identified in three main categories: i) individual perceptions of the health behaviour, ii) modifying factors (e.g. age, socioeconomic background), iii) and likelihood of action to initiate change. Individual perceptions are factors that affect the perception of their illness or disease; they deal with the importance of health to the individual, perceived susceptibility to, and the perceived severity of a condition or illness (Becker, 1974).

There are several factors that need to be taken into consideration with regards to the HBM. These include demographic variables (e.g. age, ethnicity, educational level), perceived threat (the threat of getting a disease or disease worsening), and cues to action (strategies to implement change).

The HBM states that the perception of a threat to personal health behavior is itself influenced by at least three further factors: general health values, which include interest and concern about health; specific health beliefs about vulnerability to a particular health threat; and beliefs about the consequences of the health problem. The model suggests that when an individual perceives a threat to their health, they weigh up their perceptions on the benefit of action compared to the costs, before deciding to undertake the recommended preventive action.

3.4.1 Key descriptors of the HBM

The following key descriptors serve as the main constructs of the HBM. The original HBM had four main constructs: perceived susceptibility, perceived seriousness, perceived benefits and perceived barriers. Over time the model has expanded and now includes constructs such as cues to action and self-efficacy (Figure 3.1) (Champion and Skinner, 2008).

Perceived Susceptibility

Individuals differ in their own perception of the likelihood of experiencing a condition that negatively affects health. With varying degrees, some deny the possibility of improving physical health as a result of doing more PA, whilst others believe that there is a high chance that they will improve some aspects of health.

Perceived Seriousness/Severity

This descriptor represents the beliefs an individual has concerning the effects their disease would have on them. This can include financial issues due to reduced work hours, associated pain with disease, family and relationship issues, and increased susceptibility to other co-morbid conditions.

Perceived Benefits of Taking Action

After accepting and recognising the seriousness of their disease, the next step for the individual is to take action in dealing with the disease. The specific action to be taken is to be guided and influenced by their current beliefs regarding the action available to them.

Perceived Barriers to Taking Action

When an individual believes that there are benefits to taking action, the action itself may still not take place. This may be due to barriers that prevent uptake of the desired action. Barriers can include treatments or measures that are expensive or inconvenient or even painful. For example, travel, cost, time constraints, lack of carers to take them to PA activities, feeling frightened, embarrassed and accessibility to venues.

Cues to Action

A 'cue to action' may be needed to precipitate or prompt a desired action to occur. The cues that the individual acts upon may be internal (e.g. belief, change in symptoms or feeling unwell) or external (e.g. media coverage, prompting by family members).

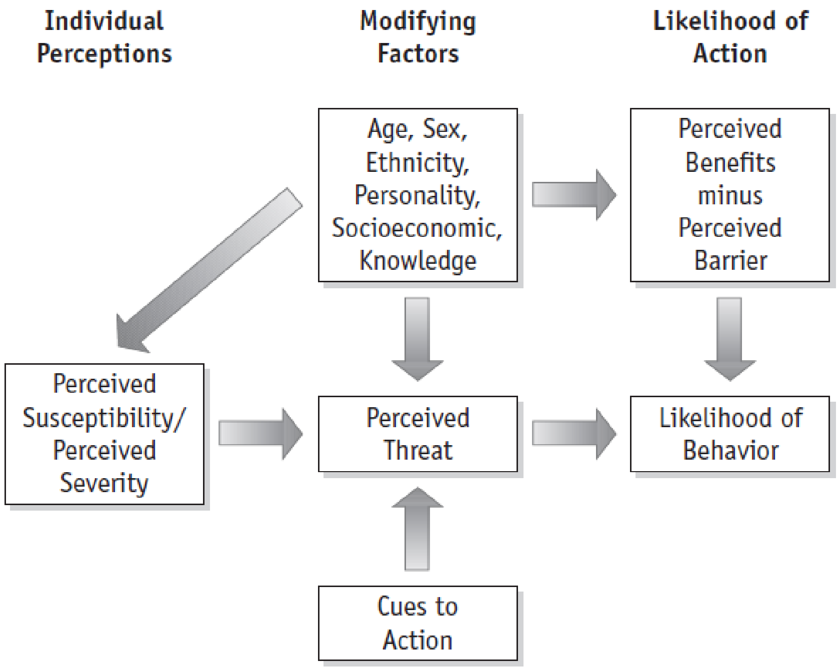


Figure 3.1 Health Belief Model **Diagram**
According to the HBM, Modifying factors, cues to action that potentially affect perceptions of susceptibility of a disease, benefits and barriers and behaviour.

Taken from Stretcher and Rosenstock (1997) The Health Belief Model in Glanz, K., Lewis, FM., and Rimer, BK. (Eds.) *Health behaviour and health: Theory, research and practice*. San Francisco: Jossey-Bass.

It is important in this phase of the study that the use of a theoretical framework should be stated clearly as described in the MRC framework (UKMRC, 2006). The HBM can also be adapted as long as the main constructs remain true to the original HBM (Sutton, 2001). In a recent meta-analysis, 2 constructs of the HBM, perceived barriers of disease and perceived benefits, were found to be the strongest predictors of behaviour (Carpenter, 2010). However, the HBM has been found to be a poor predictor of behaviour change. Despite this, the HBM has been used in several studies of renal patients assessing adherence to the renal diet (Katz et al., 1998, Nooriani et al., 2019) and medication adherence in transplant patients (Kung et al., 2017). Studies have shown statistically significant changes using the HBM as a framework to promote healthy behaviour change.

3.4.2 Limitations of the HBM

The HBM does not take into account previous experiences with action, and socioeconomic status that may influence the nature and extent of individual changes in health behaviour. The HBM additionally does not focus on participant habitual routine that already inform individual decision-making processes. There is also no clear relationship between the modifying factors (Orji et al., 2012).

3.4.3 Adaptation of HBM for current study

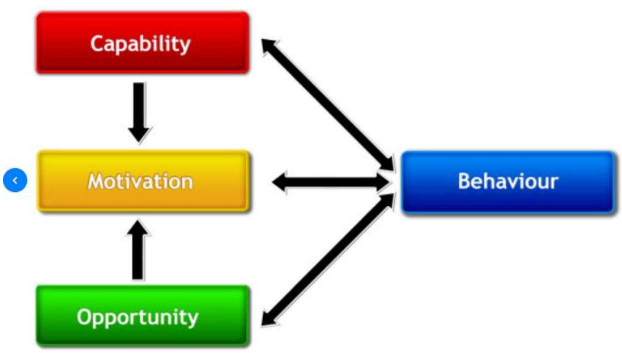
For the purpose of this study, the constructs of the HBM were given subthemes specified on the basis of the interview element of this observational study (study 1) (See Chapter 5). The current observational study was to determine the motivators and barriers towards PA, therefore the first two construct of 'perceived susceptibility' and 'perceived severity' were not utilised. If any comments provided by participants in the interviews were related to the severity of their current disease, this was noted. The remaining constructs of the HBM were modified around participant attitudes and beliefs around PA. Pre-determined constructs included: perceived benefits of PA, perceived barriers to PA and cues to PA participation (See Chapter 5).

3.5 Behaviour change techniques

Procedures to bring about behaviour change can be delivered at several levels including individual, household and family, community and population levels. Implementing behavioural change strategies must also take into account the points in the lives of the individual, such as bereavement, family commitments and lack of employment as this may hinder or aid the behavioural change process (NICE, 2014).

3.6 The COM-B system and Behaviour Change Wheel

To initiate a change in a specific behaviour pattern, coordinated sets of activities are required (Michie et al., 2011). Changing PA behaviour is a complex matter and involves several levels of external influences (Buchan et al., 2012) including personal and social circumstances and physical environments (Sallis et al., 2008) as well as other environmental factors (Humpel et al., 2002). Michie et al. (2011), establishing a need for a new framework method, sought to identify and evaluate frameworks of behavioural change interventions. Up to 19 different frameworks were identified classifying different behaviour interventions. Interventions as part of a study are commonly designed without evidence to support its likely efficacy or analysis of desired target behaviour. Proposing a new framework, at the centre of the 'behavioural system', the COM-B system was developed (Figure 3.2) (Michie et al., 2011).



The COM-B system - a framework for understanding behaviour.

Image taken from Michie et al, 2011

Figure 3.2: The COM-B System- framework.

The COM-B illustrates that capability, opportunity and motivation interlink and interact with each other to generate behaviour. Behaviour also generates capability, opportunity and motivation. The capability is the individual's capacity to engage with the activity with their current skill set and knowledge base. Motivation encompasses a range of habitual processes and emotional responses to the decision-making processes and the direct behaviour to engaging with the activity. The opportunities are all the external factors that allow that individual to make that behaviour change possible. These 3 components generate behaviour and can be developed further with 6 components: 1) physical 2) psychological, 3) physical, 4) environmental, 5) reflective process and 6) automatic process (Michie et al, 2011).

The COM-B system forms the centre of the Behaviour Change Wheel (BCW) which houses 9 intervention functions that address the insufficient intervention functions. The BCW also includes 7 policy categories that can enable specific interventions to take place and be successful (Figure 3.3).

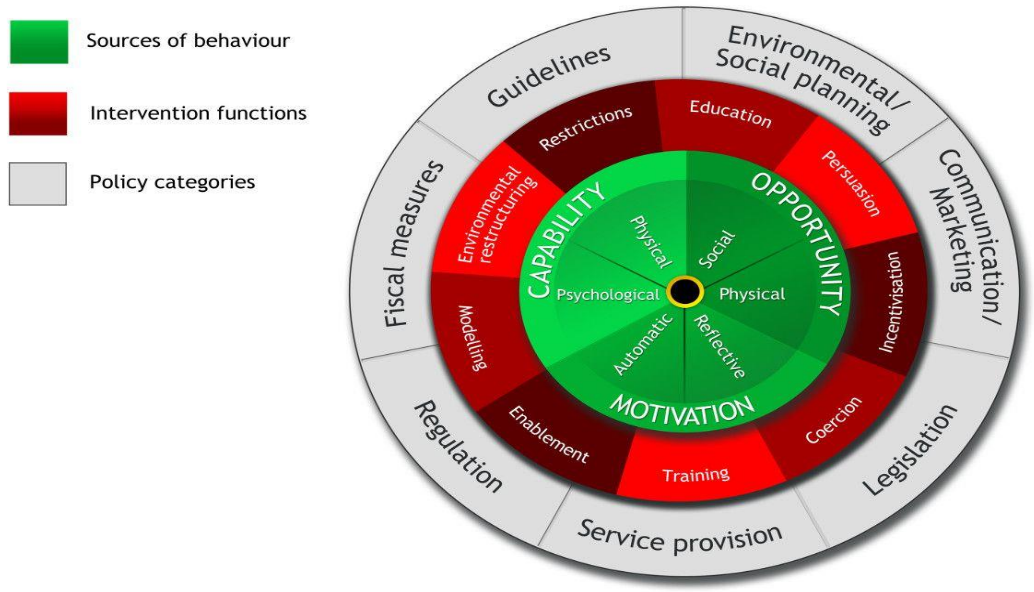


Figure 3.3 - Behaviour change wheel

Taken from Michie et al (2013)

Whilst the COM-B is not formally used in this study, elements of the wheel will be used. Motivation and provision of an opportunity for PA within the clinical setting will be drawn to support the intervention. The COM-B with or without the BCW have been used in healthcare in several areas such as auditory rehabilitation (Barker et al., 2016), increase of sexual health services for university students (Cassidy et al., 2018a), smoking cessation (Gould et al., 2017) and implementing exercise in renal patients (Clarke et al., 2019). By using the BCW, Clarke et al. (2019) were able to identify barriers in both patients and health care professionals in engaging and promoting physical activity which included reduced physical opportunities, lack of PA culture, education and training respectively. The authors recommend that future research should be theory based as well as evidence based to inform clinical PA interventions.

3.7 Motivational interviewing

Developed by Miller (1983), motivational interviewing (MI) was initially used to treat patients with alcohol abuse. MI is used as a tool to address the patient’s lack of motivation, or intrinsic motivation to initiate behaviour change. Further revised by Miller and Rollnick (1991), MI has since been incorporated to treat other clinical health care settings such as diabetes, obesity and asthma (Chen et al., 2012, Hutchinson et al., 2013, Perrin et al., 2007). MI is not about the health care professional directly providing advice or the information. MI is designed to provide the patient the opportunity to do most of the speaking whilst the health care provider is guiding the initial process. This practice allows the patient to identify and realise the goals themselves and internalise the change process (Rollnick and Miller, 1995).

3.7.1 Key principles of MI

MI has four key principles to facilitate a successful outcome (Martino, 2011):

i) Roll with resistance:

Confronting any issues head on with the patient should essentially be avoided to reduce any resistance already experienced. Empowerment to seek solutions is brought about by ''rolling with resistance'' (Britt et al., 2003).

ii) Express empathy and use reflective listening:

Empathy is required to build on trust between patient and health care professional. Empathy promotes rapport and reflective listening demonstrates that the patient is recognised and understood (Scales et al., 2003).

iii) Develop discrepancy

This principle involves the health care professional providing the patient with differences in current behaviour and goal treatment targets. This technique allows the patient to reflect on their progress and behaviour to continue to develop to make changes (Westra and Aviram, 2013).

iv) Support self-efficacy

Self-efficacy of the individual is key to empowering patients make change. It is the patient's belief that they have the ability to make the change and achieve goals. This involves regular feedback and encouragement to develop self-efficacy (Martino, 2011).

3.7.2 Motivational interviewing in renal care

MI is a recommended intervention and 'tool for change' identified by the Transforming Participation in Chronic Kidney Disease (TP-CKD) programme (NHS-England, 2020). The Motivational Interviewing in Dialysis Adherence Study (MIDAS) (Russell et al., 2011) assessed the effect of MI in response to dialysis adherence and medication regimen. With 29 participants enrolled to the study, results indicated that MI reduced the frequency of missed dialysis treatments from 25 per cent to 5 per cent over a 3 month interventional period (Russell et al., 2011). MI has also been effective in other key areas of dialysis such as control of intradialytic fluid gains (Fisher et al., 2006), improved diet (Barnes and Cassidy, 2018) decision making (Sanders et al., 2013) as well as ESRD related co-morbid diseases such as diabetes (Clark and Hampson, 2001).

3.7.3 Motivational interviewing in changing PA behaviour

MI can be used as a technique to change behaviour in physical activity in an array of age groups. In a study by Gourlan et al. (2013), MI was used as part of an intervention in a weight loss program in adolescents over a 6-month period. Findings indicated that those receiving MI in addition to the standard weight loss programme had a greater decrease Body Mass Index (BMI) compared to those just receiving the standard loss programme. Greater autonomy, greater increase in goals was reported in addition to an increase in PA practice (Gourlan et al., 2013). In addition to cancer, diabetes, CRF, brain injury and rehabilitation, MI has been used with renal dialysis patients to increase uptake of PA.

van Vilsteren et al. (2005) sought to determine whether a low-to-moderate pre-conditioning exercise programme combined with exercise counselling could improve behavioural change in 53 dialysis patients. Behavioural change, quality of life, lower extremity muscle strength and reaction time increased in an exercise group of HD patients (van Vilsteren et al., 2005). Smitham and Lawn (2010) pilot study provided patients with MI whilst undertaking intradialytic exercise. MI was given to patients who did minimal activity or did not exercise. Although this study was small with only 8 patients and a dropout rate was noted, generalised trends such as individual patient benefits towards PA were ascertained although no causal link between MI and intradialytic exercise was established. In a more recent study involving transplant recipients, receiving a 12 week supervised aerobic or resistance training intervention which included MI. Results indicated that facilitation of supervised training to self-managed activity programmes was successful in 42 out of the 60 participants recruited (O'Connor et al., 2017). The positive impact of supervised exercise programmes, provision of education and regular feedback has been highlighted in previous studies (Greenwood et al., 2015, Greenwood et al., 2014, Koufaki et al., 2013).

3.8 Using theory to identify motivators and barriers towards PA

The above theories and interventions suggest that all possess advantages and limitations. The use of the HBM for this research study was deemed suitable as it would bring out key information to understand patient health beliefs and attitudes and to understand suitable cues to action. MI is already used as an intervention method in the Oxford dialysis unit and is already successful in supporting patients with fluid management and therefore MI was incorporated into the design of this study.

Chapter 4

Methods to identify barriers to PA dialysis patients

4.1 Overview and aim.

This chapter sets out to test the feasibility as measured by acceptability, usability and utility of three approaches to measuring PA in patients with CKD and then identify motivators and barriers towards PA in this patient group. Specifically, the study set out to describe: recruitment to participating in the study, completion of measures used, usability of measures as determined by a usability scale, and the views and opinions of using the measures as an aid to help describe daily activities from process interviews. The findings from this study were then implemented in Chapter 5 to describe physical activity in people living with haemodialysis.

4.2 Rationale for observational study

This observational study aims to establish the acceptability of accelerometers to determine PA levels in this cohort and establish if wearable cameras are an acceptable method to aid in memory recall to determine types of activities over a defined period of time. The wearable cameras will be used to facilitate the semi-structured interview process to aid memory recall in determining participant activities undertaken. Questionnaires, the third method to measure PA in will be used to determine current and previous PA levels. The information obtained from these methods, specifically from the semi-structured interviews, will help identify the motivators and barriers to PA and with participant input, help inform a suitable PA intervention.

4.3 Methods to measure PA in the study

This study draws on both quantitative and qualitative methods to capture PA levels of haemodialysis patients. While most studies use questionnaires and interviews to conduct mixed method study, there are strengths and weaknesses to both methods of data collection. Using self-report questionnaires as a quantitative method to capture PA levels can be prone to bias and may give an inflexibility in participant responses (Harris and Brown, 2010). Questionnaires alone may provide inaccurate reporting and activity outcomes (Ainsworth et al., 2012).

Wearable devices, such as accelerometers offer an objective and quantitative method to capture PA levels. Accelerometers on their own may not be accurate due to participant wear time compliance rates (Vallance et al., 2019) or monitoring failure (Vanhelst et al., 2019). Despite this accelerometers are the best objective method to accurately capture PA levels in individuals (Vallance et al., 2019) as they provide continuous longitudinal recording of activity (Hills et al., 2014) and are easy to use.

4.4 Questionnaires

4.4.1 EQ-5D-3L ™- Quality of Life

EuroQol's EQ-5D quality of life (QoL) health status questionnaire has been utilised in healthcare for nearly three decades (EuroQol, 2020). There are other QoL questionnaires such as the short form -36 (SF-36) however due to the length of the questionnaire this can be burdensome for research participants to complete and can contribute to missing data (Brazier et al., 1996, Loosman et al., 2015). The EQ-5D has been validated in the renal dialysis population (Mitchell et al., 2020) and in transplant population (Cleemput et al., 2004) due to ease of completion and that the questionnaire can be incorporated into study design to assess QoL, economic evaluation to improve patient outcomes (Mitchell et al., 2020).

The original EQ-5D-3L (Appendix 2), was used for this study to capture participant general health status and continues to be considered to be a valid measure (Janssen et al., 2018). As renal patients have multiple co-morbidities, the EQ-5D-3L questionnaire can be used for a variety of conditions, and captures a patient's health state at one particular moment of time (EuroQol, 2020).

The EQ-5D-3L™ includes five domains on a three-part level which include mobility, self-care, usual activities, pain/discomfort and anxiety and depression. Each domain is scored on one of three levels; 1) indicating if they have no problems, 2) they have some problems, or 3) they have extreme problems. The domains are rated using the levels indicated by the respondent which will create a five-digit number indicating the respondent's health status. Respondents having a five-digit number of 11111 have no problems in all domains, though those indicating

33333 in all domains indicate having extreme problems. Outputs from this section of the questionnaire generates 243 health states and respondents' results can vary widely.

The second part of the EQ-5D-3L™ is the visual analogue scale where respondents are asked to measure their health status on a scale between 0-100, where 0 is experiencing the worst health state imaginable and a measure of 100 is experiencing the best health state at that time. Respondents are asked to draw a line where they perceive their health state for that day to indicate quality of life (EuroQol, 2020).

4.4.2 Human Activity Profile – Physical Function

Whilst the EQ-5D-3L™ measures participant quality of life, the Human Activity Profile (HAP) measures perceived physical fitness using a self-reported questionnaire. The Human Activity Profile is used widely across the health spectrum and validated in numerous health conditions including stroke (Teixeira-Salmela et al., 2007), stem cell transplantation (Herzberg et al., 2010), and the elderly in the community (de Carvalho Bastone et al., 2014). The HAP has been validated in renal dialysis patients (Johansen et al., 2001) and has been used in several studies thereafter as an assessment tool to assess physical activity levels (Bonner et al., 2010a, Hayhurst and Ahmed, 2015, Robinson-Cohen et al., 2013).

The HAP requires the respondent to indicate whether they continue to do an activity, have stopped doing an activity or never did an activity from a list of 94 activities (Daughton et al., 1983) (Appendix 3). The activities are ranked according to the identified energy expenditure needed to perform the specific task. From this, the maximal activity score is calculated as the respondents' last task that they are able to perform. The adjusted activity score is calculated by totalling the number of activities that the respondent has stopped and subtracting this from the maximal activity score.

Metabolic Equivalent of Task (MET) are associated with each of the 94 items on the HAP questionnaire, determining what activity the respondent is still able to do, compared to what they were able to do in the past. The structure of the HAP also takes into consideration 4 muscle subgroup scales (hand use, leg effort, back effort and wheelchair use) and 4 activity subscales (personal/household work, self-care, entertainment and independent exercise) (Daughton et al., 1983, Davidson and de Morton, 2007).

A systematic review in 2007 found the HAP to be a beneficial tool in assessing PA levels in patients with various co-morbid conditions including renal failure (Davidson and de Morton, 2007). The use of self-report questionnaires has been used in the CKD population (Johansen et al., 2001) and more notably the HAP correlates best against objectively measured accelerometer data (Robinson-Cohen et al., 2013).

4.5 Wearable devices

Objective measurement devices such as accelerometers and small wearable cameras facilitate quantitative validation of self-report data. These will now be detailed in the following subsections.

4.5.1 Accelerometers - Objective measures to capture PA

Accelerometers are devices that capture or measure the acceleration and deceleration of human movement (Munsch and Zack, 2018) (Figure 4.1). Accelerometers have been used to determine PA levels and sedentary behaviour. The accelerometer measures movement in three directions and detects vibrations, movement and changes in orientation or direction of the individual (Figure 4.2).

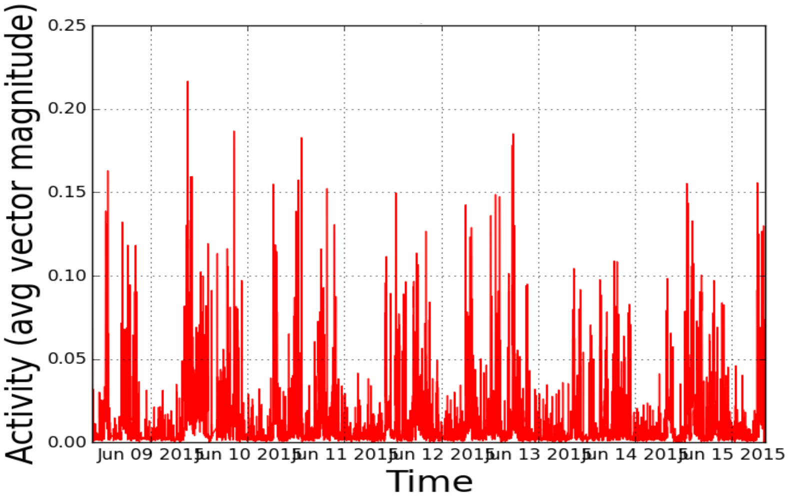


Figure 4.1 Figure 4.2

Figure 4.1: Image of Axivity AX3 Wrist worn accelerometer
Figure 4.2: Accelerometer output over a 7 day period. The average vector magnitude (VM) is derived from the square root of the square of the following 3 planes; vertical, anterior-posterior2, and medial-lateral. The accelerometer detects the motion with the 3 planes and the VM is generated.

Measuring habitual physical activity with an accelerometer is widely used in sports and preventive medicine and has been shown to be a valid measure of PA at varying levels of intensity (Esliger et al., 2011). Accelerometers have been used to assess PA in co-morbid diseases such as cardiovascular disease (Cassidy et al., 2018b), diabetes (Baskerville et al., 2017) and renal disease (Kosaki et al., 2020, Reboredo et al., 2017). Whilst there have been limited studies using accelerometers to describe PA associations with kidney function (Guo et al., 2016, Hawkins et al., 2011, Martens et al., 2018), several studies have used accelerometers to assess PA in day to day life in the renal population (Gomes et al., 2015, Shiota and Hashimoto, 2016). Although participant numbers are small for both Gomes et al. (2015) and Shiota and Hashimoto (2016) studies, wrist worn accelerometers were worn for 7 days suggesting participant device acceptability although this was never captured as part of their studies.

(Martens et al., 2018) examined and reviewed PA levels and sedentary behaviour of 2,258 participants involved in the Maastricht study. Accelerometers were worn for one week and were compared to continuous eGFR and albuminaria. Findings suggest that high sedentary behaviour was associated with an increase in adverse kidney function. Conversely, participants with increased PA had lower levels of kidney damage (Martens et al., 2018).

The use of accelerometers in this population allows for improved accuracy in data collection of PA levels (Pitta et al., 2006). Axivity (Newcastle upon Tyne, United Kingdom) (Figure 4.1) AX3 wrist worn data loggers were used for this study to capture one weeks' worth of data. Axivity AX3 accelerometers have been used in a large scale cohort studies to capture PA levels and health related outcomes over time (Doherty et al., 2017).

4.5.2 Data processing of accelerometer

The raw 100Hz accelerometer data was converted into summary episodes of sedentary behaviour and PA. An in-house software tool converted the raw data into summary 1 minute epochs (Esliger et al., 2011). Thereafter, episodes of non-wear time were identified for each participant where the standard deviation for each of the three axes was less than 13mg for at least an hour (Doherty et al., 2017). Daily wear time was determined by subtracting non-wear time from 24 hours.

4.5.3 Data Analysis

To ensure data quality only participants who had sufficient wear time were included. Patients with less than 3 day total wear time were excluded from analysis (Doherty et al., 2017). Activity was identified as sedentary, light, moderate or active using OmGui software; Esliger model cut off points were used as reference (Esliger et al., 2011). Activity data was analysed for both dialysis and non-dialysis days.

4.5.4 Wearable cameras - to validate how other methods measure PA behaviours

While accelerometers are useful to detect movement over a desired period of time, they do not have the ability to determine the type of PA (Kelly et al., 2016) being undertaken by the participant. However, wearable cameras do offer the potential to capture determinants of active or sedentary behaviour in individuals. A wearable camera automatically captures on a continuous basis first-person point-of-view images of the wearer's environment. A review by Loveday et al. (2015) sought to identify and evaluate current technology used in PA and sedentary behaviour. The authors found that wearable cameras are a useful device to capture useful contextual information, such as location and provide duration of activity. Wearable cameras are also being used more to assess lifestyle behaviours in children (Hänggi et al., 2020, Zhou et al., 2019), improve autobiographical memory in Alzheimer patients (Silva et al., 2018, Woodberry et al., 2015) and capture situation encounters in the healthy population (Brown et al., 2017). Furthermore, wearable cameras provide a more accurate measure of activity as self-report questionnaires may be underreported (Prince et al., 2020).

For this study, the Autograph Wearable Camera (OMG Life, Oxford) was used to capture daily images (Figures 4.3a and 4.3b below). The camera has a 136° outward facing eye viewer with the addition of a swivel lens cover to prevent sensitive data being captured (such as going to the toilet and entering computer passwords). Each camera has an inbuilt 5 megapixel low light image sensor and has 8GB of storage and can store up to 27,000 images. The camera can work up to 12 hours of continuous data collection, recharged via USB and has no audio recordings. The camera's internal sensor is triggered by a change in temperature, movement, or lighting and in a typical day of wear it may take up to 2000 images.

Figure 4.3a: Image of Autographer wearable camera with swivel lens.

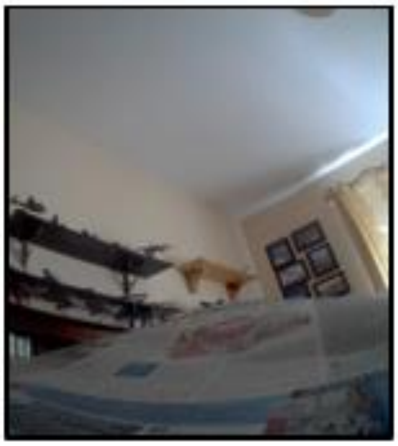
Figure 4.3b: Image of camera when worn.

When the camera is worn simultaneously with an accelerometer, data collected can be time-synchronised to determine the environmental and social context of episodes of PA and sedentary behaviour. In a study by Doherty et al. (2013a), the use of wearable cameras and accelerometers determined 311 out of 386 (81%) of the randomly selected activity episodes recognised by the accelerometer. These episodes were then identified by the wearable camera to determine the type of activity or behaviour that was experienced at the same exact moment (Doherty et al., 2013a).

Code 07 Inactivity # 7020 Sitting and watching television

Code DC1 Attending unit for haemodialysis

Code DC4: Domestic activity with mobility aid



Code 09 Miscellaneous # 9030 Sitting and reading newspaper

Code 07 Inactivity # 7024 Sitting and smoking

Code DC7: Shopping with mobility scooter

Figure 4.4: Examples of images from the wearable camera after download with relevant codes.

The use of wearable cameras in image based research and health behaviour research have brought about numerous ethical issues (Kelly et al., 2013). Wearing of outward facing cameras can be deemed intrusive and the confidentiality of the data captured by the participant may be breeched. Additionally, the unwanted attention by third parties may also bring an air of intrusiveness. Ethical considerations regarding wearable cameras will be discussed in section 4.6 of this chapter. However, the use of wearable cameras has allowed for more robust methods to capture and understand patterns of individual or cohort behaviour of PA (Hodges et al., 2011).

4.5.5 Data processing of camera

Data was downloaded from the device into a custom software application (SenseCam), which is free to access (Doherty et al., 2011). Once an episode was selected in the browser, a new screen appeared showing all the camera images recorded between the start and end time of the episode. Participants were given an opportunity to review and delete camera images before these were viewed and analysed by researchers. The data from the two synchronised devices was analysed quantitatively to provide evidence of frequency, duration, dose and intensity of a range of types of activities (e.g. activities of daily living (ADL), leisure, social engagement).

4.6 Annotation protocol

To be able to analyse and code the images extensively, I developed a haemodialysis specific annotation protocol for the wearable camera data. This new protocol builds on Doherty and Wong's wearable camera coding protocol (Doherty and Wong, 2015, Willetts et al., 2018) (Appendix 4) and the camera data was coded with the Compendium of Physical Activity (Ainsworth et al., 2011).

The Compendium was developed in 1989, published in 1993 with further editions published in 2000 and 2011 (Ainsworth et al., 2011). The compendium comprises of 21 major categories of activities, such as 'home activities', 'self-care', 'walking' and 'sports'. Each major category has a list of sub-headings and contributes to a total of 821 activities. All activities identified in the compendium are assigned an intensity level or MET. However, the compendium does not determine the exact energy cost of each activity as efficiency of the actual movement, body mass and gender are unidentified. Thus, the compendium provides generalised classification of MET for each activity (Ainsworth et al., 2000). As there were several activities that were not available in the original compendium, new codes were added (Table 4.1).

Table 4.1: List of added dialysis codes for annotating camera images

Dialysis Code	**Code name**	**Rationale**
DC1	Dialysis	Approximately 4 hours per session-
DC2 (Misc)	Standing and smoking	Some participants smoke and stand outside- not in compendium however can be linked to Compendium code: Inactivity 07-7024 sitting and smoking.
DC3 (walking)	Walking with frame	Compendium has using crutches (17Walking 17140)- use of frame not in compendium
DC4 (Misc)	Transferring with frame/mobility aid	Participants require mobility aids to transfer from bed to chair or vice versa.
DC5 (Misc)	Wheelchair movement on firm surface	Some participants use wheelchairs and push themselves- (17 walking17105 Pushing a wheelchair non-occupational)
DC6 (Misc)	Wheelchair movement at home	Participants use own wheelchair at home
DC6 (Misc)	Wheelchair movement-shopping	Participants using own wheelchair/movement to do shopping misc
DC7 (Misc/Transport)	Using scooter	As means to travel and shop
DC8 (Misc)	Uncodeable	Where images are uncodeable
DC9(Misc)	Sitting/Lying down reading a book/Kindle/Sudoku-crosswords	Compendium has codes 09 9030-sitting reading book/07-inactivity – 7070 quiet reclining reading. However, some participants were reclining and lying on sofa using Kindles and iPads and doing crosswords/Sudoku
DC10 (Misc)	Taking own blood pressure	Participants take own blood pressure sometimes at home
DC11 (self-care)	General getting ready to go out in morning- waiting for transport for dialysis	Code 13 self-care- 13000- getting ready to for bed- Does not have getting ready to go out.
DC12 (self-care)	Eating and drinking or drinking only	Code 13 selfcare-13030/13035. Eating, but some participants only drank tea/coffee and added code to reflect this.
DC13 (walking)	Walking and talking in person	Participants may walk and talk at same time. Code 09 misc9050- standing talking in person on phone/20 religious activities 20030- standing talking in church. Nothing indicated in walking codes 17 re walking and talking at same time.

Episodes of images from the camera were coded on 6 dimensions. The first two dimensions describe the PA behaviour type and subtype, using the 21 categories suggested by the Compendium (Ainsworth et al., 2011). The third-dimension records whether the activity bout predominantly occurs indoors or outdoors. The fourth-dimension records the domain in which the activity occurred, using the following CDC suggested categories: occupational, domestic, transportation, leisure-time. The fifth-dimension records if the participant carried out their episode of activity alone, in a social environment with no interaction (e.g. in clinic waiting room), or in direct social engagement (e.g. talking to a friend). The final dimension is an optional comment field to describe why an episode could not be confidently annotated. Two members of the research team (SS and RP) annotated the data independently and a third researcher (KN) annotated a random subsample of 5 data sets to ensure the protocol is appropriate for our participant group (Figure 4.4 shows sample images from the camera and Figure 4.5 shows new codes that were added). To ensure that the coding of the images between the 2 coders (or raters) is in agreement, the Cohen's kappa (k) agreement test was used. A score of at least 0.8 (80%) indicates that there is an agreement or substantial agreement between coders (Cohen, 1960). A Cohen's kappa (k) less than 0.6 (60%) or would indicate inadequate agreement. The Kappa score in this analysis is 0.69.

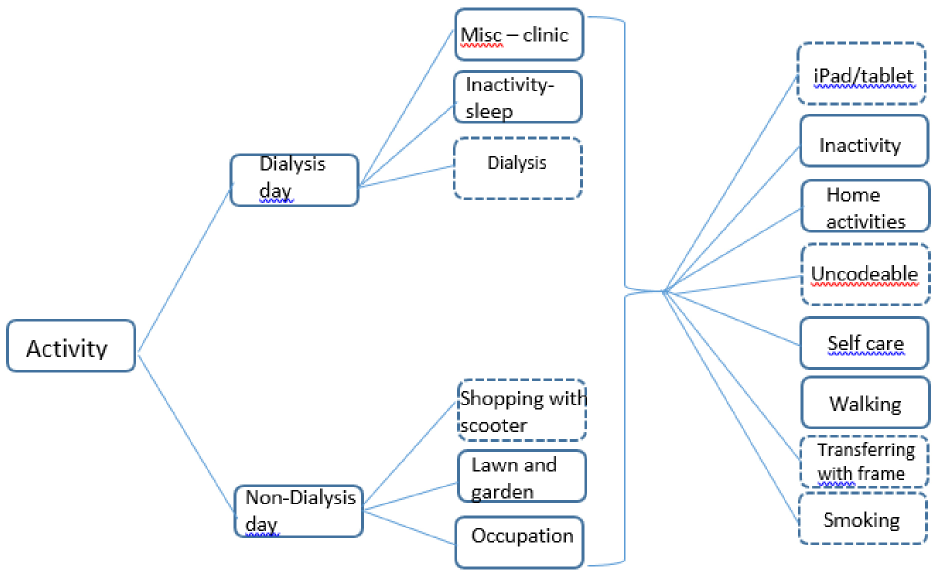


Figure 4.5: Codes annotated by Compendium of Physical Activity with new codes that were added are indicated by dashed lines.

4.7 Ethical considerations with wearable cameras

In general, the right to take photographs in the public domain is legal in the UK unless otherwise stated (Metropolitan-Police, 2020). Existing guidelines state that when taking images of individuals and groups in public spaces, it is not practical or necessary to obtain informed consent unless the images are published or disseminated in such a way that they can be recognised.

To promote and maintain ethical approaches to this type of research, informed and written consent from the participant was vital and that an understanding of how their data was going to be used needed to be clear. It was demonstrated to participants they could block the camera with the swivel lens at any point to ensure that their privacy was maintained if they felt it was necessary to do so. This may result in lost data but allows the participant to maintain autonomy in the research that they are participating in (Kelly et al., 2013). Wearable cameras were encrypted prior to participant use so that third parties were unable to use the cameras if they were misplaced. Consideration should be given to research in certain cultural settings in which photography is disapproved of or considered inappropriate. Examples of these potential situations were discussed with participants when the devices were distributed.

An ethical framework for the use of wearable cameras in human health behaviour research was published by Kelly et al. (2013). Whilst this mode of data collection is passive and allows for participant autonomy (Kelly et al., 2013), the use of wearable cameras gives the researchers access and insight to the lives of dialysis patients on the days that they do not attend for treatment to understand the level of PA and sedentary behaviour.

4.8 Semi structured interviews

The addition of semi-structured interviews can be helpful in gaining an understanding of the participants experience (DeJonckheere and Vaughn, 2019). They are an effective method of collecting rich data and allow responses to be explored in detail and new ideas to emerge (Britten, 1999, Pope et al., 2002, Schultze and Avital, 2011). They are effective with time due to interview preparation with a topic guide (Doody and Noonan, 2013) and contribute to the validity of the study. However, this does not limit the exploration of new thoughts or ideas voiced by participants as probing questions are used to develop explanations (Brosy et al., 2020, Majid et al., 2017) in order to understand feelings and behaviours (Brosy et al., 2020). Questionnaires and interviews may trigger participants to respond differently, with interviews more effective in producing personal response than self-report questionnaires (Oei and Zwart, 1986). The use of images as prompts in previous studies (Cowburn et al., 2016, Kelly et al., 2015) has been found to be beneficial, more so than keeping a diary or telephone recall (Hannan et al., 2010).

Semi-structured interviews were conducted using a topic guide which enabled further exploration of motivators and barriers towards physical activity on dialysis and non-dialysis days. Participant and interviewer together selected segments from the accelerometer data indicating periods of high and low activity and viewed corresponding time stamped images from the camera. Participants were asked what they were doing at the time and were encouraged to reflect on the episode. They were also asked about PA prior to commencing dialysis and to describe their feelings and attitudes towards PA. A topic guide was used to aid and direct the discussion (Table 4.2). Further details of methods of data collection and analysis of semi-structured interviews are outlined in Chapter 5.

4.9 Ethics

Local ethics committee approval (Ref 14/EE/1094 Appendix 5) was obtained and all patient-facing members of the research team undertook Good Clinical Practice (GCP) training prior to study commencement.

4.10 Design, setting and participants

This cross-sectional observational study with nested process interviews was conducted in a tertiary and associated satellite renal unit in Oxford, UK. Between November 2014 and August 2015, all male and female participants aged 18 years and above, established on HD for at least four months and attending at least twice a week were invited to participate (Appendix 6). Exclusion criteria included: unable to give consent, planning to leave geographical area during study period, recent acute deterioration requiring hospital admission or acute cardiac event within 2 days of most recent dialysis treatment. All eligible participants were invited to complete the questionnaire and were informed that they could

Table 4.2**:** Topic guide for Semi-structured interview

Reference time periods:	Tell me what your physical activity levels were like before you started dialysis. How would you describe your feelings/attitudes towards physical activity? When you were told that you were going to start dialysis, how has this impacted on your daily life and physical activity levels? How do you feel after dialysis? How do you feel during your non-dialysis days?
Reconstruction process: (with camera images)	Tell me what you are doing here in this image? How did you feel when doing this activity? Is there any reason you did this activity at this time? Was anyone with you at the time? Did that have an impact on the activity that you were doing? Tell me more about that. How did you feel after the activity?
Theorising /contrasting questions:	Some people have mentioned that they are *X (tired)* after dialysis. What are your thoughts on that?
Probing/open questions:	And when you said you had *X*, what was that like? You mention that X, can you elaborate on that/ can you tell me more about that?
Transition questions:	I'd now like to move on and talk about your experience during this activity/or activity X? Can you tell me more about that? What you are telling me is really interesting, so can we now to talk about…..*X*
Cross checking questions: (If required)	I just wanted to clarify…earlier you said X, and now you have said Y, can you elaborate on that?

opt out of the wearable device phase. Informed consent was obtained during a subsequent dialysis session by a trained research team member (Appendix 7). The study period was one week with no further follow-up.

4.11 Data collection and preparation methods

4.11.1 Self-Report Measures

All participants were given EQ-5D-3L™ (Euro-Qol Group, Registration ID 23961) and the HAP questionnaires during a treatment session and asked to return it the same day, or at a subsequent session. EQ-5D-3L™ data is presented by dimension and age group as described in the User Guide (EuroQol, 2015).

4.11.2 Semi-structured interviews

Participants were invited to participate in semi-structured interviews on the motivators and barriers to physical activity. Interviews were conducted between April and July 2015 using a topic guide informed by a previous pilot study (Kluzek et al., 2013). Interviews were carried out in the haemodialysis unit. Other settings (e.g. a clinic room) were offered but declined by all participants. Interviews lasted approximately 40 minutes. Interviews were recorded on a digital recorder, transcribed verbatim by SS and RP and transcripts uploaded to NVivo software (QSR International, Melbourne, Australia) for analysis.

4.11.3 Body worn devices

Participants wore Axivity AX3 accelerometers (da Silva et al., 2014, Doherty et al., 2017, Ladha et al., 2013, Sabia et al., 2014, White et al., 2016) and Vicon Autographer wearable cameras (Kelly et al., 2015) for seven days prior to interview. Data obtained was used to inform the interviews. Devices were time synchronised at point of issue and data downloaded to an encrypted computer. Participants were given the opportunity to review and delete images, using a custom software application, which is open-source and free to download (Doherty et al., 2011). Those who participated in the interviews were given a brief questionnaire to assess the acceptability of wearing these devices. Accelerometer data were processed following UK Biobank data processing guidelines (Doherty et al., 2017).

Participants were asked about experiences of PA prior to commencing dialysis and current feelings and attitudes towards PA. To prompt participants, the interviewer (SS and RP) selected segments of accelerometer data indicating periods of high and low activity. Participant and interviewer viewed corresponding time stamped images from the camera wearable device. Participants were asked what they were doing at these times and for their reflections on both high and low activity episodes. Previous studies have used images captured by wearable cameras to aid participant memory recall (Cowburn, 2016, Cowburn et al., 2016, Doherty et al., 2011, Kelly et al., 2015).

Interviews were transcribed verbatim and analysed using the Framework Method (Gale et al., 2013) which involved familiarisation with the interview, coding, developing and applying an analytical framework, charting data into the analytical framework for analysis. The analytic framework was developed by two researchers based on the constructs of the Health Belief Model (Becker, 1974, Stretcher and Rosenstock, 1997) – including perceived benefits of PA, perceived barriers to PA and cues to action on PA participation – and informed by the themes which had emerged from a pilot focus group of patients with CKD (Kluzek et al., 2013). Interview transcripts were coded using NVivo software. Each interview was independently coded by two reviewers (SS and RP). After coding four transcripts, reviewers compared codes and discrepancies were discussed and resolved prior to coding the remaining transcripts. Interim analysis was conducted following an initial sample of 20 patients to determine whether saturation of themes had been reached (Guest et al., 2006).

4.12 Statistical analysis

Count data were used to describe recruitment with mean (+/-standard deviation) or median and interquartile range values used to summarise participants' demographic data and physical activity levels. Spearman's coefficient was used to measure correlation. Primary diagnoses are summarised as numbers and percentages.

4.13 Towards a targeted PA intervention

Developing an effective intervention requires a detailed understanding of physical activity levels, types of activity, previous activity and perceptions of physical activity and exercise of haemodialysis participants. This chapter has described how information may be obtained through written questionnaires, semi-structured interviews or objective methods such as wearable devices. By using a multi-method approach, any developed intervention will be more specifically targeted to take account of factors of importance in this group of people such as perceived benefits and barriers towards PA. More personalised approaches are likely to better engage and change behaviour in patients (Tzvetanov et al., 2014). Whilst there may be some limitations with the methods discussed, there are benefits to both qualitative and quantitative methods. Designing a cross sectional study to assess whether wearable devices are a suitable method to capture PA levels and sedentary behaviour in the haemodialysis population is novel (UKMRC, 2006). The data can then be used in the design of safe, feasible and achievable interventions in future studies.

Chapter 5

Results from observational study: Motivators and barriers towards physical activity

5.1 Overview

Utilising the findings from Chapter 4, this chapter outlines the results from the observational study. The objectives of this study were to: 1) describe current PA levels and experiences in HD patients and 2) explore perceptions of PA and the motivators and barriers which facilitate or constrain exercise participation. This will inform co-development of targeted education and PA interventions for renal dialysis patients.

5.2 Results

Of 154 eligible participants, 101 (66%) consented to participate. Of these, a total of 98 (97%) participants completed the study, one withdrew, one received a transplant and one did not complete the questionnaires and was excluded from analysis (See figure 5.1). A sub-group of 20 participants consented to the wearable camera and accelerometer and participated in a semi-structured interview. Participant baseline characteristics are shown in Table 5.1 There was no significant difference between the non-interview group and the interview group for these characteristics.

5.2.1 Self-Report Measure of Health Status

98 participants completed the EQ-5D-3L™. Pain (n=67, 68%), mobility (n=67, 68%) and usual activities (n=64, 65%) were dimensions in which participants experienced some or major problems. Dimensions of self-care (n=23, 23%) and anxiety (n=36, 37%) indicated better health states in which participants indicated they had some or extreme problems (Table 5.2 Results from EQ-5D-3L™). Median VAS score was 60/100 (IQR +/- 30).

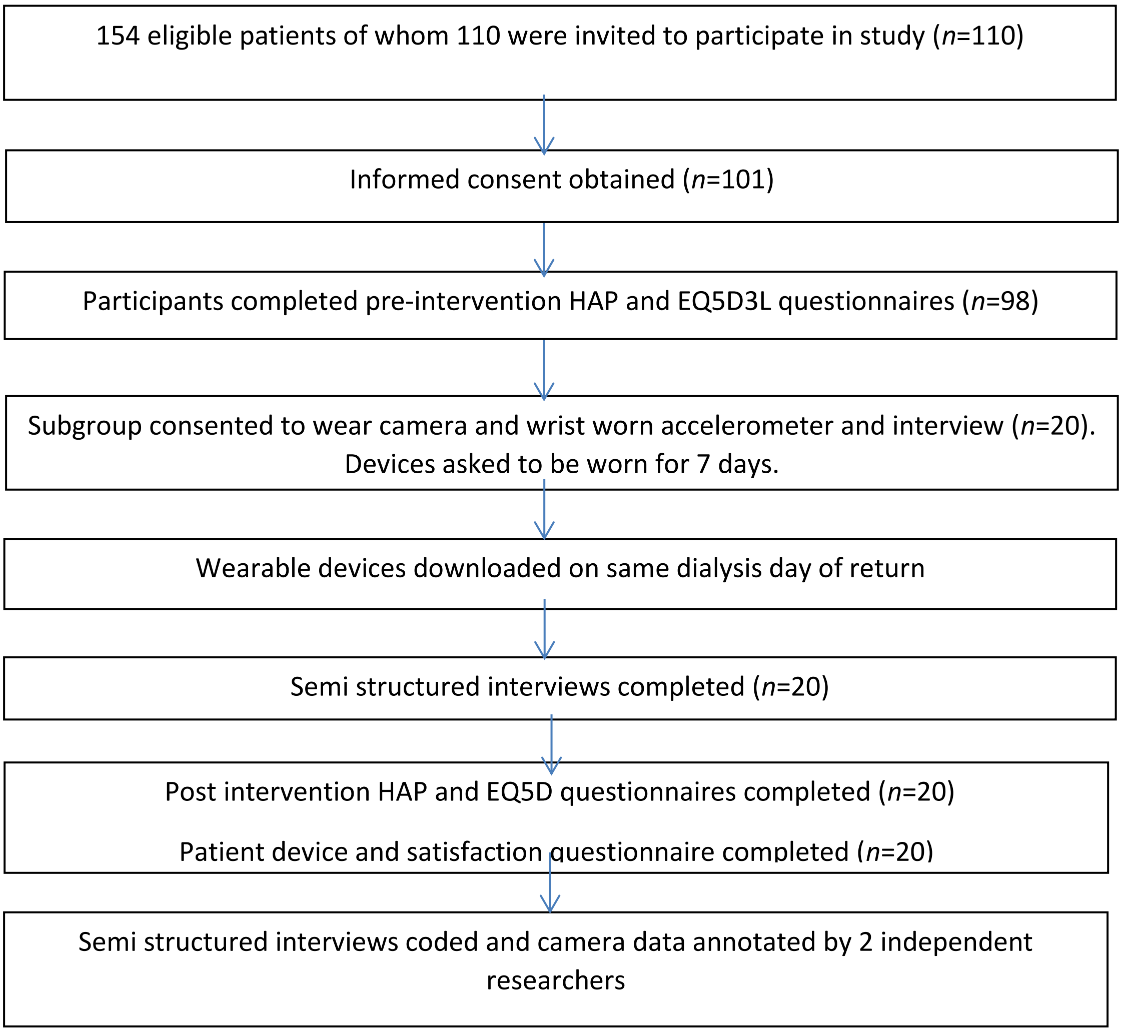


Figure 5.1: Progression of observational study. In the non-camera group, one patient withdrew due to a decline in health. One voluntary withdrew as they received a kidney transplant during the study. 1 did not return pre-intervention HAP questionnaire.

Table 5.1: Characteristics of study participants

	Non Interviewed Group(*n*=78)	Interviewed Group (*n*=20)
Male: Female	55:23	11:9
Age, years median (IQR)	68 (55-79)	59.7 (47-74)
HD Vintage months, median (IQR)	24.5 (6-51.7)	23.5 (7-54.7)
Ethnicity		
Caucasian	63	20
Black	9	0
South Asian	6	0
Other	0	0
Primary Diagnosis		
Glomerulonephritis/ IgA Nephropathy/ FSGN	14 (18%)	5
Diabetic Nephropathy	18 (23%)	3
Hypertensive/Renovascular	7 (9%)	0
Polycystic Disease	1 (1%)	2
Pyelonephritis	2(3%)	2
Renal Dysplasia	1 (1%)	0
Other or Unknown	35(49%)	8

HD = Haemodialysis, IQR = Interquartile Range
FSGN = Focal Segmental Glomuleronephritis

Table 5.2: Results from EQ-5D-3L™

Results by dimension and age group; proportional

Dimension		18-29	30-39	40-49	50-59	60-69	70-79	80+	Total number of participants
Mobility	Level 1	3	2	2	2	9	9	4	31
	Level 2	0	4	6	17	10	14	14	65
	Level 3	0	0	0	2	0	0	0	2
Self-care	Level 1	2	6	6	15	15	17	14	75
	Level 2	1	0	1	5	5	5	4	21
	Level 3	0	0	1	0	0	1	0	2
Usual activities	Level 1	2	3	2	3	8	11	5	34
	Level 2	1	3	6	17	17	9	11	57
	Level 3	0	0	0	0	2	3	2	7
Pain	Level 1	3	2	1	8	6	5	6	31
	Level 2	0	4	6	10	12	14	12	58
	Level 3	0	0	1	2	2	3	0	9
Anxiety/ depression	Level 1	2	4	4	11	11	19	11	62
	Level 2	1	1	3	9	7	4	7	32
	Level 3	0	1	1	0	2	0	0	4

Results indicate number of participants in each group. EQ-5D-3L™ Categories: 1) Mobility (1-I have no problems, 2- I have some problems, 3- I am unable/in extreme discomfort) 2) Self-care (1-I have no problems, 2- I have some problems, 3- I am unable/in extreme discomfort) 3) Usual activities (1-I have no problems, 2- I have some problems, 3- I am unable/in extreme discomfort) 4)Pain and discomfort (1-I have no problems, 2- I have some problems, 3- I am unable/in extreme discomfort) 5) Anxiety and Depression (1-I have no problems, 2- I have some problems, 3- I am unable/in extreme discomfort).

5.2.2 Self-report Measures of Activity

98 participants completed the HAP questionnaire. Sixty-nine (68%) had impaired PA levels overall, 23 (23%) participants were moderately active and only six (6%) were active according to AAS (Table 5.3). 49 (50%) participants had an AAS indicating impaired activity. Activities that patients continued to participate in included: 1) for the impaired: household activities such as bed making, carrying light shopping, and able to climb 9-12 stairs: 2) for the moderately active: household chores such as vacuuming, able to walk for one mile; and 3) for the active: gardening, swimming and cycling.

Table 5.3**:** Results from Human Activity Profile (HAP)

	Overall n = 78			Camera group n =20		
	MAS	AAS	% sample	MAS	AAS	% sample
Impaired <53	57 (±15.1)	38 (±12.9)	54.6	59(±11.9)	36(±14.8)	14.4
Moderately Active 53-74	73(±6.5)	65(±7.1)	16.4	73(±4.8)	67(±7.9)	5.1
Active >74	81(±3.25)	77(±2.25)	6.1	94	94	1

Questionnaire results are expressed as mean (standard deviation). MAS=Maximal Activity indicates most energy expending activity. AAS= Adjusted Activity Score. AAS results <53= Impaired, between 53-74+ moderately active, >74= active (Daughton et al., 1983).

5.2.3 Activity levels captured with body worn devices

Camera: Images captured activities including: home activities (cooking, cleaning), self-care, lawn and garden and walking. Sedentary activities included watching television, time on dialysis, use of transport (mainly to and from dialysis), sleeping during parts of the day and night.

Accelerometer: Mean daily accelerometer wear time amounted to 8.15 hours and ranged from three to seven days. Comparison of activity levels between dialysis and non-dialysis days is shown in figure 5.2.

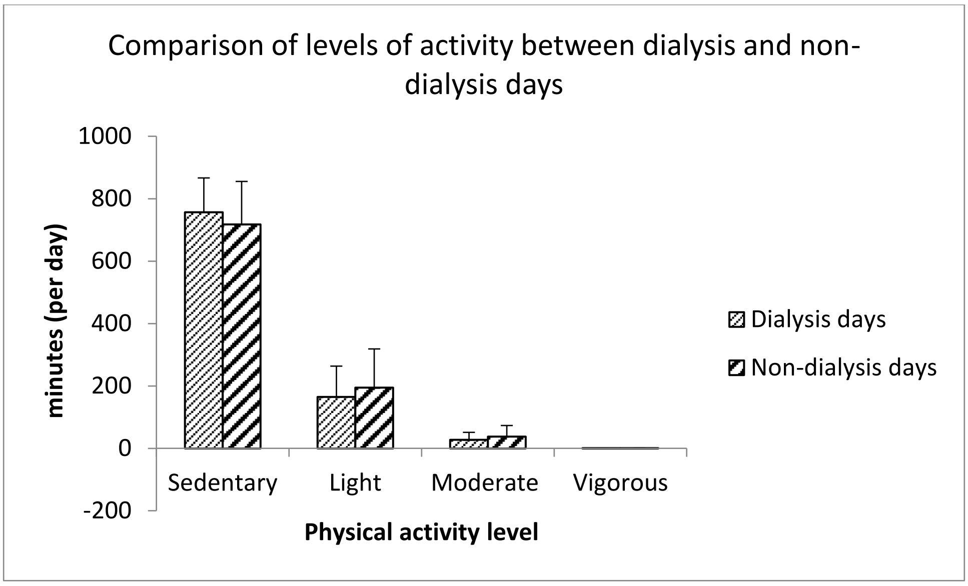


Figure 5.2: Comparison of levels of activity between dialysis and non-dialysis days.

Results expressed as mean (±Standard Deviation). Dialysis days: Sedentary 759 (±109), Light 183 (±98), moderate 20 (±24), Vigorous 0 (±0.7). Non- dialysis days: Sedentary 712 (±137), Light 199 (±124), moderate 32 (±35), Vigorous 0 (±1.5).

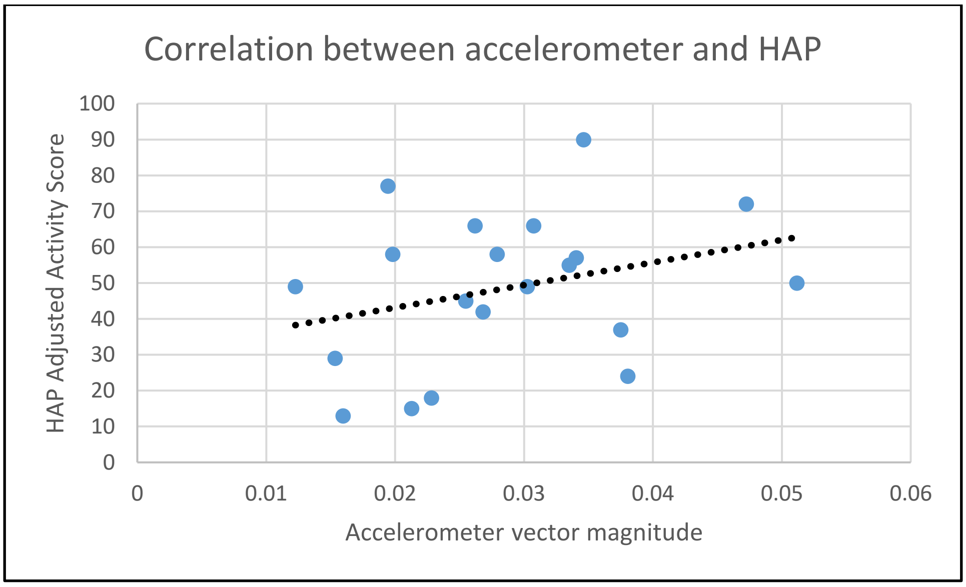


Figure 5.3: Correlation between accelerometer and HAP for 20 participants.

The coefficient value of R is 0.28378. Although technically there is no significance (Cohen, 1960), there is a degree of variability between what individuals report to do and what they do. This may be due to where self-report activities may be reported as active and the accelerometer captures lower activity levels.

5.2.4 Self-report Measure of Acceptability of Worn Devices

Twenty participants completed the device acceptability questionnaires and 18 found device wear acceptable overall. However, concerns included forgetting to wear the devices (8/20), discomfort (2/20) and reactions of others towards the camera (17/20).

5.2.5 Semi Structured Interviews on Motivators and Barriers to PA

Following analysis of 20 semi-structured interview transcripts it was determined that saturation of themes had been reached. Key themes included: 1) Limited belief in the benefits of PA for dialysis patients, 2) The view that PA is incompatible with dialysis 3) The perception that PA presents specific risks for patients on dialysis and 4) The need for external prompts to engage in PA. These themes are organised under headings based on the constructs of the Health Belief Model and illustrated by representative participant quotes (table 5.4).

1) Perceived benefits of increased PA

(i) Mixed views on the benefits of PA for dialysis patients:

Many participants were aware of the benefits of PA in general, commenting that they had enjoyed PA prior to their illness and that it was important to keep active in order to stay well and maintain their independence. However, nine (45%) participants (5 females, age range 35-73, and four males, age between 36 and 84) found difficulty in identifying benefits that might arise from increasing PA and some expressed the view that PA offered little or no benefit for patients on dialysis (Table 5.4).

> *'' I don't think it [PA] would make any difference……You're limited in what you can do. You know you are coming here for treatment basically.''* (Participant 35, female, aged 73)

Table 5.4: Exemplar quotes from participants for Perceived benefits to increased PA

Key theme	Sub-theme	Exemplar Quotes
Perceived benefits to increased PA	Mixed views on the benefits of PA	*''I think exercise can be good, if you have got the right energy levels you know. Don't want to puff yourself out too much''* (Participant 28, male, aged 39) *''I think I mean I think for young people it can benefit. I mean obviously, erm, running, jogging is always good''* (Participant 28, male, aged 39) *''Well it might get the circulation going. But I don't think it would actually make any difference to the kidneys…I'm not medical so I don't know''* (Participant 35, female, aged 73) *''I think just going out and getting fresh air it, you know getting the kids and i can walk at a pace i like to do. And it makes it more enjoyable''* (Participant 43, male, aged 26) *''If I've got spare time then I tend to go for walks. Clears my head and come back and start all over again''* (participant 43, female aged 35) *.'' I feel okay when I am out in the fresh air''* (Participant 62, male, aged 68) *'' Hmmm, I don't know if there are'* {benefits of exercise to kidney patients] (Participant 98, male, aged 75)

2) Perceived barriers to increased PA

(i) The demands of PA are incompatible with dialysis:

Most participants found that dialysis reduced motivation to undertake PA, including some who felt that if the opportunity arose, they would not take it: Twelve participants (60%) (five females aged 53 to 73 and seven males aged 36 to 82) believed dialysis reduced their capacity to continue with regular physical activities or muscle wasting (table 5.5).

> *''…you can't do much especially when you are in a dialysis centre…..dialysis comes in and dominates your life a bit…''* (Participant 10, male, aged 80)

Concern that something may happen to their fistula (dialysis access) if they exercised during dialysis was common. Tiredness was also commonly perceived as a barrier: seventeen participants (85%) (eight female age 35 to 74 and eight male aged 36 to 82) reported they felt too tired to participate in PA especially on dialysis days.

Table 5.5: Exemplar quotes from participants for Perceived barriers to PA and sub-theme of demands of PA are incompatible with dialysis

Key Theme	**Sub-theme**	**Exemplar quotes**
Perceived barriers to increased PA	The demands of PA are incompatible with dialysis	*''I don't think people realise how draining dialysis is. It's more lethargy. Now people come in and say "you're always sleeping" …. but you know it's all to do with the dialysis''*. (Participant 34, female, aged 67) *'' I can't do anything too strenuous, I'm not getting the benefit of it [exercise] because I feel so tired and I've got to stop.''* (Participant 86, male, aged 59) *''Pain. Discomfort. I mean it is with me. I would love to walk for miles. But I get to the point where I just can't, I have had enough of the pain''* (Participant 98, male, aged 75) *''I know there was a program that was mentioned that we do exercise while we're here, but a day like today shows me that that much movement in my arm could actually blow the vein*.'' (Participant 1, female, aged 60)

(ii) PA presents a risk for patients on dialysis:

Fourteen (70%) participants on dialysis (six female aged 35 to 74 and eight male aged 36 to 82) feared that PA would cause further pain or other adverse consequences. Six (30%) participants (two females aged 53 and 74 and four males aged 54 to 82) found that their fear of falling limited daily activities including walking, although others felt less at risk if they used a stick or other mobility aid (table 5.6).

Table 5.6: Exemplar quotes for Perceived barriers to PA and sub-theme of PA presents a risk for patients on dialysis

Key Theme	Sub-theme	Exemplar quotes
Perceived barriers to increased PA	PA presents a risk for patients on dialysis	*''….. walking long distances is impossible. Well it is possible but I have to deal with the pain afterwards.''* (Participant 22, male, aged 36) *''I now use a stick quite a lot now, I can't go to the shop without using a stick, I take it with me wherever go''* (Participant 17, male, aged 54) *''It is the only way because with walking long distances is impossible. Well it is possible but I have to deal with the pain afterwards''* (Participant 22, male, aged 36) *''Well I don't know. I suppose it is a mixture of things. I don't think you can pinpoint anything. I mean, as I say, it's age, it's the fact I've got this vascular problem, and diabetes, and dialysis''* (Participant 35, female, aged 73) *''usually in the evening I can get quite dizzy, erm, to the point where I can't stand up because it feels like I am going to fall over''* (Participant 24, female, aged 53) *''I feel unstable on my feet more than anything else…it is the moving, the walking, that I find is the one thing that really hinders me''* (Participant 50, male, aged 82)

3) Cues to Action on PA

Some participants reported a desire to engage in more PA and suggested the circumstances in which they would feel more able to do so.

(i) PA designed specifically for patients on dialysis:

Seven participants (35%) (three females aged 53 to 67, four males aged 39 to 75) identified the need for tailored, professional help in increasing PA specifically for dialysis which was currently lacking for most participants (Table 5.7).

> *'' I think nobody's sort of helping me with that sort of thing [PA]. No-one is helping you to do these things or suggesting doing these things……I would like more outside activity.''* (Participant 62, male, aged 68)

Others wanted tailored support in maintaining a sense of community and social engagement while continuing in paid employment.

(ii) PA supervised by experienced trainer:

Ten participants (50%) (five female aged 53 to 74, five male aged 39 to 82) said that they would like to be offered more physiotherapy, stretching or rehabilitation exercises as these would be suitable to their physical needs. Some had experienced rehabilitation support from previous hospital inpatient admission and felt they would have benefitted from more. They also pointed to the need for supervision, for example by a physiotherapist in a healthcare setting, their own home or another designated area that was not a public space, and suggested that demonstrating the exercises in a group or on a one-to-one basis would also be helpful (table 5.8). Only two participants (10%) (one female aged 46 and one male aged 39) mentioned that they would prefer to attend a gym.

Table 5.7 Exemplar quotes for cues to action and sub-theme of PA designed for patients specifically on dialysis

Key Theme	Sub-theme	Exemplar quotes
Cues to Action	PA designed for patients specifically on dialysis	*''Well this [the study] has helped anyway. I suppose just encouraging people, obviously younger people. I mean otherwise you could come up with a daily plan. Like you see those exercise videos on TV, a daily plan you know… a booklet, with charts on it you know. Like walk 5 minutes a day, walk 10 minutes a day''* (Participant 28, male, aged 39) *''Well I suppose you could do sort of cycling with your legs…down with your feet and things. I suppose you've got your free arm, and could lift small weights or something''* (Participant 31, female, aged 53) *''..all sorts of things like sitting on a chair and continually moving your ankles or your feet, or that also comes up your legs, you know, so that was a help. Urm, and then there was a couple of sessions where you just walk around the room. Either with your walking stick, or frame, or without anything. Then there was a couple of little step exercises, if you couldn't do them standing up, they let you do them sitting down''* (Participant 34, female, aged 67)

Table 5.8 Exemplar quotes from participants for cues to action and sub-theme of PA supervised by experienced trainer.

Key Theme	Sub-theme	Exemplar Quotes
Cues to action	PA supervised by experienced trainer	*''…there should be a form of rehabilitation exercises….just some light exercise. You've got to have a bit of supervision, because you've got to know you are doing them right.''* (Participant 34, female, aged 67) *''well I'd like to do it [exercise], but I'd start slowly and build up….and maybe do some arm exercises or leg exercises …if there is somewhere in the hospital I could get transport to come a bit later and go after dialysis and have an hour session somewhere''* (Participant 62, male, aged 68) *''Erm, well I suppose a physio would sort of give you things to do, to move your legs up and down or whatever…but, erm, I suppose you've got people at all different levels, some people can't move very well and what have you'' (*Participant 31, female aged 53) *''You would have to have physio department or something like that to do more [PA]''* (Participant 35, female, aged 73)

(iii) PA in the company of friends:

Eleven participants (55%) (four females aged 53 to 74 and eight males aged 36 to 82) felt that having someone to participate in PA with them would be beneficial and motivational and would help maintain a normal lifestyle and sense of community outside of dialysis. Support from family members and good relationships with healthcare professionals were also identified as potentially important cues to action as was the offer of an exercise bicycle on their dialysis days (table 5.9).

Table 5.9 Exemplar quotes from participants for cues to action and sub-theme of PA in the company of friends

Key theme	Sub-theme	Exemplar quotes
Cues to action	PA in the company of friends	*''It would be good if we [wife] did them [exercises] together, it would encourage us to do them''* (Participant 85, male, aged 56) *''the walks...if i don't do walks [with the kids], i'd go mental. I'd be mental if i was stuck in doors not doing nothing. I can't do that. Walking is what we do and .. You know and I do get rewarded after it you know. It makes you feel good''* (Participant 42, aged 35) *''…just something that we do together, …like we're both going to golf tomorrow. I play; she drives round in the buggy''* (Participant 22, male, aged 36) *''…well I would be happy to do any exercises that I would be able to do definitely. I mean, my daughter has just given me a resistance band thing, because my daughter does nutrition and fitness, she's just training, so she's given me a resistance band thing which she showed me some exercises''* (Participant 24, female, aged 53 ''a gentle cycle might be something that I would entertain to do, er, obviously it would have to fit on the end of my bed'' (Participant 85, male, aged 56)

5.3 Discussion

This study has brought together data from self-report questionnaires, semi-structured interviews and quantitative activity data, to provide greater insight into current activity levels and perceptions of PA among HD patients. This study found, as with previous studies (Bonner et al., 2010b, Johansen et al., 2001), that despite being active prior to starting dialysis, this population currently has low overall activity levels with high sedentary behaviour. Non-specific symptoms such as pain and fear of falling and no reason to leave the house were perceived to limit PA, as well as CKD specific barriers such as muscle wasting. These barriers were identified by both male and female participants across the age range. Some participants did not want to exercise or engage in PA due to perceived poor health, a lack of time due to dialysis commitments or the view that PA would not benefit their wellbeing. Participants also reported that there was limited provision of, or access to, appropriate PA classes or groups suggesting a need for information of suitable PA opportunities or adjustments to existing exercise environments. Five participants were concerned about their fistula if they exercised during dialysis and some also reported a reluctance to engage in public classes as they were worried about changes in their blood pressure would lead to dizziness. Our findings add to previous studies where time constraints associated with dialysis and worries about fistulas (Jhamb et al., 2016) were identified as reducing motivation to engage in PA (Orcy et al., 2012).

Our observations further augment existing evidence suggesting that information and guidance for renal patients on how best to look after their fistula when exercising would enable them to be more active in the community or at home. Participants further report the need for support from either PA instructors or their family to initiate, continue and adapt a structured and safe exercise programme on dialysis and at home. The need to utilise an approach to meet the needs of home and hospital exercise interventions was an important finding.

Wearable cameras and accelerometers have been used in previous studies both in healthy and disease cohorts (Doherty et al., 2013b, Lee and Shiroma, 2014, Miller et al., 2017b). To our knowledge, this was the first time accelerometers and cameras have been used together in dialysis patients. Participants found these methods of data collection acceptable. Some reported difficulties in remembering to turn the camera on/off. Feedback suggested it would be helpful to have a light on the wearable camera to confirm whether the device was on or off. Participants had minimal issues with the accelerometer although some forgot to wear the device. Whilst recommended accelerometer wear time have been suggested for the general population (Matthews et al., 2002) and in other disease areas (Demeyer et al., 2014), at the time of the observational study, there were no recommendations for the dialysis population. However, a study by Young et al. (2019b) sought to determine acceptable wear time of accelerometers in the haemodialysis population that would be suitable for analysis. By analysing physical activity data from 77 participants wearing SenseWear Arm band for a period of seven days, seven hours of data from one dialysis day and three non-dialysis days are required to obtain optimum data for processing. The recommendation for one haemodialysis day is due to the low level of physical activity compared to those on non-dialysis days (Young et al., 2019b). In a more recent study, a recommendation of one haemodialysis day and two non-haemodialysis day with wear time of 8 hours is sufficient for physical activity estimates (Prescott et al., 2020).

Use of wearable cameras in image-based research and health behaviour research can be deemed intrusive. Participants were able to block the camera with a swivel lens to ensure privacy. While this may reduce the volume of data collected, it provides autonomy in research participation (Kelly et al., 2013). Wearable cameras are currently the most objective method to capture and identify episodes of PA behaviour (Doherty et al., 2013b, Kelly et al., 2013). The research team found camera images were useful prompts to engage participants and add context to interviews but will not be used as an outcome measure for a further feasibility study as activity recall is not required.

Interviews identified a number of modifiable factors such as individualised support and educational approaches that could increase PA. Current strategies to engage HD patients in PA are broad and include counselling by nephrology staff and referrals for physical therapy, routine care planning and follow up assessments of physical functioning (K/DOQI-Workgroup, 2005); however, effectiveness of these strategies remains inadequately described (Morishita and Nagata, 2015). Our findings indicate that health professionals may be necessary to support patients engaging in PA on non-dialysis days as well as dialysis days. Most current research focuses on intra-dialytic PA interventions and research on factors affecting PA participation outside the clinical environment is essential to develop these interventions (Zhao et al., 2019) so they are efficacious in real-world settings. Walking programs have been found to improve post-dialysis fatigue, and exercise rehabilitation programs have improved general physical function (Greenwood et al., 2012, Malagoni et al., 2008) suggesting a place for combined programs which incorporate both general mobility and strength and conditioning components. Our findings support an approach towards PA management in HD that is individualised and guided by professionals with expertise in HD. The British Renal Society Rehabilitation Network (BRSRN, 2018) has a role in informing and supporting renal clinicians and health professionals including the implementation of PA strategies such as intradialytic cycling (Greenwood et al., 2014).

Dialysis patients have indicated they would benefit from the involvement and encouragement of healthcare professionals (HCPs). However, not all health care practitioners have the appropriate skills and knowledge to provide support and advice to renal patients regarding safe exercise participation (Delgado and Johansen, 2010) and this would be needed (Zhao et al., 2019).With up to three times a week contact with HCPs, there is an opportunity here to engage with this patient group in a sustainable way. Education is needed for both patients and their carers about the benefits of PA and that it is safe for HD patients.

Our findings highlight individual motivators, and the importance of determining what matters to each person in order to tailor PA preferences appropriately. For example, PA enables HD patients to carry out their own activities of daily living (ADLs) or spend more time out and about in the community. Future clinical interventions should focus, in addition to intradialytic cycling, on activities that patients can do outside the dialysis clinic setting such as exercise programmes but studies on appropriate types of exercise are needed (Zhao et al., 2019).

The dialysis clinic provides the opportunity to monitor patient progress but also the opportunity for activity. Active promotion of PA in dialysis units involves sharing positive and good practice at local, regional and national level. For example, the BRS rehabilitation network is a leading online resource for kidney patients on the benefits of PA and the provision of tailored exercise prescriptions. However, our findings suggest there is a need for professional support and guidance as part of this approach so that patients know their exercise is beneficial and safe.

5.4 Limitations

Our region may not be representative of the HD population in other geographical regions. The interview sub-study recruited a small non-random sample who were all Caucasian and may not represent views or experience of the wider population. Activity monitoring devices had poor wear-time compliance. Self-report PA questionnaires may be prone to recall bias.

5.5 Chapter summary

Our participants reported low overall activity levels with high levels of sedentary behaviour, and perceived both general and disease-specific barriers to PA. There is a need for education regarding the benefits of PA for dialysis patients and ways of undertaking PA safely, with the support of carers and HCPs. Our findings suggest the need for the co-development and coimplementation of tailored PA interventions, delivered with the support of an experienced instructor on dialysis or non-dialysis days, or both, to support CKD/HD patients to increase their PA levels.

Chapter 6

Development of the Intervention

6.1 Overview

This chapter will discuss the components to address phase II of the Medical Research Council (MRC) Framework (UKMRC, 2006), to develop a feasible protocol to assess whether an active exercise intervention could work in a busy dialysis unit.

6.2 Intervention development and design

The success of the design and implementation of the intervention is a dynamic process with a continuous synergy to it. As detailed in figure 6.1, the development, feasibility, evaluation and implementation of an intervention is a continuous process (UKMRC, 2006).

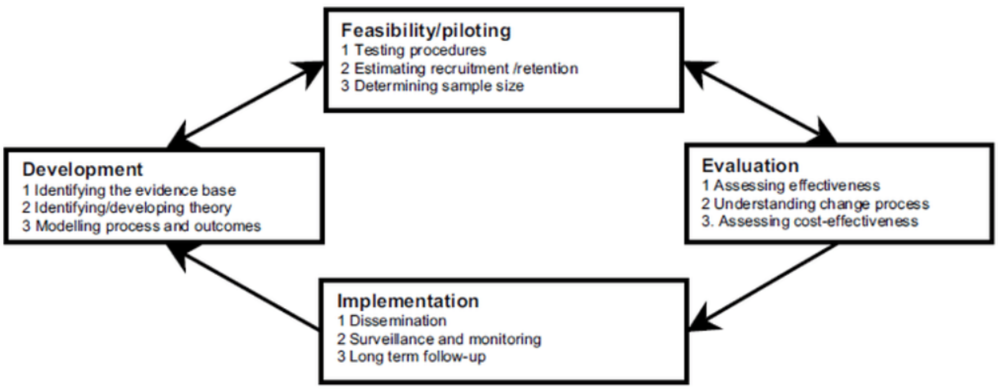


Figure 6.1 UKMRC- Fundamentals of the development and evaluation process

Taken from and available at: https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/

6.2.1 Identifying the evidence base in relation to the findings from chapter 5

Before designing the intervention, there were several actions that needed to happen. This is based on the MRC framework which outlines key points when undertaking a complex intervention but in greater detail (Caitlin et al., 2019). An understanding of the evidence is important and this was part of the pilot work, to understand why patients would not partake in exercise and ask them specifically what and how this could be addressed. The other component is to understand what is already available in terms of PA provision in this cohort of patients. The aim was not to develop a brand-new intervention but to adapt an existing exercise programme that could meet the health needs of the population and could potentially suit individuals and target any possible interventions that could work both in a busy unit and at home on off days as highlighted as important from chapter 5.

A review of exercise interventional approaches was carried out through searching in Cochrane Library, MEDLINE, CINHAL, PSYCINFO, OVID Embase databases in June 2019, and a number of evidenced approaches found that they could be safely and effectively used in both home and hospital settings safely without compromising the fistula. Types of programmes included the Falls Management Exercise programme (Charters and Age-UK, 2013), Otago Exercise Programme (Campbell et al., 1999) and Chair-based exercises (Anthony et al., 2013). There was no information about the Falls Management Exercise programme with regards to renal patients and with discussion with expert panel, that this programme was not suitable as it was mainly focused on leg strengthening and balance (Charters and Age-UK, 2013) with no cardiac component. While falls prevention is ideal in the management of frail older patients and relevant to the renal population, this programme required instructor training.

The Otago Exercise Programme (OEP) was initially considered to form the intervention and is a set of exercises specifically designed to strengthen muscles and maintain balance. Developed in New Zealand, the OEP has been clinically proven to reduce falls in the elderly and promote confidence in patients in and out of hospital (Campbell et al., 1999, Campbell et al., 1997). While the OEP is cost effective, the exercises are generally more suitable for those over 80 years old (Martins et al., 2018, Thomas et al., 2010). The renal patient population has a wide range of ages and the OEP has a limited cardiovascular component and therefore was not used for this study. The Otago exercises take about 30 minutes to complete and patient feedback indicated that this was too long for patients to complete pre-dialysis.

An established set of chair-based exercises (CBE) developed by Professor Patrick Doherty (BHF, 2020b, Dalal et al., 2019), was also viewed as a suitable intervention. The set of chair-based exercises was adapted from the British Heart Foundation (BHF, 2020b) and some of the exercises were modified to intensify a cardiac component with additional information regarding renal care. These chair-based exercises are drawn from programmes recommended for similar long term clinical conditions (e.g. cardiovascular disease, sarcopenia, frail and elderly and renal disease) and can be performed both in the clinical environment or at home (Onofre et al., 2017, Robinson et al., 2015, Robinson et al., 2018b, Tsekoura et al., 2018). The delivery of chair-based exercises have also been found to be acceptable and suitable in community settings (Robinson et al., 2018b). A systematic review by Anthony et al. (2013) shows that existing literature is varied, with some studies showing that CBE has no benefit to mental health, mobility and function or cardio fitness , while some studies show benefit. CBE demonstrated improvements in Timed up and Go (TUG) scores (Baum et al., 2003, Thomas and Hageman, 2003), improved gait times (Hruda et al., 2003, Thomas and Hageman, 2003), muscle strength (Baum et al., 2003, Thomas and Hageman, 2003), reduced depression levels (Baum et al., 2003, Nicholson et al., 1997) and improved systolic blood pressures and heart rate (Nicholson et al., 1997).Renal and transplant patients have associated cardiac issues (Lentine et al., 2005, Tabriziani et al., 2019), thus the frequency, intensity, time and type (FITT) of exercises to be delivered to patients needed to be determined. Delivery of exercises would be up to three times a week to coincide with participant treatment regimen, dependent on how they were feeling and that participants could do at home. Participants wished exercises to be delivered pre-dialysis treatment as tiredness is often experienced post-dialysis treatment (Brys et al., 2019), and thus the length of the exercise program was vital so that there would some intensity to the exercises whilst sitting in a chair.

6.2.2 Identifying and developing theory

The review of theories in this thesis are part of the process to support the intervention process, and there is evidence to suggest that interventions designed with a health based theory are just as effective as interventions without a health based theory (Dalgetty et al., 2019). The implementation of theory is essential so that understanding of change process, expected or unexpected can be evaluated to support the refinement of the complex intervention. With numerous health promotion and disease prevention theories and models available, consideration of the population in question, the health concern and the program being implemented to help explain people's behaviour and change behaviour. To support and understand how the intervention causes change, a behaviour change theory, the Health Belief Model (HBM) as described in Chapter 3 was utilised to support this intervention.

6.2.3 Modelling processes and outcomes - Understanding the short term and long term effects

6.2.3.1 Short term effects

Discussions with the clinical team and stakeholders were needed to identify if the exercises would be acceptable and engaging to patients and if the delivery of the exercises would be feasible. As discussed by Turner et al. (2019), the success of an intervention should possess several factors that demonstrate feasibility, acceptability, and relevant to the population identified. Therefore, for this study involving the patients and giving them the opportunity to feedback was essential to understand if the intervention would be feasible and acceptable.

6.2.3.2 Long term effects

Further to the short term effects and outcomes, the intervention would optimally be transferrable and not only for renal patients. When designing the routine for exercise programme, the exercise movements were derived from already existing programmes that were designed by the British Heart Foundation (BHF, 2020b). The design of the intervention needed to consider effectiveness, sustainability, health benefits and cost-effectiveness (Turner et al., 2019) as part of the long term plan. These outcomes were discussed with the research team in the development of the study design after the observational study was complete.

6.3 Refining the intervention

The design and content of the exercises were based to reflect the core themes identified from the semi-structured interviews described in chapter 5. Participants described that they wished for exercise to be safe and achievable and could be done in their own home. Whilst the CBE is not regarded as high intensity interval training (HIIT), the development of the CBE program for renal patients was tested in the Clinical Exercise and Rehabilitation Research Unit (CLEAR) at Oxford Brookes University involving 20 hours of testing over a period of several months. Members of the research team (exercise physiologist, 2 sport exercise trainers, physiotherapist and myself) measured heart rate pre, during and post adapted exercise regimen and noticed an increase in heart rate and rate of perceived exertion. The CBE was then designed to be 10 minutes long so it would not impact on patients getting on dialysis machines for treatment. All the exercises were discussed with some of the dialysis patients as part of a Patient and Public Involvement (PPI) panel. When the chair-based exercises were tested by the expert panel in the CLEAR unit, baseline resting heart rate increased (e.g. from 66 to 112 beats per minute) at the end of the exercise program. This indicated that the exercises were achieving an increase of 60-70% of maximum heart rate (BHF, 2021, ACSM, 2013). When tested with one or two patients as part of PPI, and not to overburden patient's with a heart rate of 70 or 80, heart rate increased, indicating they were reaching 60-70% of their maximum heart rate with rate of perceived exertion in the zone of moderate (Borg, 1982). Patients, as well as the expert panel felt that these exercises were safe and evidence indicates that 10 minute bouts of exercise improves health and wellbeing (Chan et al., 2019, Dempsey et al., 2016).

6.4 Methodological issues of delivery of intervention and the assessment (feasibility and fidelity issues)

In order to ensure fidelity of the intervention and its delivery, the delivery of the intervention was to be monitored throughout by experienced qualified exercise professionals. Delivery of the exercise was to be in the clinical environment and delivered by one of the study team (KW, BDS, SS and AM). All those delivering the exercise were trained by AM on the exercise routine. The exercises were to be delivered face to face by a member of the team pre-dialysis. The assessment of functional mobility tests will be completed by another member of the study team (HD) to minimise bias.

6.5 Study Logic Model ready for final feasibility testing

In order to bring together the intervention components, objectives and theoretical underpinning a simple logic model (figure 6.2) was developed. In summary the model outlines the intervention components demonstrating the short and long term outcomes from the intervention and that potential challenges which are targeted (Mills et al., 2019). A logic model provides a graphic or a simplified 'map' to the complex intervention and resources required. It is illustrative of the inputs, outputs, implementation of the intervention and outcomes. The use of the logic model is also beneficial to be able to process evaluate any stage of intervention so that any issues can be addressed and that change process is understood (Moore and Evans, 2017, UKMRC, 2006). This is equally important so that processes can be addressed so that all stages of the intervention process; development, piloting and implementation of complex intervention are continually evaluated.

6.6 Stakeholder consensus panel to determine final intervention and logic model

There was a need to bring together the intervention, assessment and underpinning logic model. To generate consensus, a team that would understand exercise physiology and the frailty and mobility concerns for this patient group was brought together throughout and then formed a final panel to finalise the study and intervention. The panel met remotely and in an asynchronous manner as an adaption to the pandemic. This team included an expert exercise physiologist, a physiotherapist and support from a sports exercise medicine consultant who are all locally based. Support from the renal team, included the Matron, Professor of Renal Medicine, the dialysis units and patients who were all apprised of the study and intervention. As part of the discussion a logic model was created to provide a visual statement of activities to bring about change.

6.7 Patient and Public Involvement

Throughout this process, patient and public involvement was a continuous process that fed into the developed logic model and intervention. As indicated from the findings from the observational study, patients wanted an exercise intervention that would improve their muscle strength and balance and could be done in their own home as well as in the unit. Prior to the start of the intervention study, there was an opportunity for patients and healthcare professionals to participate in Patient Public Involvement (PPI) and focus groups on the design of the study and educational booklet. Contributions of ideas and views were listened to on a regular basis and involvement from patients and family members is always encouraged and has been proved useful from previous projects.

Patients were consulted to provide feedback on the study design, patient information leaflets and their readability, including content, wording and safety aspects of PA activities that should be included in the educational booklet.

The aim of the chair-based exercise (CBE) booklet and intervention was to provide patients with information, resources and opportunity to allow them to re-engage and continue with a safe exercise activity as part of a healthy lifestyle whilst living with kidney failure.

6.8 Chapter summary

By using the MRC Framework for complex interventions provides a foundation to evaluate design of research interventions to improve health. The combination through the expert panel of existing theory, evidence base and participant feedback facilitated the development of the exercise intervention.

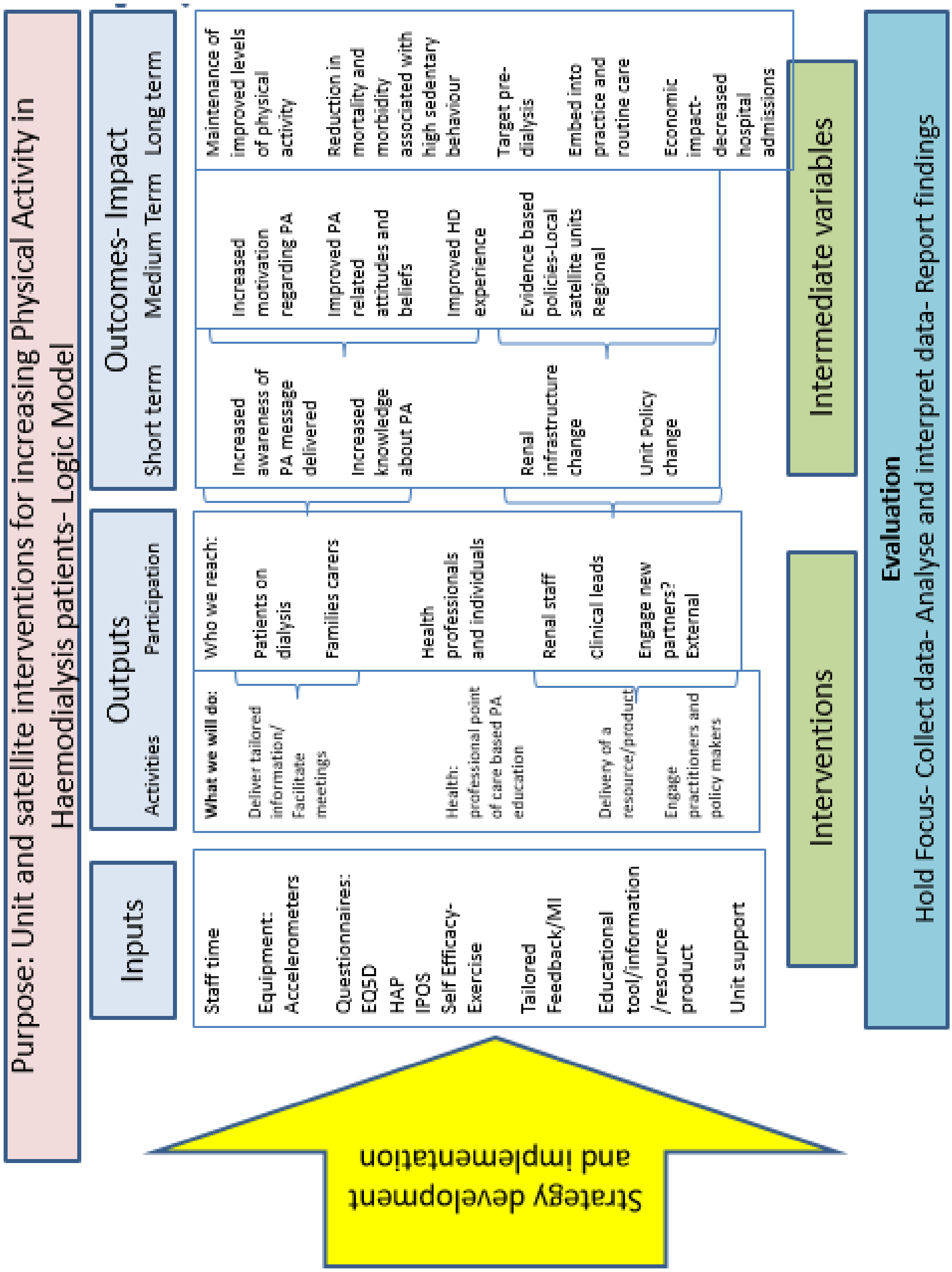


Figure 6.2 Logic Model for strategy development and implementation of the exercise intervention in renal dialysis.

Chapter7

Feasibility study – Preliminary results for the Chair-Based Exercise Programme

7.1 Overview

This chapter will describe the rationale for the intervention study, and details the trial design and preliminary outcomes and results. This chapter will also raise the challenges and successes experienced during the Coronavirus COVID-19 pandemic in early 2020.

7.2 Rationale for feasibility study

The term 'feasibility' essentially asks whether a study can be done on a larger scale (Eldridge et al., 2016). Feasibility studies have become more standard in research and if done well these studies can provide useful methodological information in future developments of randomised control studies (Blatch-Jones et al., 2018).

The purpose of this feasibility study was to determine acceptability and suitability of an exercise intervention for patients in the clinical environment. To measure acceptability of the intervention, short semi-structured interview with participants were used. Evaluation of eligibility, recruitment and retention of study participants, and completion of measures were also assessed as markers of feasibility.

7.3 Capturing adherence to exercise

While exercise interventions may be made available to patients, the uptake and adherence in the long term can be challenging. Exercise adherence is described as how an individual's behaviour relates to the advice and recommendations from a health care provider (WHO, 2003). Factors that hinder adherence include psychosocial, environmental or situational factors. Depression, pain and belief of one's own capability to adhere to exercise are common and living arrangements and access to healthcare provider support all contribute to lower adherence rates (Rivera-Torres et al., 2019). A better socioeconomic status and fewer health related conditions correlate to better exercise adherence to exercise programs (Picorelli et al., 2014).

To capture adherence there are four measures which need to be taken into consideration: i) completion or retention of exercise (how many times participants attend sessions) ii) attendance iii) duration adherence (self-report of exercise in and out of the class) iv) intensity adherence (level of effort to undertake the exercise) (Rivera-Torres et al., 2019). The main methods to capture adherence for example are number of participants who attend the exercise programme and frequency of session attended, number of participants adhering to exercises at home or number of participants achieving activity guidelines (Picorelli et al., 2014).

A review by Bullard et al. (2019) found that dropout rates for patients across three different chronic conditions were low with adherence rates at 77% and participants sustained aerobic exercise for longer than three months. The authors found that there was no difference in adherence between centre or home based training. The reasons for participant adherence is not yet clear (Bullard et al., 2019) but adherence rates remain higher when exercise programmes are supervised (Picorelli et al., 2014) and is associated with the relationship the participant has with the exercise activity (Rivera-Torres et al., 2019).

To facilitate adherence of PA, dialogue between clinician and service user, the patient, and relevant parties should be maintained throughout all phases of trial design including feasibility studies (Young et al., 2019a). Trial requirements such as recruitment and eligibility are criteria that may need to be modified. In terms of recruitment, as much information about the study should be given including images of exercise modes (Young et al., 2019a). In terms of feasibility, transparency of exercises and what is expected within a study should be provided by the research or nursing team so that recruitment and those who chose to participate will engage in their own intensity and goals (Young et al., 2019a).

7.4 Safety of patients engaging with PA

The safety of haemodialysis patients or any patients undertaking any exercise or physical activity with exertions is paramount. Exercise is not without risk but the benefits outweigh the possible harms. All participants were screened for safe participation prior to recruitment to the study. All the research nurses were trained in haemodialysis skills and the trainers were also trained in management of distress. A nurse on duty will be sought and additional support from the clinical team will be provided. However, the team routinely administers exercise interventions and has trained nursing and other clinical professionals to safely support people with a range of conditions to exercise according to prescribed activities in both hospital and home environments.

7.5 Trial design and objectives

The study design for the feasibility study is indicated in figure 7.1. This feasibility study aimed to assess a combined structured and educational intervention to increase physical activity levels in haemodialysis patients undergoing treatment in 2 dialysis units. The secondary objective was to assess the quality of life in this cohort and assess the feasibility and acceptability of proposed outcome measures for a larger study to both patients and staff. The secondary aims are as follows:

1) Provide estimates for patient activity levels and health status using the a) Human Activity Profile self-report Questionnaire b) EQ-5D-3L health status questionnaire c) IPOS renal questionnaire,
2) Identify the extent to which PA activity levels change with a delivered structured approach from a Sports Exercise Trainer
3) Identify the extent to which PA activity levels change measured by wrist worn accelerometry (e.g. changes increase/decrease in PA levels).
4) Document recruitment flow, reasons for non-recruitment, feasibility, adherence,
5) Assess safety of exercises (using Client service receipt inventory and falls and fractures questionnaires) and measuring participant heart rate and blood pressure.
6) Identify challenges and solutions with respect to the processes of feasibly delivering the intervention.
7) Develop an acceptable delivery pathway for implementing educational interventions in conjunction with tailored feedback within dialysis units and to be evaluated in a future trial.

7.5.1 Study Participants

Participants with end-stage renal failure, being treated with haemodialysis 2 or 3 times per week were invited to participate.

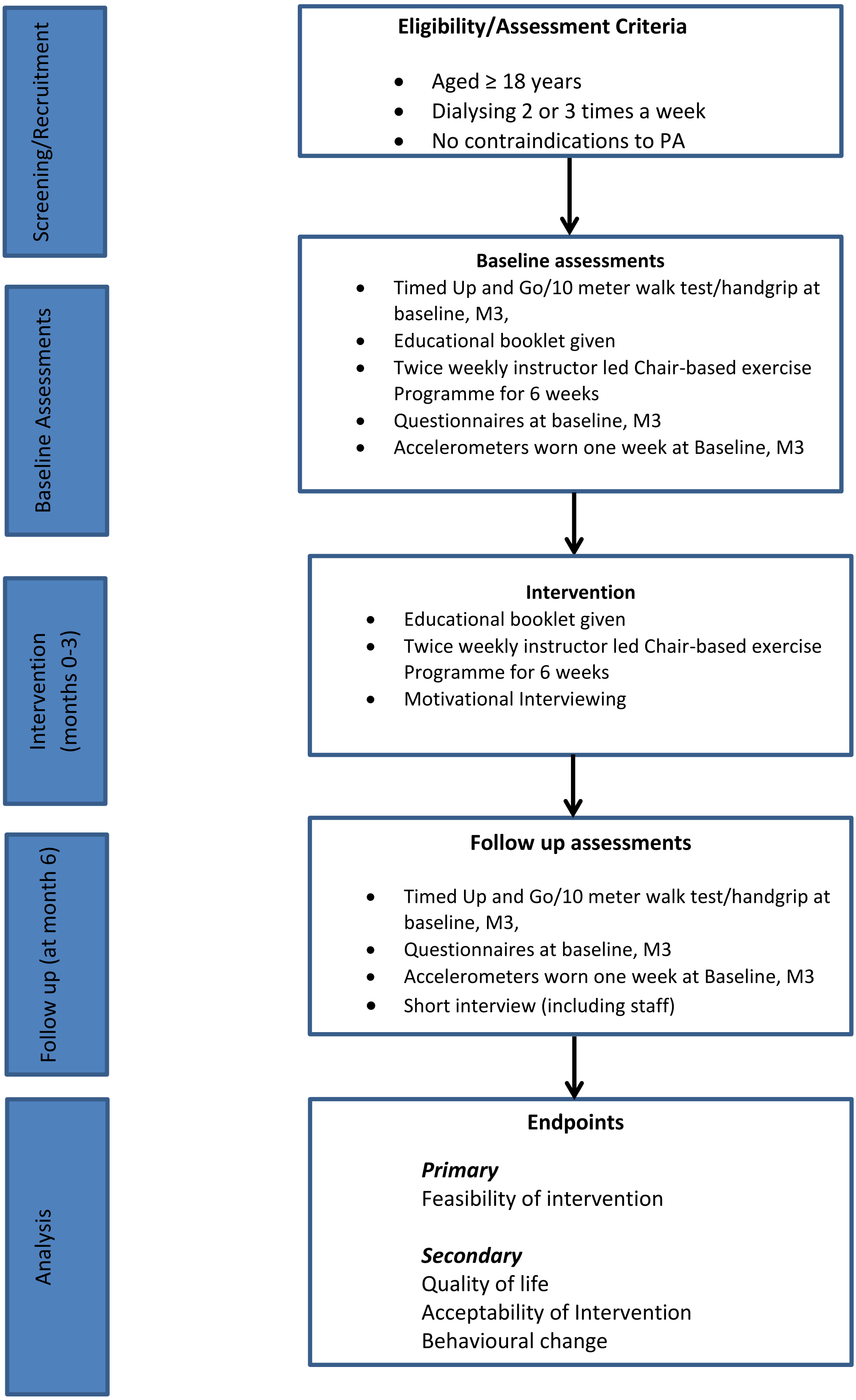

Screening/Recruitment
Baseline Assessments
Intervention (months 0-3)
Follow up (at month 6)
Analysis
Eligibility/Assessment Criteria
Aged ≥ 18 years
Dialysing 2 or 3 times a week
No contraindications to PA
Baseline assessments
Timed Up and Go/10 meter walk test/handgrip at baseline, M3,
Educational booklet given
Twice weekly instructor led Chair-based exercise Programme for 6 weeks
Questionnaires at baseline, M3
Accelerometers worn one week at Baseline, M3
Intervention
Educational booklet given
Twice weekly instructor led Chair-based exercise Programme for 6 weeks
Motivational Interviewing
Follow up assessments
Timed Up and Go/10 meter walk test/handgrip at baseline, M3,
Questionnaires at baseline, M3
Accelerometers worn one week at Baseline, M3
Short interview (including staff)
Endpoints
Primary
Feasibility of intervention
Secondary
Quality of life
Acceptability of Intervention
Behavioural change

Figure 7.1 Study design for feasibility study

7.5.2 Inclusion/exclusion Criteria

Male or female patients, aged 18 years and above, undergoing haemodialysis two or three times a week for at least three months and were willing to give informed consent were recruited to the study. Any participant who were pregnant, had known uncontrollable cardiac arrhythmias, receiving palliative care or unable to give consent were excluded from the study.

7.6 Methods

Ethics was obtained from Nottingham 1 Research Ethics Committee (REC 19/EM/0042) (Appendix 8) in May 2019 and clinical trial number NCT04103177. This feasibility study involved the following processes:

7.6.1 Informed consent

Patients were approached one of their dialysis sessions by a research nurse who discussed the study in detail and were given a patient information leaflet (Appendix 9). On the following or subsequent dialysis session, if they wished to participate, written informed would be obtained (Appendix 10) and then flagged on the Electronic Patient Record system so that this identified the participant was active in the trial.

7.6.2 Measures

7.6.2.1 Assessment of intervention feasibility

Both participants and dialysis staff were invited to participate in a short interview conducted by a member of the study team at month three study in order to explore the feasibility and acceptability of the study intervention and outcome measures for use in a larger study. The topic guide is outlined in Appendix 11.

7.6.2.2. Safety of Intervention

A short fractures and falls questionnaire was given and filled out in discussion with the research nurse (Appendix 12). The Client Service Receipt Inventory (CSRI) questionnaire was given at baseline and at month six to assess usage of outpatient's and inpatient services over a six month period The CSRI has been used in research to understand other services patient may use, such as outpatient clinics or hospital admissions or changes in mobility aids (PSSRU, 2021). Participant vital signs were also taken at the start, middle and end of the exercise program.

7.6.2.3 Patient self-report Questionnaires

Quality of life at baseline was assessed by use of the EuroQol EQ-5D-3L (https://euroqol.org/eq-5d-instruments/eq-5d-3l-about/) questionnaire (Appendix 2) and the Integrated Palliative care Outcome Scale- Renal (IPOS- Renal) questionnaire (Appendix 13). The IPOS -renal was used to determine symptoms that participants are experiencing, such as shortness of breath, itching and restless legs. The IPOS renal has been validated in renal patients in assessing symptom burden and quality of life (Raj et al., 2018). Participants were asked to indicate from a scale of zero to four, zero indicating that no symptoms are experienced and four, where symptoms are overwhelming. A score of more than 30 out of 110 was raised to a member of the nursing team.

7.6.3 Functional Mobility Tests

7.6.3.1 Timed Up and Go

The Timed Up and Go (TUG) is a mobility assessment and takes approximately one minute to undertake. The TUG was initially designed to assess mobility in the elderly population and to determine falls risk and the measure of balance, walking and sit to stand (Nightingale et al., 2019, Steffen et al., 2002). A 0 and 3 metre walkway was marked out on the floor in the corridor next to the dialysis units. A member of the research team asked participants to sit in a chair and rest their arms on the side of the chair. If participants needed any walking aids then this was available next to them. When the instructor said 'go' the participant was asked to rise from the chair, walk to the 3 metre line, turnaround and walk back to the chair. The test stopped when the buttocks of the participant touched the seat. The TUG was repeated 3 times and performed at baseline, months three and six using the same chair.

7.6.3.2 10 Metre walk test

The 10 metre walk test is used to assess walking speed and functional mobility and only takes 10 minutes to complete. The 10 metre walk test has been validated in various disease populations (Stuck et al., 2020) and has been used in renal patients (Abe et al., 2016). The floor in the corridor next to each dialysis unit where tests were undertaken was marked at 0, 2, 8 and 10 meters as per TUG instructions. A member of the research team asked participants were asked to stand at the start of a 10 meter walk way and to walk without assistance for 10 metres, however walking aids were permitted. The research team member would say *'I will say ready, set, go. When I say go, walk at your normal comfortable speed until I say stop'*. Timing of the walk started when the participant's foot crossed the two meter line and stopped when they crossed the 8 metre line. This was repeated three times for each visit.

7.6.3.3 Hand Grip Strength

The purpose of this test was measure the participant's maximum strength in their hands and forearm. Measuring hand grip strength is a reliable procedure in patients with clinical conditions as well as the healthy population (Bobos et al., 2020). The participant was asked to hold a dynamometer (Marsden MG 4800, Rotherham, UK) and squeeze as hard as they could for five seconds using their dominant hand. Participants were instructed to repeat this three times but with a 10 to 20 second pause between tests to avoid fatigue. Each result was recorded and average was taken.

7.6.4 Intervention

All patients who entered the study were assessed by one of the renal doctors to make sure that participants were suitable to participate. The intervention was multifaceted comprising of the following; an educational chair-based exercise booklet about PA, face to face instructor led support detailing the chair-based exercises and nurse led motivational interviewing.

7.6.4.1 Chair-based exercise intervention

Patients were given Sports Exercise Instructor led training on how to perform the chair-based exercises, for six weeks. This was delivered during one of the patients' dialysis sessions. Patients were notified of the day the session would take place. The instructor would deliver a short 10 minute session to patients including a safety instruction. This did not impact on time or curtail patients' haemodialysis sessions or hinder routine care. Research nurses and dialysis nurses also sought any risk to injury on subsequent dialysis sessions.

The benefit of a sports exercise trainer or a 'wellbeing trainer' delivering face to face meetings has proven to be successful in past studies (Annesi and Unruh, 2007, Irwin et al., 2017). Known as the 'Coach Approach', six sessions are delivered over a six-month period. Within the contact time, motivational interviewing and tailored feedback are given to participants who are new to an exercise program (Annesi, 2003, Annesi and Unruh, 2007). The aim of the Coach Approach is to support the learner in establishing and maintaining an exercise habit and to incorporate between 2-3 instructor-led sessions a week over a 12-week intervention phase to integrate a structured exercise programme into the dialysis setting.

7.6.4.2 Educational booklet

Each participant was given an educational / information booklet. Patients and healthcare providers had a say in the content which included, symptoms of haemodialysis, safety of exercise. The booklet was reviewed by the Oxford University Hospitals NHS Foundation Trust Renal Patient Information Group (Appendix 14).

Findings from the observational study indicated a need for educational input and support, such as booklets to provide information about the benefits of exercise whilst receiving regular haemodialysis treatment (Sutherland et al., 2019). There are several educational booklets in the form of downloadable booklets for Multiple Sclerosis, Physical Activity for Neurological Conditions(https://community.mssociety.org.uk/sites/default/files/resources/resource_files/Physical%20activity%20for%20neurological%20conditions.pdf) devised by researchers at Oxford Brookes University and across other national sites. A further book, 'Getting on with your life with MS' (https://issuu.com/barbarabarkley/docs/ms_gowylwms_dec_2_2015) is another example of education and support. These booklets have been successful and have been co-designed by patients and clinical specialists in this field.

7.6.4.3 Motivational Interviewing

MI is regularly used in the dialysis setting to motivate patients to accept responsibility for change by internalising the need for positive action (Levensky et al., 2007). MI is currently used in the Oxford dialysis units to engage patients in elements of shared care of their routine treatment, and was incorporated into the study design to encourage patients to support self-efficacy and enable patients to self-identify goals and improve outcomes (Levensky et al., 2007). The role of MI is discussed in detail in Chapter 3, section.3.7.

7.6.4.4 Borg Scale – Rate of perceived exertion

The Borg scale was used to capture patient's rate of perceived exertion. This tool is used widely to monitor exercise intensity (Borg, 1982). The scale was developed using healthy individuals to correlate exercise heart rates. The revised category scale was used, and patients were asked by the exercise instructor during the exercise where they perceived rate of exertion is (Appendix 15). Originally consisting of a 15 point scale, it was later revised as a 10 point scale enabling it to be more applicable to a wider variety of physical functions and mode of exercise and therefore not requiring to reflect on heart rate (Borg, 1990).

7.6.5 Data analysis

Mean (+/-standard deviation), median values (interquartile range), numbers and percentages were used as appropriate to summarise participants' data.

7.7 Results

As a feasibility study, this section will describe the participant flow, process evaluation and completed measures, safety of participants and provisional findings of the potential effect of the intervention.

7.7.1 Participants

Table 7.1: Participant characteristics for feasibility study are indicated in the table below.

Participant	Sex	Age	Ethnicity	Height (cm)	Weight (Kg)	Vintage HD months	CVD	Diabetes
CBE01	Female	79	Caucasian	152	105	168	No	No
CBE02	Male	24	Caucasian	169	59	14	No	No
CBE03	Male	70	Caucasian	170	85	18	Yes	No
CBE04	Male	87	Caucasian	160	65.5	96	Yes	No
CBE05	Male	74	Caucasian	170	82.5	29	Yes	No
CBE06	Male	66	Caucasian	177	71.5	19	Yes	No
CBE07	Female	62	Caucasian	155	72	29	No	No
CBE08	Female	49	Caucasian	149	62.5	30	Yes	Yes
CBE09	Female	62	Asian	152	48	3	No	Yes
CBE10	Male	68	Caucasian	170	96.5	22	No	Yes
CBE12	Female	56	Caucasian	157	68	26	No	No
CBE13	Male	70	Caucasian	170	71	12	Yes	No
CBE14	Male	59	Caucasian	172	57	98	No	No

7.7.2 Participant participation and feasibility

38 participants were approached by the renal unit research nurses from September to November 2019 on both dialysis units at the Oxford Kidney Unit on both morning and afternoon dialysis shifts. This was to allow for maximum opportunity and uptake. After informed consent was obtained, 16 participants consented to the study: 13 participants remained in the study, one participant withdrew, one was transplanted, and one was excluded due to insufficient data (Table 7.1). However, due to Covid-19 lockdown restrictions (see section 7.11), only six participants completed the entire study and the remaining seven participants completed final questionnaires but not final mobility assessments.

7.7.2.1 Feasibility of treatment delivery

Six participants completed a study interview. Preliminary analysis of the interviews is explained below.

(i) ***Exercise trainer was beneficial***

Participants found that doing the exercises with someone prior to dialysis was beneficial. Teaching the exercises was beneficial as this gave them confidence that they were doing the exercises correctly at home. Participants also liked the social interaction and 'chat' with the trainer and gave an additional social aspect as well as attending dialysis.

(ii) ***Increased motivation***

Six of the participants indicated they liked the exercises pre-dialysis and it gave them the motivation do the exercises knowing that someone was going to be there to support them. Participants found the exercises easy to do in their own home and found it as a stepping-stone to do other activities and increased walking on non-dialysis days.

(iii) ***Increased confidence***

Five of the six participates who were interviewed found that the CBE gave them confidence to do more activities, whether this was walking or more activities of daily living at home. Three participants who use their mobility aids (e.g. walking stick) said they felt more confident in walking longer distances. Participants also found that there was an added social aspect which they enjoyed.

7.7.2.2 Acceptability of intervention over proposed trial duration

All six participants interviewed found that 10 minutes of exercise pre-dialysis, was a good length, and the booklet was useful. Two participants wanted the exercises to continue in the unit. Five of the six participants were doing the exercises at home. One participant was doing the exercise with his wife at home.

Unfortunately, nurses were not interviewed as the impact of Covid-19 affected nursing workloads and time constraints increased, including mine as I was working frontline at the end of March 2020. Verbal feedback from nurses indicate that they encouraged patients to continue with the exercises while they were waiting for dialysis. Nurses also noticed improved blood pressure readings for patients at the start of dialysis, but this is open to interpretation.

7.7.3 Safety

There were no reported deaths during the duration of the study and no direct injuries associated with the exercises. Patients felt that the exercises were safe and achievable and were surprised that some of the exercises increased their heart and breathing rate.

7.7.3.1 Client Service Inventory Receipt

All participants retired early from employment due to ill health. Four participants lived alone, and remaining participants lived with a family member or partner. All participants maintained their renal clinic appointments over the 6-month study period. Three participants saw additional outpatient clinic nurse/multidisciplinary team, such as cardiology and diabetes nurse specialists. Three participants were admitted over the 6-month study period; two participants had falls and one participant was admitted with high fever and symptoms of Covid-19 and discharged with a negative result.

7.7.3.2 Falls and Fractures

Two participants had falls in the last 12 months at baseline. Six participants were using a mobility aid (stick) outdoors and six were independent walkers and one needed a tri-wheeler for indoor and outdoor use. One participant was admitted for a fall at home (outdoor) with no sustained fractures and was discharged after one day. One participant was admitted for a fall at home (indoor) sustaining a radial fracture requiring rehabilitation (the fall was not exercise related). Four participants were using a stick indoors at month six but five were still using a stick outdoors. Only four participants had broken bones in adulthood (rib, wrist, and femur).

7.7.3.3 Chair-based exercise data

As part of patient safety participant's blood pressure and heart rate and RPE was measured at the start, middle and end of each exercise session. Mean pre and post session data for each participant is reported in table 7.2. Pre and post session blood pressure varied for each participant depending on intensity of exercise. For two participants the blood pressure decreased after each session. Data for abnormal blood pressure and heart rates pre and post exercise for one participant are shown in figure 7.2.

7.7.3.4 Rate of Perceived exertion

The mean RPE for each participant is detailed in Table 7.3. The mid RPE was taken at the end of seated exercises just prior to the first standing exercise.

7.7.4 Patient reported questionnaires

Only 12 participants returned the HAP, EQ-5D-3L™ and IPOS Renal questionnaires at baseline. All 13 participants returned all questionnaires with all items completed at month three and six.

7.7.4.1 Human Activity Profile

The HAP adjusted activity scores indicated that five participants were impaired (inactive) (40 ±6), four were moderately active (59 ±2), and three were active (78 ±2) at baseline. Over the course of the six months, there was no change in adjusted activity scores for impaired (39 ±8), moderately active (60 ±1) and active (84 ± 10).

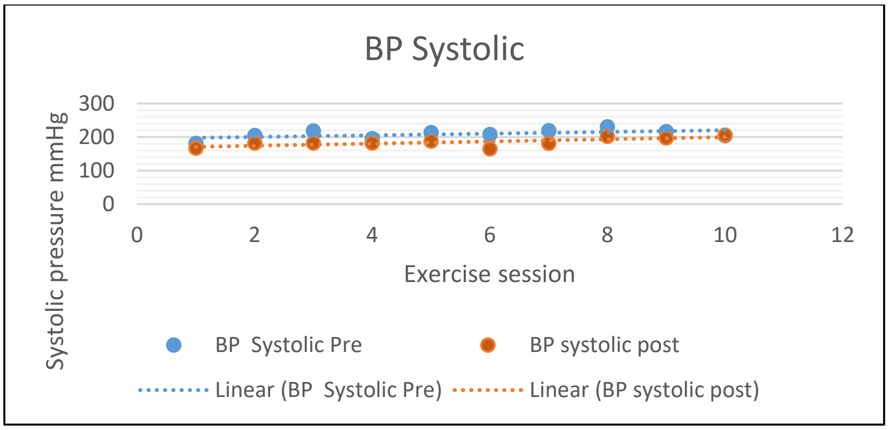
7.7.4.2 EQ-5D-3L and VAS

At baseline, three participants indicated that they had no problems with mobility or usual activities. At month three and six, participant numbers increased to five and six (mobility) and six and seven (usual activities) respectively. Ten participants indicated that they had no issues with anxiety and depression at baseline. At month three and six, six participants had no issues, and the remaining participants indicated some issues or severe issues with anxiety and depression. Any concerns were handed over to unit manager or nurse in charge. Mean health status visual analogue scale score was 64 (baseline), 60.5 (month three) and 68 (month six).

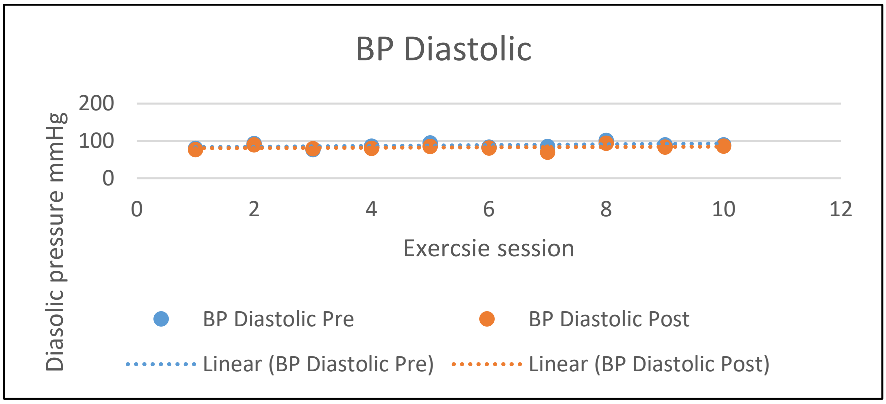
Table 7.2: Mean Blood pressures and heart rate for each participant

Participant	Number of Sessions		BP Pre Systolic (mmHg)	BP Diastolic (mmHg)	HR pre (beats per minute)	RPE pre	RPE mid	BP systolic post (mmHg)	BP Diastolic (mmHg)	HR post (beats per minute)	RPE post
CBE01	7	Mean	137	85.5	105.8	0.36	2.00	130	81.8	105.8	2.0
		S.Dev	8.91	6.80	2.91	0.48	0.89	9.56	2.97	4.74	0.5
		C.Int	8.24	6.29	2.69	0.44	0.83	8.84	2.75	4.38	0.5
CBE02	10	Mean	136.8	91.6	67.2	0.05	2.65	139.7	92.3	78.5	3.7
		S.Dev	11.14	8.17	5.16	0.16	1.06	7.29	12.47	5.46	0.67
		C. Int	7.97	5.84	3.69	0.11	0.75	5.21	8.92	3.91	0.48
CBE03	5	Mean	149.6	71.8	61.4	0.6	4.6	130.4	78.6	62.4	6.8
		Sdev	8.62	11.52	1.95	1.34	1.67	9.21	13.39	2.70	1.48
		C.Int	10.70	14.30	2.42	1.67	2.08	11.43	16.63	3.35	1.84
CBE04	10	Mean	124	73.8	89.6	0.2	0.2	125.6	74.6	88.1	1.2
		S.Dev	14.61	10.99	9.54	0.63	0.63	15.33	14.50	10.87	0.92
		C.Int	10.45	7.86	6.82	0.45	0.45	10.96	10.37	7.77	0.66
CBE05	4	Mean	124	73.8	89.6	0.2	0.2	125.6	74.6	88.1	1.2
		S.Dev	14.61	10.99	9.54	0.63	0.63	15.33	14.50	10.87	0.92
		C.Int	10.45	7.86	6.82	0.45	0.45	10.96	10.37	7.77	0.66
CBE06	11	Mean	157.5	61.9	46.9	0.75	4.7	134.9	56.8	48.9	6.95
		S.Dev	13.34	6.97	2.02	0.54	1.44	16.50	6.00	2.28	0.80
		C.Int	9.55	4.98	1.45	0.39	1.03	11.80	4.29	1.63	0.57
CBE07	12	Mean	143.75	79.58	73.33	0.13	2.21	159.83	79.50	82.75	3.38
		S.Dev	12.74	6.67	9.45	0.31	1.37	21.05	8.28	10.90	1.69
		C.Int	8.10	4.24	6.01	0.20	0.87	13.37	5.26	6.92	1.08
CBE08	7	Mean	107.25	68.00	70.88	1.25	2.94	102.63	62.50	76.25	3.50
		S.Dev	25.13	7.69	3.60	1.58	0.86	29.35	12.82	7.80	0.76
		C.Int	21.01	6.43	3.01	1.32	0.72	24.54	10.72	6.52	0.63
CBE09	10	Mean	208.9	88.2	82.8	0.65	2.3	185.2	82.6	81.5	2.5
		S.Dev	13.78	7.39	9.40	0.67	0.95	13.54	6.80	8.59	0.97
		C.Int	9.86	5.29	6.73	0.48	0.68	9.68	4.87	6.15	0.70
CBE010	10	Mean	132.2	62.5	92.1	3.27	4.45	128	62.3	88.4	4.2
		S.Dev	14.16	9.05	14.02	1.00	1.71	9.31	7.83	7.26	1.32
		C.Int	10.13	6.47	10.03	0.71	1.22	6.66	5.60	5.19	0.94
CBE012	9	Mean	156.89	84.44	85.11	0.17	0.61	158.78	85.78	87.44	0.72
		S.Dev	3.26	4.33	4.08	0.25	0.55	10.13	7.10	6.02	0.57
		C.Int	2.50	3.33	3.13	0.19	0.42	7.79	5.46	4.63	0.43
CBE013	6	Mean	152.83	57.17	65.50	0.00	0.58	148.83	63.50	72.33	1.08
		S.Dev	11.79	6.62	8.38	0.00	0.38	6.21	5.89	11.40	1.02
		C.Int	12.37	6.94	8.80	0.00	0.39	6.52	6.18	11.96	1.07
CBE014	9	Mean	86.89	56.78	71.78	2.67	4.06	90.56	57.44	75.78	4.22
		S.Dev	3.52	4.66	9.12	0.71	0.53	6.31	7.72	8.87	0.97
		C.Int	2.70	3.58	7.01	0.54	0.41	4.85	5.93	6.82	0.75

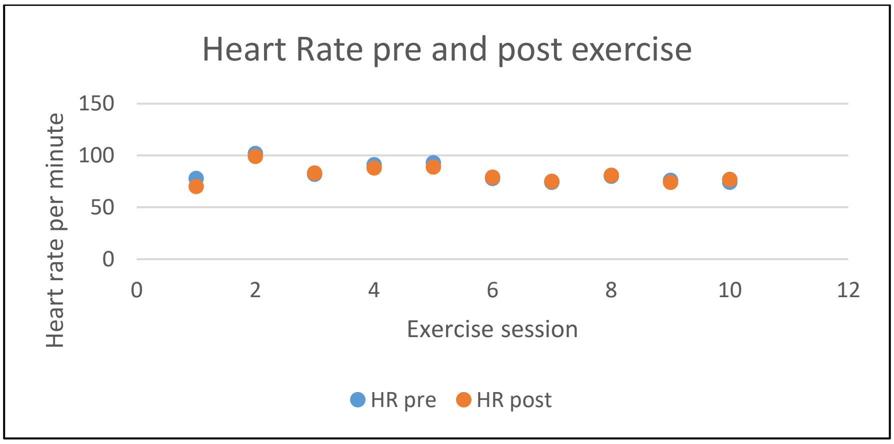
BP= Blood Pressure, HR= Heart Rate, S.dev= Standard Deviation, C.Int= Confidence Interval



(a) Systolic blood pressure trend for CBE009. Systolic BP decreases post 10 minutes of exercise.



(b) Diastolic blood pressure trend for CBE009. Systolic BP decreases post 10 minutes of exercise



(c) Heart rate for CBE009

Figure 7.2: Blood pressure and heart rate trends (10 measurements) after 10 minutes of exercise for CBE009.

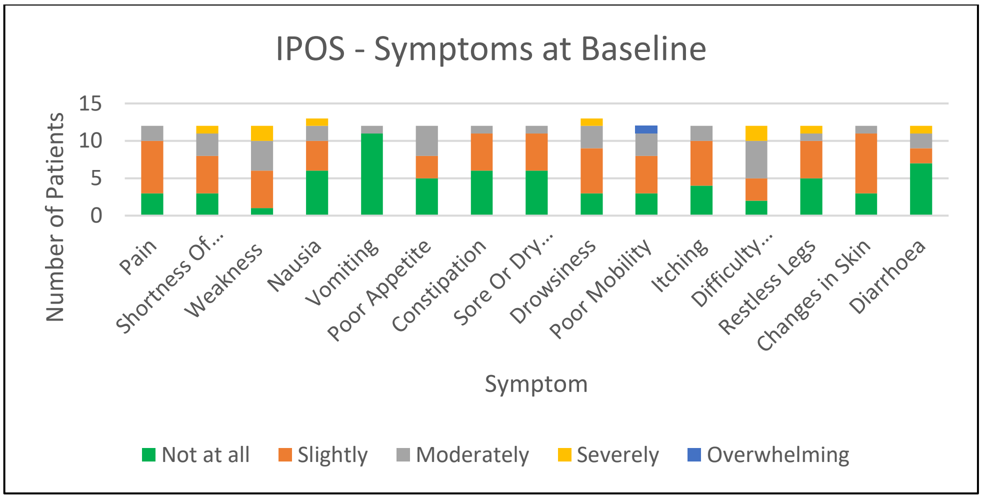
Table 7.3: Mean participant RPE during chair-based exercises

Participant	Pre RPE	Mid RPE	Post RPE
CBE01	0.35	2	2
CBE02	0.5	2.63	3.7
CBE03	0.6	4.6	6.8
CBE04	0.2	0.2	1.2
CBE05	1.3	3.4	4.5
CBE06	0.75	4.7	6.95
CBE07	0.12	2.2	3.3
CBE08	1.25	2.9	3.5
CBE09	0.69	2.3	2.5
CBE10	3.27	4.45	4.2
CBE12	0.16	0.61	0.7
CBE13	0	0.58	1.08
CBE14	2.6	4	4.8
Mean	0.9	2.65	3.47
Median	0.64	2.76	3.6
Sd DEV	0.99	1.55	2
Confidence Interval	0.6	0.93	1.21

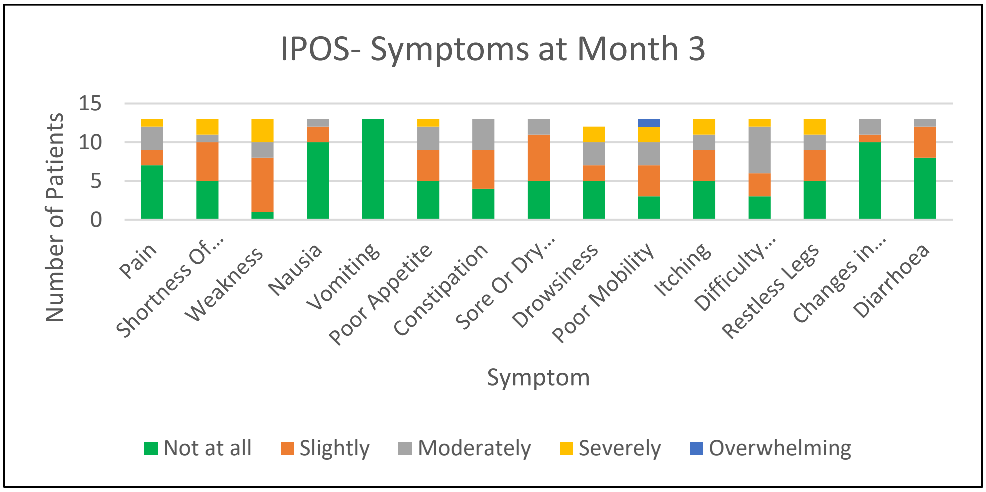
7.7.4.3 IPOS Renal

Of the 15 medical symptoms in the IPOS questionnaire, the top five mentioned dialysis related symptoms at baseline, from slightly to overwhelmingly, were pain (n=9), shortness of breath (n=9), weakness (n=11), poor mobility (n=9) and difficulty sleeping (n=10). The least mentioned symptoms were vomiting and diarrhoea where 11 and seven participants experienced no symptoms respectively. Pain scores improved at month three (n=6) but decreased by one in month six (n=7). Shortness of breath improved at month three and six (Figure 7.3).

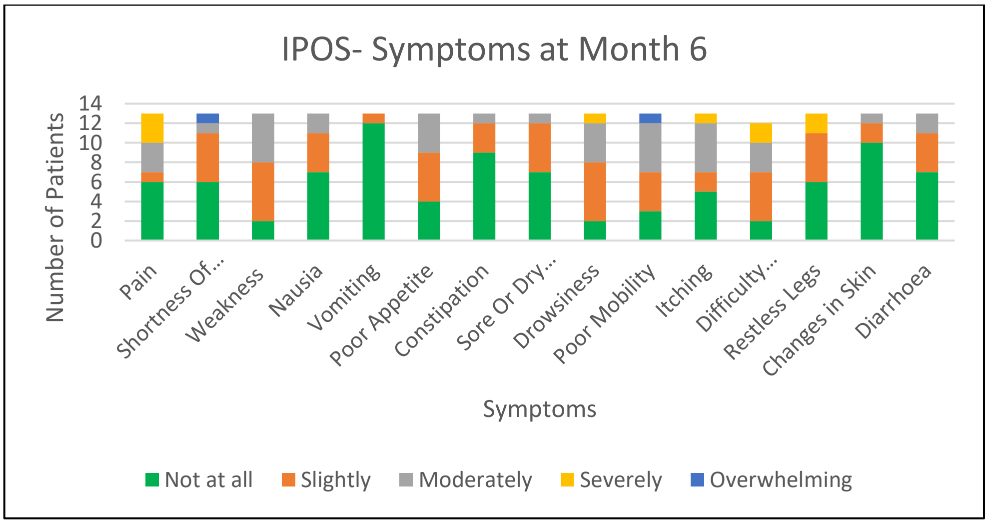
Emotional status at baseline and month six revealed that only two participants stated that they were not feeling anxious or worried about their health and dialysis care to some degree. Only one participant did not feel at peace at baseline, month three and two participants did not feel at peace at month six. Depression scores improved over the six-month period. Only three participants mentioned feeling depressed at baseline, where six and five participants mentioned they were not worried about depression at month three and six respectively.



(a) IPOS questionnaire- patient dialysis symptoms at baseline



(b) IPOS questionnaire- patient dialysis symptoms at months 3



(c) IPOS questionnaire- patient dialysis symptoms at month 6

Figure 7.3 IPOS questionnaires- patient dialysis symptoms at baseline (a), months 3 (b) and month 6 (c).

7.7.5 Functional mobility tests

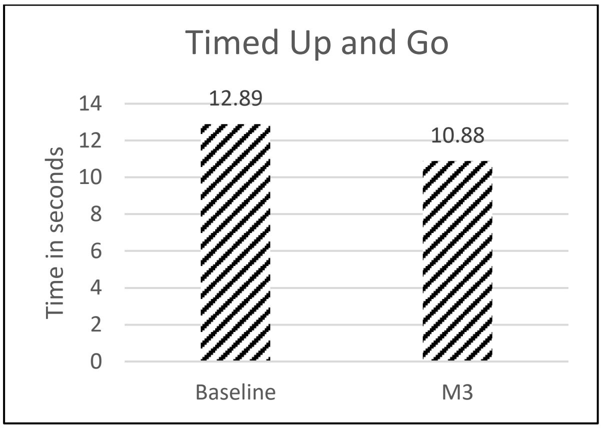
Functional mobility data for the 10 metre walk test, TUG and handgrip strength are shown in Table 7.4.

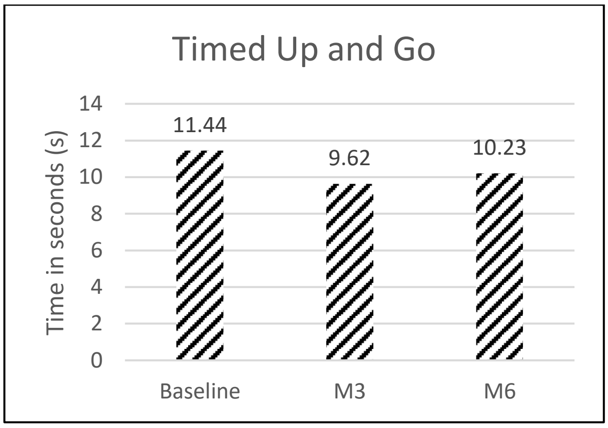
Table 7.4: Participant data for functional mobility tests.

	10 metre walk test (seconds)				TUG (seconds)				Hand grip (strength in Kg)			
Participant	Baseline	M3	Difference	M6	Baseline	M3	Difference	M6	Baseline	M3	Difference	M6
CBE01	7.67	7.53	**-0.14**		14.8	17.9	3.1		23.5	20.5	**-3**	
CBE02	3.73	3.06	**-0.67**	2.69	5.23	4.53	**-0.7**	4.28	35.1	33.9	**-1.2**	34
CBE03	3.91	5	1.09	3.84	6.05	7.22	1.17	6.34	20.6	18.5	**-2.1**	25.4
CBE04	9.9	7.25	**-2.65**	7.37	26.94	21.78	**-5.16**	23.03	22.4	23.4	1	18.1
CBE05	7.34	6.15	**-1.19**	8.13	12.49	12.01	**-0.48**	13.54	10	9.7	**-0.3**	6.9
CBE06	6.46	5.91	**-0.55**		12	8.09	**-3.91**		20.2	19.5	**-0.7**	
CBE07	4.79	3.49	**-1.3**	4.16	7.69	5.47	**-2.22**	6.81	22	22.1	0.1	21.9
CBE08	5.9	4.84	**-1.06**	4.09	10.25	6.75	**-3.5**	7.22	9.43	9.1	**-0.33**	9
CBE09	6.34	6.32	**-0.02**		10.13	7.13	**-3**		11.2	12.3	1.1	
CBE10	9.03	9.45	0.42		15.97	16.11	0.14		21.8	23.7	1.9	
CBE12	9.88	7.31	**-2.57**		9.75	6.02	**-3.73**		22.4	23.6	1.2	
CBE13	7.12	6.55	-0.57		6.97	6.16	**-0.81**		27.3	30	2.7	
CBE14	29.4	20.03	**-9.37**		29.4	22.34	**-7.06**		23.3	23.1	**-0.2**	
Mean	8.5	7.1	-1.4	5	12.8	10.8	-2	10.2	20.5	20.7	0.01	19.2
Median	7.1	6.3		4.1	10.2	7.2		7	21.9	22.6		20
25th quartile	5.9	5		3.9	7.6	6.1		6.4	20.2	18.5		11.3
75th quartile	9	7.3		6.5	14.8	16.1		11.9	23.3	23.6		24.5
Sd DEV	6.5	4.2		2.1	7.5	6.4		7	7.1	7.2		10.2

7.7.5.1 Timed Up and Go

The Timed Up and Go improved by 2.01 seconds (15% improvement) at month three after baseline. Speed increased by 1.8 seconds from baseline to month three for 6 participants but decreased by 0.6 seconds from month three to month 6 (figure 7.4).



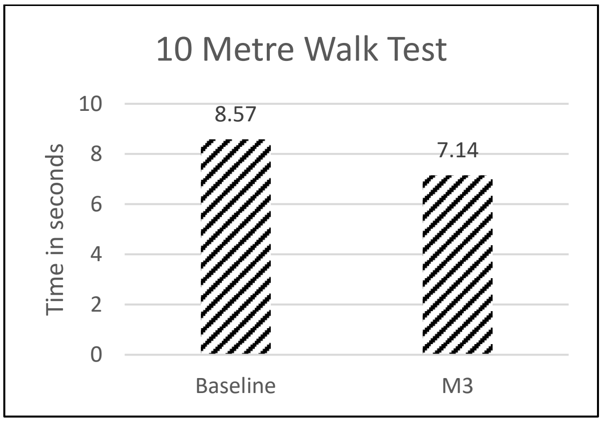


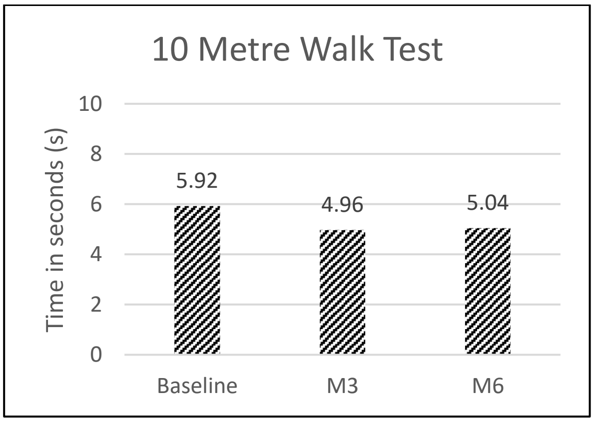
(a) Timed Up and Go (mean) of all 13 participants (b) Timed Up and Go of 6 participants completing study

Figure 7.4- Timed Up and Go over a 3 month (a) and 6 period (b).

7.7.5.2 10 Metre walk test

10 meter walk test improved by 1.42 seconds (16% improvement) in 3 months from baseline for group as a whole (Figure 7.5a). The six that completed month 6 improved by 0.8 seconds from baseline (Figure 7.5b).



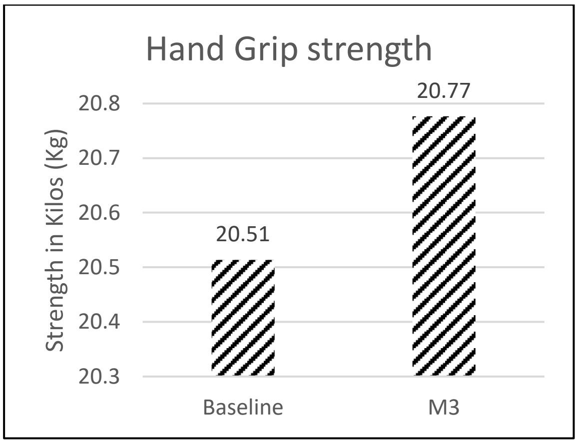


(a) 10 Metre walk test of group overall (b) 10 Metre walk test for 6 participants

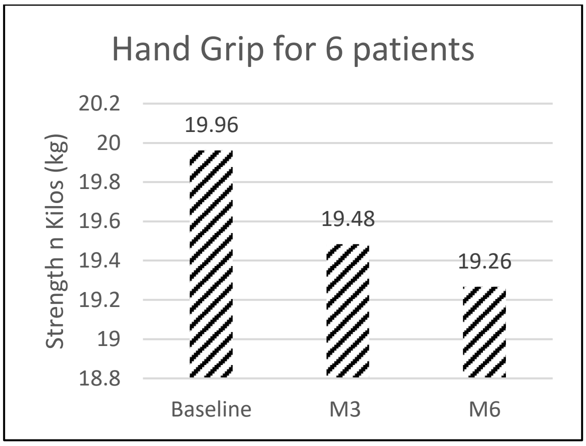
Figure 7.6 (a) 10 Metre walk test for 13 participants (b) for 6 participants who completed baseline, month three and month six.

7.7.5.3 Hand grip strength

Hand grip did not improve from baseline to month three. There was as increase of 0.26kg in strength (figure 7.6a). There was decrease of 0.96Kg in strength from baseline to month six for the six participants who completed the study (figure 7.6b).



(b) Hand grip strength (mean) of all participants



(a) Hand grip strength of 6 participants completing the study

Figure 7.6: Hand grip strength for all participants (a) and for 6 participants who completed the study (b).

7.7.6 Accelerometer data

Six participants wore the accelerometer at baseline, month three and month 6. The remaining seven participants wore the accelerometer at baseline and month three but were unable to complete month six due to the Covid-19 outbreak (Chapter 6 section 11). Oxford Brookes University Axivity Analysis tool V3.2 was used using Esliger cut-off points (Esliger et al., 2011) to calculate percentage of sedentary, light, moderate or vigorous activity between the hours of 6am and 10pm over the one week period. Mean sedentary time increased post baseline by 9.61 % (figure 7.7a).

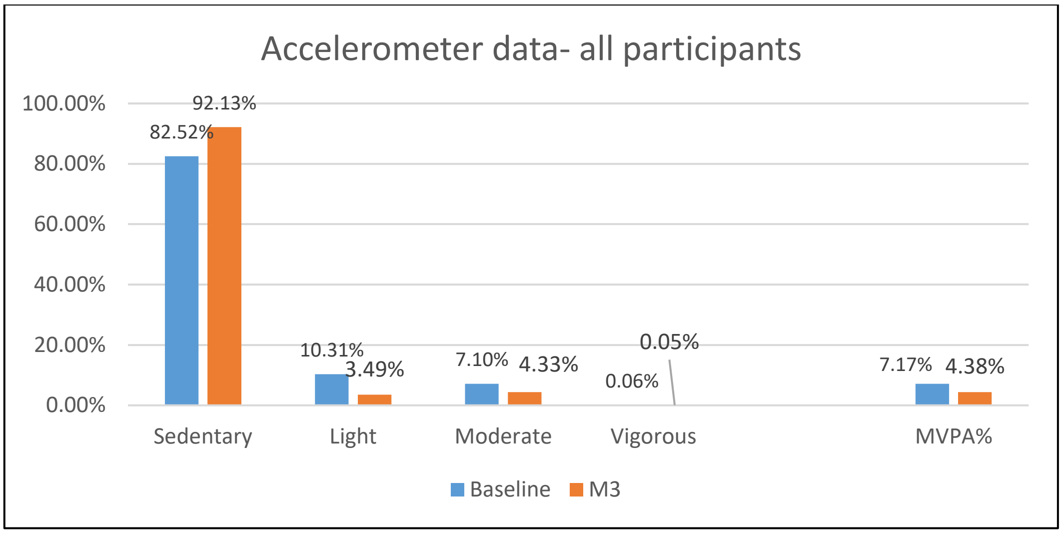


Figure 7.7a: Mean weekly accelerometer activity levels for all participants

For the six participants who wore the accelerometer at three different time points, sedentary behaviour increased by 10.95% from baseline to month three. Activity levels rose from month three to month six by 6.38%. Light activity and moderate activity decreased by 1.64% and 2.88% respectively (figure 7.7b).

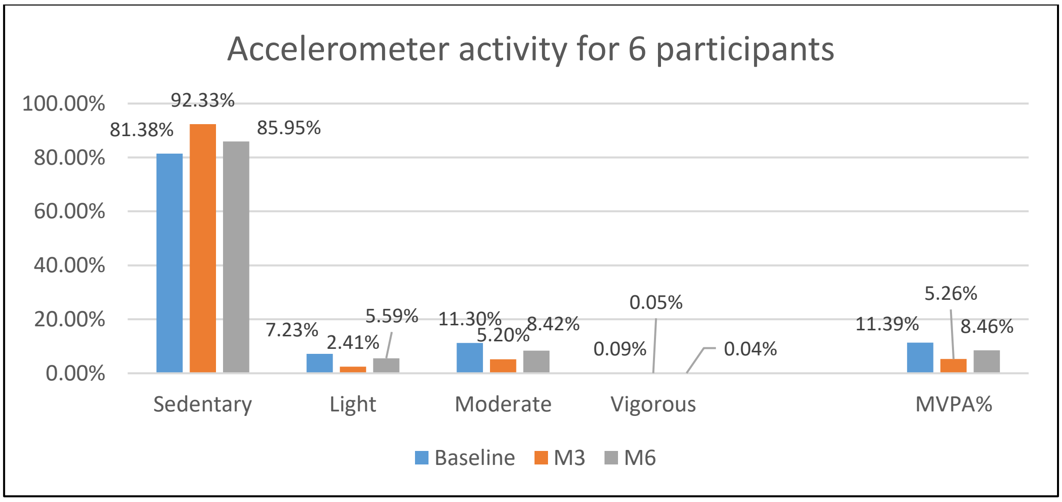


Figure 7.7b: Accelerometer data for 6 participants at baseline, month three and six.

Individual participant weekly mean Moderate-Vigorous physical activity (MVPA) is detailed in table 7.4. Four participants increased MVPA from baseline to month three.

Table 7.5: %MVPA data for all participants

	%MVPA		
Participant	Baseline	M3	M6
CBE001	0.32	5.47	
CBE002	10.94	8.55	9.64
CBE003	3.13	2.84	4.59
CBE004	3.38	2.59	23.40
CBE005	5.80	8.65	8.11
CBE006	1.90	0.06	
CBE007	23.73	4.57	0.62
CBE008	21.36	4.35	4.42
CBE009	8.32	8.77	
CBE010	2.76	2.32	
CBE012	7.48	3.69	
CBE013	4.06	2.36	
CBE014	0.00	2.68	

7.8 Discussion

The outcomes from this feasibility indicate that the chair-based exercises are safe and that they were liked by the participants. Overall, exercises were adhered to however, this was dependent on patient's arrival time to the unit as some were dependent on transport and general feelings of wellbeing. The functional mobility tests were easy to do in the clinical environment to capture data.

The potential benefits in strength and mobility were demonstrated by the Timed-Up and Go (TUG). The use of the TUG is a common and valuable measure to assess mobility and frailty (NICE, 2016). While one must take into account the small sample size, I found some evidence that the TUG improved at month thee and month six from baseline. These findings are supported by a study by Meng et al. (2020) where TUG, and walking speeds improved after three months undertaking a supervised and home based exercise programme in older adults. Similarly, frailty was reversed in older adults who participated in a multicomponent exercise program (aerobic, resistance and balance training) three days per week for 12 weeks

(Sadjapong et al., 2020). Renal patients are one of the most frail population groups yet frailty screening in the CKD population is not embedded in to routine renal clinical care (Nixon et al., 2019). Walking speed tests or the Clinical Frailty Score could be used to assess physical assessment (Nixon et al., 2019) and exercise training could be tailored to suit the needs of each individual to at least prevent frailty decline (Sadjapong et al., 2020).

The outcomes from this feasibility can potentially act as a blueprint for a well powered randomised controlled trial. Further discussion regarding the feasibility of the CBE and duration of exercises are raised in chapter 7. However, there are several key strengths and limitations that need to be taken into consideration.

7.9 Strengths of study

The CBE was easy to show patients and the length of time the CBE took to do was a positive factor. Staff found that patients' determination to do the exercise was a positive and staff noticed positive changes with patients' blood pressures (Qiu et al., 2017), mobility (Suhardjono et al., 2019) and energy (Chan et al., 2019).

Participants enjoyed the interaction with those facilitating the exercises as this was someone separate to their dialysis routine. The design of the booklet which incorporated step by step images was beneficial to patients and that it helped them do the exercise at home. The peritoneal dialysis (PD) team liked the design of the booklet and have now given it to their PD patients. PD patient feedback has been positive.

7.10 Limitations of study

The dialysis units have limited space, and this was found to be a challenge. The Tarver dialysis unit has no additional rooms and therefore exercises were done in the corridor, while an office space was used in the Main Unit. Whilst this was an issue, participants voiced that this was not a problem as they liked to be away from the activity of the dialysis unit. It was found from the research nurses that it was easier to recruit participants from the morning sessions. The changeover period, where morning patients are coming off dialysis and afternoon patients are attending to go on dialysis was a slight issue. While two participants who participated were dialysing in the afternoon slots, they were also on hospital transport and sometimes there was no way of knowing exactly when they were going to arrive. This was also one of the factors for patients who did not want to take part in the study as they were worried about being late do go on dialysis due to late transport. All participants who were recruited were all Caucasian, even though demographics of all ethnic groups at time of recruitment were invited to participate. Therefore, ethnic and cultural backgrounds may not be representative of other population groups. This feasibility study also has a small sample size; however, drop-out rates were low. It should also be mentioned that the CBE may not suit everyone and this needs to be taken into consideration.

7.11 Impact of Corona Virus COVID-19 2020

During the write up of this thesis, a human pathogenic coronavirus (severe acute respiratory syndrome coronavirus [SARS-CoV] known as COVID-19 originated in Wuhan, China December 2019 and a worldwide outbreak of the disease spread globally to 213 countries over several months (WHO, 2020a). The COVID-19 pandemic led to a suspension of most, if not all. NHS related research. This led to COVID-19 research taking priority in the race to develop a vaccine and stem transmission and deaths (WHO, 2020a).

7.11.1. Chair-Based Exercises Video

As a result of COVID-19, I was unable to collect final follow up data for 7 participants as social distancing measures had taken place in the UK and globally and I was pulled to work clinically in the frontline. With the UK population in lockdown from March 23rd 2020, until easing of restrictions in June 2020, the risk of further inactivity from decreased social contact can reduce health and wellbeing further. Therefore, over a week-long period between March 30th and April 9th 2020 a 10 minute video was produced to demonstrate the exercise and that is was for 'everyone' whether viewers had an identifiable long term condition or not (figure 7.8).

The video is available on the CLEAR Trust website and on YouTube: https://youtu.be/EJgZygWBKaE

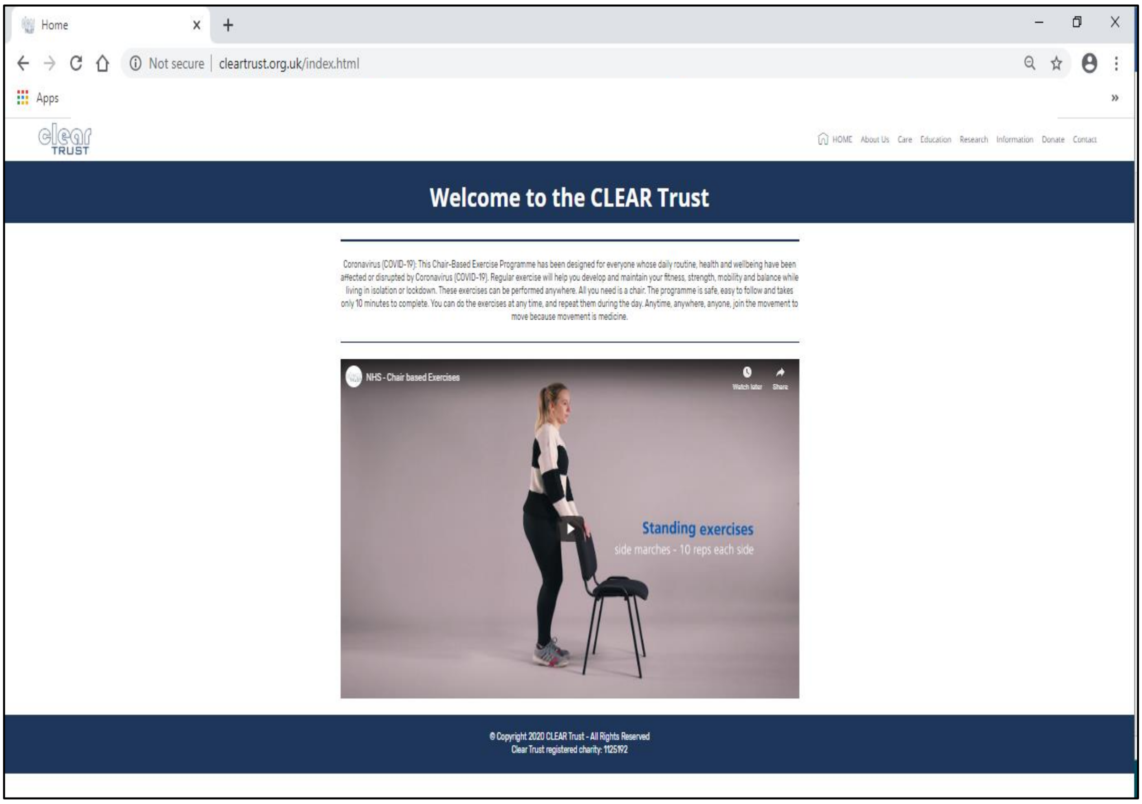


Figure 7.8**:** Video of the Chair-Based Exercises on the CLEAR Trust Home Page.

The video was endorsed by Oxford Brookes University, CLEAR Trust, Oxford Health NHS Foundation Trust, Oxford Health Biomedical Research Centre and University of York, Department of Health Sciences. The video starts with thumb and hand exercises which is different from the booklet as this starts with feet exercises to set the pace and allow for patients to count in a certain way. The reason for the video starting with hand exercises was to draw the viewer in and still target all muscle groups. By August 30th 2020, there were over 8,000 views suggesting that the video was reaching a specific target audience.

7.12 Chapter summary

Despite the described limitations, this feasibility study was welcomed by patients and staff. Patients who needed support in engaging in exercise saw an opportunity to enhance their health and wellbeing. While participant numbers are small, data indicates that the chair-based exercise is feasible, safe and acceptable to this patients group. Even with unforeseen and challenging times, initiatives to develop further online resources to ensure that exercises are available to those with internet access is positive and can pave the way to further exercise programmes to targeted audiences.

Chapter 8

General discussion

8.1 Overview

This chapter will discuss the key points, specific challenges and successes resulting from both observational and feasibility studies. The delivery and results of the CBE provide a new perspective on implementing an exercise programme to an already established cohort of renal patients with existing challenges.

8.2 Discussion

The existing challenges to patients with chronic renal failure (CRF) and who are on haemodialysis (HD) are well known. Symptoms associated with HD can be varied from patient to patient due to age, underlying co-morbidities or attitude or engagement with physical activity (PA). For some patients there is a goal, whether that be aiming for a transplant, wishing to do more in day-to-day life, or walk more and be more active with grandchildren or friends. Acknowledgment of patients who choose not to participate in PA should be respected, but the offer of a form of rehabilitation or exercise program should be available and accessible to all renal patients.

With awareness and understanding of these associated symptoms and potential prescribed exercise benefits, the development of rehabilitation programmes should be suitable to improve strength, balance and provide a cardiovascular component tailored to those who need or wish guided support and structure (Robinson et al., 2016).

The observational and feasibility studies that were conducted as part of this thesis addressed the following objectives:

1) Understand patient activity behaviour prior to dialysis

2) Understand current activity levels, types, frequency barriers and motivation for physical activity informed from wearable devices and interviews in the observational study

3) Co-develop with key stakeholders a suitable and safe intervention for patients on dialysis

4) Trial the intervention

The main findings of this thesis have shown that our renal population have low levels of PA and would prefer more education, support and motivation to engage in PA. Other findings include patients need for exercises that are achievable and safe and that they have someone, such as a healthcare professional to motivate them. Wearable devices were found to be suitable methods to capture PA levels and behaviours. The chair-based exercise programme was found to be a suitable intervention. Pre-dialysis exercise was found to be acceptable and safe but a suitable space to facilitate this can be difficult. The impact of Covid-19 was challenging but allowed for alternative approaches to be developed in a short space of time and so web-based applications of the chair-based exercise could be accessible widely. Despite small participant numbers, the Timed-Up and Go and 10-meter walk functional mobility tests improved over a 3-month period and more robust data would be needed to see any significance. This thesis adds new knowledge to current literature by showing that an alternative rehabilitation programme such as chair-based exercises is feasible in the renal clinical setting and at time of writing this thesis had not been previously explored. Whilst intradialytic cycling remains the most common form of exercise, provision of alternative programmes should be offered to target all patients who are either frail or mobile and who wish to increase exercise capacity.

The results of the observational study allowed exploration of patient views on PA and the objective and subjective methods used were central to this study. The use of the wearable cameras was novel to assist in the interview process to obtain rich data. The interviews gave a rare insight into the PA levels of this population group and with discussion allowed a better understanding to what type of PA intervention was needed.

There are several strengths and limitations of the research methodology for this study. By using the Medical Research Council Framework (UKMRC, 2006) created a foundation and structure to develop, pilot, evaluate an exploratory feasible protocol. The framework is designed to be the most suitable method in developing a plan using suitable theory and an approach to evaluate outcomes of the plan (Shahsavari et al., 2020). In a recent review by Pinto et al. (2021), the MRC framework has become more prominent in nursing research, and the careful design of complex interventions across all health care streams can improve validity of research and reduce unnecessary research waste (Bleijenberg et al., 2018). To support the design of the complex intervention, the Health Belief Model despite some limitations, was useful to determine perceived barriers, perceived benefits and cues to action towards exercise and these variables are strong predictors of health outcomes (Sulat et al., 2018).

The questionnaires given to participants for the observational and feasibility studies were easy to administer. Even though the HAP is a validated questionnaire in the renal population, it is an American questionnaire and a useful one to capture previous and current activity levels. Participants found the HAP cumbersome and sometimes to fill in. However, in future studies, shorter questionnaires such as General Physical Activity Questionnaire would be considered as it is shorter and validated in renal population (Wilkinson et al., 2020) as well as a range of co-morbidities and patients in primary care (Ahmad et al., 2015).

The IPOS-Renal questionnaire used in the feasibility study is useful in terms of allowing participants to voice their concerns they may have with regards to renal symptoms or anxiety. Participants may not usually voice concerns when asked directly in the clinical setting (Siriwardana et al., 2020) and therefore allows participants a chance to indicate symptoms another way. Understanding of patient symptom burden allowed the research team to modify the exercise programme to suit participant needs and to listen to participant fears and goals. It is important to be mindful for both participant and researcher the impact of renal disease and the changes on a physical, mental and personal domains (Morton et al., 2020) and whether the exercise programme needs to stop or restart at appropriate times.

Intradialytic exercise is more common, especially with the use of ergonomic bikes (Sheng et al., 2014). This may not be suitable to all dialysis unit and while there have been successful exercise programmes that have been sustained, lack of resources and training hinder long term implementation (Viana et al., 2019). The use of bikes at the end of the dialysis bed or couch provides limited space within a dialysis unit. Adaptation to programmes need to be explored to support patients and staff and be successful.

The use of chair-based exercises (CBE) was key to the design of the intervention. The key factors that were mentioned by participants were ‘fear of falls’ and ‘muscle wasting’ and improving leg strength was important. CBE has been used in care homes and found that this was a useful programme and participants in the care homes enjoyed taking part (Robinson et al., 2018a), however, delivery of CBE was in group format. Most of our participants preferred one to one as the pace and intensity and progression of exercises was tailored to their individual needs (Dinan et al., 2006). Robinson et al. (2016) state that instructors of CBE expressed that chair-based types of exercises are beneficial for the frail and elderly and that progression from seated to standing exercises are needed. In this feasibility study incorporation of both seated and standing exercises was important to allow participants to progress at an individual pace. Participants mentioned that they were walking more and were able to do more activities of daily living on non-dialysis days.

This feasibility study has demonstrated that a chair-based exercise programme can be taught to patients in the clinical environment, and that these types of exercises can be done in their own home. The success of transferring taught functional exercises such as squats and lunges has been shown in previous studies (Bogataj et al., 2020, Tao et al., 2015). In a study by Bogataj et al. (2020), additional functional training provided by a kinesiologist were delivered 30 minutes prior to each dialysis session followed by intradialytic cycling for the first eight weeks, followed by eight weeks of home exercises. Participant self-report rates indicated that 73% of participants were completing exercise at home on their non-dialysis days. Furthermore, 12 weeks of taught functional exercises and nurse-led education has been found to be practical method to transfer exercises from the clinical setting to the home environment whilst improving functional mobility (Tao et al., 2015). As well as dialysis patients, home exercises for pre-dialysis patients in the early stages of CKD stages 1-4 should also be individualised as a cost effective and simple method to improve quality of life (Tang et al., 2017).

A systematic review by Chan et al. (2019) found that 10-30 minutes of exercises was enough to change participants mood in a positive way. This review identified six studies relied on university students using cycling and running interventions and only one study recruited participants over the age of 50 (implementing Qigong). Three out of the seven studies implemented 10 minutes of exercises as an intervention and found that this was enough to enhance a positive mood (Hansen et al., 2001, Rejeski et al., 1995, Rudolph and Butki, 1998). Recent literature supports these findings to suggest that breaks in sedentary behaviour and accumulative bouts of exercise are beneficial for health (Dempsey et al., 2016, Kehler et al., 2018, Peven et al., 2018). Due to the demands of dialysis and clinic times, a 10-minute exercise routine was felt to be the optimum length for a programme that could be easily delivered pre-dialysis and patients had voiced change in mood and energy on subsequent dialysis sessions. Whilst mood was not measured, participant interviews found that the exercises gave them increased confidence in day-to-day activities.

The increase in confidence mentioned by the participants is similar to previous studies where supervised exercise programmes improved walking stability and balance (Hafström et al., 2016, Miller et al., 2017a). Whilst activity balance scale was not captured in this present study, increased walking speeds in the 10-meter walk test may indicate increase balance confidence and functional mobility in patients. Patients with low individual perceptions of balance confidence are less willing to walk at faster walking speeds (Kongsuk et al., 2019). Falls prevention exercise programmes in elderly populations has been found to be beneficial in preventing injuries and reducing unnecessary costs (Hafström et al., 2016).

Greenwood et al. (2019) found that a 12-week renal rehabilitation programme is associated with longer periods of reduced untoward cardiac events and hospitalisation. Of the 16 participants recruited for this feasibility study, there were no deaths and only one hospitalisation that was not related to the exercise over the study period. The number recruited is small, however, for three participants the CBE programme was a stepping-stone to getting on to the transplant list. For all of the participants recruited, all were motivated to engage in exercise for one reason or another. Exercise motivation and adapted exercise behaviour may be brought about 'variety', exposure and experience. Personal variety in social context, environment and positive exercise experience can contribute to positive engagement with exercise and autonomous motivation. Anyone with low autonomous motivation may have had a poor exercise experience (Sylvester et al., 2018). Therefore, theories to understand health and exercise behaviour are useful and also to understand the reasons why those who did not wish to participate in exercise can be supported for future rehabilitation programmes in or out of the clinical environment. However, flexibility for patients to reach a renal rehabilitation programme or receive social and education support may be factors limiting patients in engaging in exercise (Greenwood et al., 2019). Pre-habilitation programmes for pre dialysis patients may be needed to address frailty in the earlier stages of CKD in order to embed the benefits of exercise earlier and to prevent decline in mobility before commencement of renal replacement therapy (Sheshadri and Johansen, 2017). However a physical activity or rehabilitation pathway should be integrated to all CKD patients including transplant recipients to improve quality of life post-transplant (Kumar et al., 2020). There may not be a one size suits all with regards to exercise programmes however, the provision of adaptive exercise programmes should be available through all stages of the CKD pathway.

The research and outcomes of this thesis demonstrate that the development of a chair-based exercise programme in a busy haemodialysis unit can be achieved. Early observational methods in understanding motivators and barriers towards PA in the dialysis population has helped determine careful development of outcome measures. In addition, the involvement of patient input and concerns regarding exercise achievability and safety were vital in developing the intervention. The objective measurements of the accelerometers and the perceived rate of exertion are useful tools to determine levels of current PA and intensity of exercise for each participant. For example, I recently contributed to an article published in the Clinical Kidney Journal that used accelerometer measurements to show that dialysis participants are much less active than age, sex, and season matched healthy controls (Nawab et al., 2020).

The capability and adaptability of PA for each individual need to be taken into consideration. Goal setting and individual exercise targets and prescription need to be identified and reviewed daily, especially considering participants who feel unwell or have been for routine procedures or hospitalised.

There are several strengths and limitations of the intervention development process. The testing of the intervention was vital to the integrity of the study design. The intervention was co-designed with patients, an exercise physiologist and rehabilitation experts to help facilitate safe and suitable exercise and interpret outcomes (El-Kotob and Giangregorio, 2018). To improve the intervention process, additional focus groups with both research team and patients could have been ongoing rather than just involving patients at the start of the study. Whilst this may have been challenging due to time constraints, ongoing patient perceptions and evaluation of intervention implementation would have been beneficial (Ward et al., 2018). For future study designs, I would also think about incorporating elements of the 'Plan, Do, Study, Act (PDSA) model so that there would have been continuous review of the intervention within the clinical setting (Taylor et al., 2014). This could add benefit to the development of a larger study as well as lessons learnt from the feasibility study keeping in mind the time and investment needed from those involved (Reed and Card, 2016).

The limitations of the intervention included difficulty in capturing patient adherence at home after the 6 weeks pre-dialysis training in hospital. Even though a progress chart was imbedded at the back of the chair-based exercise booklet, some participants did not complete it due to forgetfulness or did not want to complete it. Thus, participant fidelity in frequency and duration of the CBE was not always achieved which is challenging to evaluate in PA interventions (El-Kotob and Giangregorio, 2018).

Chair-based exercise are not suitable for everyone and the screening process would need to be refined for a future randomised control trial. Screening for patients who are frail and who are frequent users of mobility aids would benefit most (Van Munster et al., 2016, Worthen and Tennankore, 2019). Patients who are new to dialysis should be seen by a physiotherapist within one month after starting dialysis. This can allow the physiotherapist or other suitable health care professional to assess patient PA status and provide relevant PA education so that the behaviour change process can be started and maintained early after starting dialysis therapy.

8.2.1 Adaptations of the Renal Chair-Based Exercises and future applications

Several of the exercises developed for this study have been modified for another study involving adolescents (OxSOCRATES, 2020). Whilst COVID-19 has suspended this study at time of writing, the exercises were developed as part of a cost-effective intervention and to assess cardio-metabolic risk in adolescent groups (OxSOCRATES, 2020).

8.3 Future work

This is a feasibility study, and a larger randomised controlled trial powered to assess a real effect between a control and exercise group will be needed. To achieve statistical significance this would need to involve all 5 network haemodialysis provider units in addition to the 2 Oxford units that fall within the umbrella of the Oxford Kidney Unit and other renal units across the UK. However, this would need to take into consideration cost (e.g. staff time), availability of space in each dialysis unit, and identifiable staff delivering the exercises. The adaptability of these exercises can be delivered in care home setting, schools and other hospital settings as well as renal and transplant settings.

To assess the effectiveness of a larger RCT, outcome measures would need to be realistic so that all units would be able to implement easily. Functional mobility tests such as the Timed Up and Go and 10 Metre walk test worked well in this feasibility study, and I would utilise them again as they are cost efficient, quick, easy and reliable outcome measures. In terms of questionnaires, I would reduce the number of questionnaires given as not to add to patient burden, and would not use the modified version of the CRSI or HAP due to patient verbal feedback. The HAP while useful and correlates with accelerometers, is a long questionnaire for patients to fill out. However, I would use a one page physical activity questionnaire such as the validated General Practice Physical Activity Questionnaire (Wilkinson et al., 2020). Fatigue is captured in the IPOS-Renal and therefore would not introduce a new fatigue assessment tool.

In terms of implementation process to ensure successful delivery of a larger RCT, review of the inclusion and exclusion criteria would be of value. Patients randomised to a control group would receive regular standard of care but would complete questionnaires to capture symptom burden and activity levels compared to those who would be randomised to the CBE intervention. What I have learnt is to keep elements and outcome measures of the study in question simple as not overwhelm data and that the research question can be answered to provide evidence based research (Bhide et al., 2018).

8.4 Final remarks

The main findings from this study indicate that renal patients enjoyed the exercises in this study and that they can be done in the unit environment and at home. The intensity and frequency should be dependent on frailty and goal setting and assessed regularly. An increase in speed with regards to the 10-meter walk test and the Timed Up and Go was observed. Furthermore, the endorsements of government and health bodies realising the need for a short and effective exercise programme to improve strength and balance has proved this project worthwhile and rewarding, not just to renal patients, but to anyone with or without a long-term condition. The outcomes of this study can inform further guidance and support to renal healthcare teams in setting up to deliver a safe and feasible exercise programme that is suitable for this unique group of patients.

Appendices

Appendix 1: Classification of Chronic Kidney Disease

Classification of chronic kidney disease using GFR and ACR categories

GFR and ACR categories and risk of adverse outcomes			ACR categories (mg/mmol), description and range		
			<3 Normal to mildly increased	3–30 Moderately increased	>30 Severely increased
			A1	A2	A3
GFR categories (ml/min/1.73 m^2), description and range	≥90 Normal and high	G1	No CKD in the absence of markers of kidney damage		
	60–89 Mild reduction related to normal range for a young adult	G2			
	45–59 Mild–moderate reduction	G3a[1]			
	30–44 Moderate–severe reduction	G3b			
	15–29 Severe reduction	G4			
	<15 Kidney failure	G5			

Increasing risk (downwards)

Increasing risk (to the right)

Appendix 1: Renal Association guidelines (2018), adapted from Kidney Disease: Improving Global Outcomes (KDIGO) CKD workgroup 2013 KDIGO 2012. Clinical practice guidelines for the evaluation and management of chronic kidney disease. Kidney International. Suppl 3, 1-50.

Appendix 2: EQ-5D-3L Questionnaire

EQ-5D Health Questionnaire

Client ID ☐ New User ☐ Existing User ☐

Date ☐

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Self-Care

I have no problems with self-care ☐
I have some problems with washing or dressing myself ☐
I am unable to wash or dress myself ☐

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

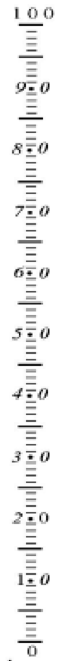
Pain / Discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

Anxiety / Depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

Best imaginable
health state



Worst imaginable
health state

Visual Analogue Scale

Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from the box to the point on the scale that indicates how good or bad your health state is today.

Your own health state today

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

Appendix 3: Human Activity Profile Questionnaire

Human Activity Profile

Please place a tick in the appropriate box; until there are clearly no activities listed that you are able to do at the present time. If you are still doing an activity tick the first box, if you have stopped doing an activity tick the second box, if you have never done an activity tick the third box.

This questionnaire was constructed by A J Fix and DM Daughton and published in the *Human Activity Profile Professional Manual*, Psychological Assessment Resources Inc., 1988

		Still doing this activity	Have stopped doing this activity	Never did this activity
1	Getting in & out of chairs or bed without assistance....			
2	Listening to the radio..			
3	Reading books, magazines or newspapers..............			
4	Writing letters or notes..			
5	Working at a desk or table....................................			
6	Standing for more than 1 minute...........................			
7	Standing for more than 5 minutes.........................			
8	Dressing or undressing without assistance..............			
9	Getting clothes from drawers or closets..................			
10	Getting in and out of cars without assistance...........			
11	Dining at a restaurant..			
12	Playing cards / table games..................................			
13	Taking a bath without assistance...........................			
14	Putting on shoes, stockings or socks, no rest or breaks required			
15	Attending a movie, play, church event or sports .... activity			
16	Walking 30 yards / 27 meters...............................			
17	Walking 30 yards non-stop...................................			
18	Dressing / undressing, no rest or break needed..........			
19	Using public transport or driving a car 99 miles or less			
20	Using public transport or driving a car 100 miles or.... more			

		Still doing this activity	Have stopped doing this activity	Never did this activity
21	Cooking your own meals..................................	☐	☐	☐
22	Washing or drying dishes.................................	☐	☐	☐
23	Putting groceries on shelves.............................	☐	☐	☐
24	Ironing or folding clothes................................	☐	☐	☐
25	Dusting / polishing furniture or polishing a car.........	☐	☐	☐
26	Showering...	☐	☐	☐
27	Climbing 6 steps..	☐	☐	☐
28	Climbing 6 steps non stop.................................	☐	☐	☐
29	Climbing 9 steps..	☐	☐	☐
30	Climbing 12 steps...	☐	☐	☐
31	Walking ½ block on level ground........................	☐	☐	☐
32	Walking ½ block on level ground non-stop............	☐	☐	☐
33	Making a bed (not changing sheets).....................	☐	☐	☐
34	Cleaning windows..	☐	☐	☐
35	Kneeling, squatting to do light work.....................	☐	☐	☐
36	Carrying a light load of groceries .... (milk bread)	☐	☐	☐
37	Climbing 9 steps non-stop.................................	☐	☐	☐
38	Climbing 12 steps non-stop...............................	☐	☐	☐
39	Walking ½ city block uphill...............................	☐	☐	☐
40	Walking ½ city block uphill non-stop....................	☐	☐	☐
41	Shopping by yourself......................................	☐	☐	☐
42	Washing clothes by yourself..............................	☐	☐	☐
43	Walking 1 city block on level ground....................	☐	☐	☐
44	Walking 2 city blocks on level ground..................	☐	☐	☐
45	Walking 1 city block on level ground non-stop.........	☐	☐	☐
46	Walking 2 city block on level ground non-stop.........	☐	☐	☐

		Still doing this activity	Have stopped doing this activity	Never did this activity
47	Scrubbing floors, walls or cars..............................	☐	☐	☐
48	Making a bed, changing sheets............................	☐	☐	☐
49	Sweeping..	☐	☐	☐
50	Sweeping 5 minutes non-stop..............................	☐	☐	☐
51	Carrying a large suitcase or bowling 1 game............	☐	☐	☐
52	Vacuuming carpets......................................	☐	☐	☐
53	Vacuuming carpets 5 minutes non-stop..................	☐	☐	☐
54	Painting interior / exterior..................................	☐	☐	☐
55	Walking 6 city blocks on level ground....................	☐	☐	☐
56	Walking 6 city blocks on level ground non-stop.........	☐	☐	☐
57	Taking out the garbage....................................	☐	☐	☐
58	Carrying a heavy load of groceries.......................	☐	☐	☐
59	Climbing 24 steps..	☐	☐	☐
60	Climbing 36 steps..	☐	☐	☐
61	Climbing 24 steps non-stop..................................	☐	☐	☐
62	Climbing 36 steps non-stop..................................	☐	☐	☐
63	Walking 1 mile..	☐	☐	☐
64	Walking 1 mile non-stop.....................................	☐	☐	☐
65	Running 110 yards (100 m) or playing softball / .... baseball	☐	☐	☐
66	Dancing (social)..	☐	☐	☐
67	Doing callisthenics or aerobic dancing .... (5 minutes non-stop)	☐	☐	☐
68	Mowing the lawn .... (power mower but not a ride on mower)	☐	☐	☐
69	Walking 2 miles..	☐	☐	☐
70	Walking 2 miles non-stop..................................	☐	☐	☐
71	Climbing 50 steps (2 ½ floors)...........................	☐	☐	☐

Page 3 of 4

		Still doing this activity	Have stopped doing this activity	Never did this activity
72	Shovelling, digging or spading			
73	Shovelling, digging or spading 5 minutes non-stop…..			
74	Climbing 50 steps (2 ½ floors) non-stop……………..			
75	Walking 3 miles or golfing 18 holes without golf cart..			
76	Walking 3 miles non stop………………………………			
77	Swimming 25 yards………………………………....			
78	Swimming 25 yards non-stop…………………………			
79	Bicycling 1 mile………………………………….....			
80	Bicycling 2 miles………………………………….....			
81	Bicycling 1 mile non-stop……………………………			
82	Bicycling 2 miles non-stop…………………………..			
83	Running or jogging ¼ mile……………………………			
84	Running or jogging ½ mile…………………………....			
85	Playing tennis or racquetball…………………………			
86	Playing basketball / soccer (game play)………………			
87	Running or jogging ¼ mile non-stop…………………..			
88	Running or jogging ½ mile non-stop…………………..			
89	Running or jogging 1 mile……………………………..			
90	Running or jogging 2 miles…………………………....			
91	Running or jogging 3 miles…………………………....			
92	Running or jogging 1 mile in 12 minutes or less……..			
93	Running or jogging 2 miles in 20 minutes or less…….			
94	Running or jogging 3 miles in 30 minutes or less…….			

Maximum Activity Score (MAS) = highest ranking activity still being done
Adjusted Activity Score (AAS) = MAS – the number of items that have been stopped that fall below the MAS
Activities that were 'never done' are not counted

Appendix 4: Excerpt from Camera Annotation Protocol

Aiden Doherty, Angel Wong (Updated on 14 August 2015)

British Heart Foundation Centre on Population Approaches for Non-Communicable Disease Prevention
Nuffield Department of Population Health Old
Road Campus, Roosevelt Drive, Headington, Oxford OX3 7LF, UK
Old Road Campus, Roosevelt Drive, Headington, Oxford OX3 7LF, UK
Tel: +44 (0)1865 289245, Fax: +44 (0) 1865 617789,

Extracting physical activity information from wearable camera images: annotation protocol

Events

An "event" means a series of images grouped thematically. Firstly, the manual will run through how to split event accurately.

Three-image rule

Activities will be split into episodic "events" with at least three images. The start of an event is the first image in a set of three (or more) consecutive images that depict the same activity, or where the researcher is almost certain that the same activity is occurring across the images. An event ends when the next event begins, so activities that last less than three images will be grouped with the preceding event.

Dominating activities

It is possible that the event does not depict the same activity across all images. Accordingly, the researcher should annotate the dominating behaviour, in which the largest proportion of the event depicts. Researchers should prefer the specific annotation items to generic counterparts, unless the primary activity does not match with any specific annotation item. Figure 1 illustrates how events should be split and which behaviour should be annotated later.

Split here as we find 3 and more consecutive images depicting the same behavioural activities

Figure 1. An example of events split.

When the dominating behaviour is in doubt, the researcher should annotate the event with a more generic description. For example, when a series of images show that the participant shut the window, took the key and locked the door as he/she was ready to leave the home; there is no dominating event and a specific annotation for such household tasks. In this case, "home activity;miscellaneous;5165 (generic) walking non-cleaning task such as closing windows lock door putting away items" should be annotated.

Primary activities

As a participant might do multiple tasks at the same time, the researcher should identify the primary activity for the annotation. The primary activity is the one which the participant was actively performing. Watching the movements of the participant's hands would help with the identification. In image 1, the participant was looking at his laptop showing a video. In this case, the researcher should annotate the primary activity as desk work, rather than sitting watching TV.

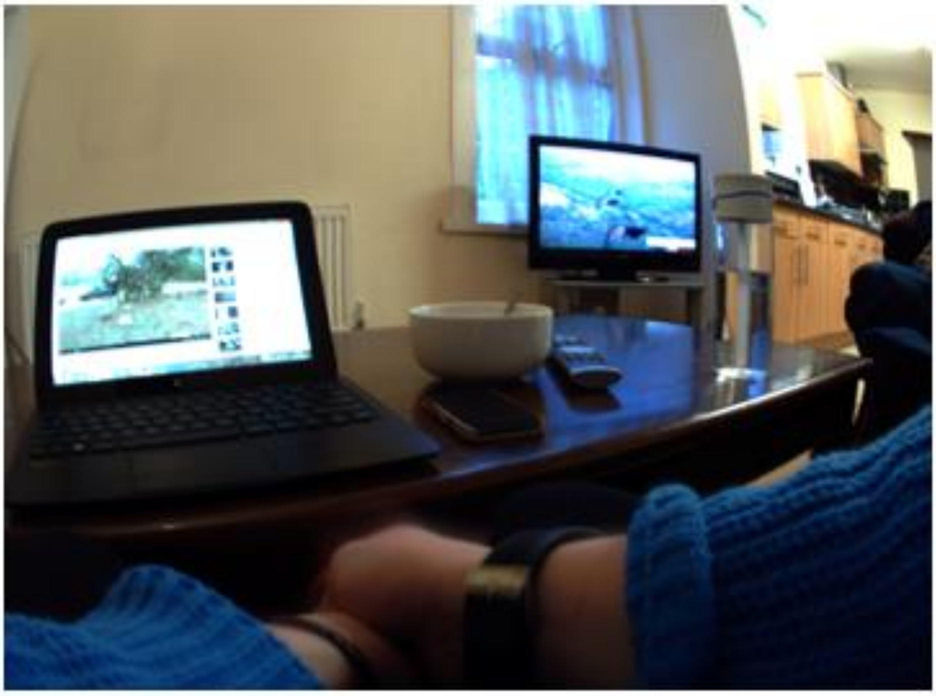


Image 1. An example of "home activity:walking/standing/sitting:9030 sitting desk work miscellaneous". (From main p033)

Image annotation

After uploading photos and import annotation list, the researcher should annotate events with the lowest tier in the list. Table 1 summarises the general rules of *the CAPTURE-24*'s annotation list for looking for the appropriate categories.

Categories	**Rules**
Uncodeable	When the images are blocked and/or dark, or the images show that the participant took off the camera
Occupation	The events after the participants had entered the working place and before they left that.
Transportation	The events after the participants had left their destination (e.g. homes, working place, churches, restaurants, shopping malls) for a certain activity and before they entered into another one.
Home activity	The events taken place at the participants' home (guest's house is regarded as leisure place)
Leisure	The events that did not fall into the above categories.

Table 1. A summary of the general rules for identifying events under each category

The next session is the descriptions of sub-categories under major categories. Supplementary notes are provided for a better understanding of appropriate annotation.

Uncodeable

Lowest trier items
Camera taken off * (MET value: undefinable)
Image dark**/blurred/obscured (including camera being blocked) (MET value: undefinable)

Table 2. Categorisation of uncodeable images.

*A series of images in which the position of the photo remains the same in relation to fixed objects. Lighting commonly changes without movement of the images. There is an exceptional case for this annotation. If the researcher can clearly identify the person captured in the images to be the participant per se over the course when the camera was taken off, the researcher should annotate the observed events that the participant was doing. Image 2 shows the image before the camera was taken off. The sleeve of the participant was red in colour. In the subsequent images in image 3 when the camera was taken off, the person in the images was in fact the participant. The corresponding annotation should be "home activity;miscellaneous;sitting;9030 sitting desk work (with or without eating at the same time),with a desk".

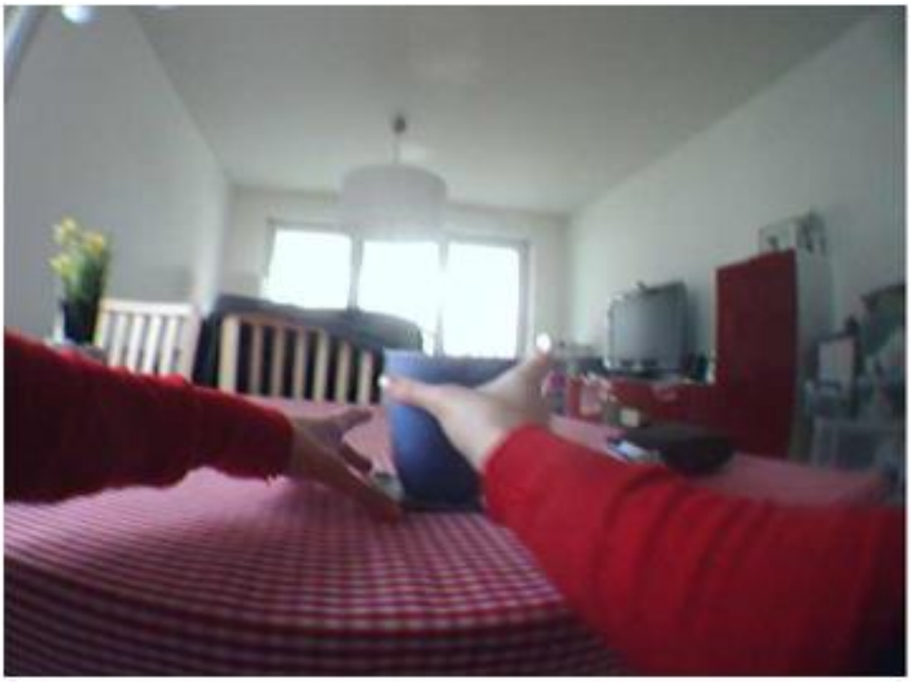


Image 2. An image before the camera was taken off.

Appendix 5: Observational study approval letter

Health Research Authority

NRES Committee East of England - Hatfield
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0191 4283564

15 August 2014

Dr Julia Newton
Honorary Lecturer and Consultant in Rheumatology/Sport and Exercise Medicine
NDORMS, University of Oxford
Botnar Centre, Windmill Road
Headington, Oxford
OX3 7LD

Dear Dr Newton

Study title:	**Physical Activity and Chronic Kidney Disease: a Cross-sectional Study in Haemodialysis Patients Investigating Motivators and Barriers towards Exercise**
REC reference:	**14/EE/1094**
IRAS project ID:	**158102**

The Proportionate Review Sub-committee of the NRES Committee East of England - Hatfield reviewed the above application on 13 August 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager Miss Kathryn Murray, nrescommittee.eastofengland-hatfield@nhs.net.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

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

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

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

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

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

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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

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

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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

Ethical review of research sites

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

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

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

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

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

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

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

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

Instructions for use of medical device		
Letter from funder		
Letter from sponsor		01 August 2014
Non-validated questionnaire	1.0	01 August 2014
Other [Email Response to Committee's Queries - Julia Newton and Sheera Sutherland]		12 August 2014
Other [Email from Sheera Sutherland]		12 August 2014
Participant consent form	1.0	01 August 2014
Participant information sheet (PIS)	1.2	12 August 2014
REC Application Form [REC_Form_06082014]		06 August 2014
REC Application Form [REC_Form_06082014]		06 August 2014
Referee's report or other scientific critique report		
Research protocol or project proposal	1.1	11 August 2014
Summary CV for Chief Investigator (CI)		04 August 2014
Validated questionnaire		
Validated questionnaire		
Validated questionnaire		

Membership of the Proportionate Review Sub-Committee

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

Statement of compliance

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

After ethical review

<u>Reporting requirements</u>

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

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

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

User Feedback

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

HRA Training

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

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

14/EE/1094	**Please quote this number on all correspondence**

Yours sincerely

K Murray

pp.
Mr David Grayson
Chair

Email: nrescommittee.eastofengland-hatfield@nhs.net

Enclosures:	*List of names and professions of members who took part in the review* *"After ethical review – guidance for researchers" [SL-AR2]*
Copy to:	*Miss Heather House, Oxford University Hospitals NHS Trust*

A Research Ethics Committee established by the Health Research Authority

Appendix 6: Observational study- Patient Information Leaflet

University of Oxford

Physical Activity and Chronic Kidney Disease: a Cross-sectional Study in Haemodialysis Patients Investigating Motivators and Barriers towards Exercise

Patient Information Leaflet

Principal Investigator: Dr Julia Newton

Rheumatology Department
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
OX3 7LD

Julia.newton@ouh.nhs.uk

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is taking place and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Please feel free to ask us if any of the following information is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. **What is the purpose of the study?**

   There is a well-established link between physical inactivity and increased mortality in the general population and patients with chronic kidney disease have low fitness levels when compared to their healthy counterparts. Studies have shown that physical activity presents many physical and mental health benefits in the dialysis population, with improvements in fitness, walking distances, heart function, and quality of life; indeed, national guidelines now consider physical activity to be a cornerstone of disease management. With this observational study, we wish to explore motivators and barriers towards physical activity in haemodialysis patients.

2. **Why have I been invited to participate?**

   You have been invited to participate in this study because you are receiving regular haemodialysis treatment under the care of the Oxford Kidney Unit. We wish to recruit 100 dialysis patients to complete the Human Activity Profile validated questionnaire looking at your current physical activity levels. 40 of you will then be contacted to wear an accelerometer and camera for up to 7 days to monitor your physical activities.

3. **Do I have to take part?**

   No. Only take part if you wish to do so. To help you decide, we will describe the study and go through this information sheet when you attend for dialysis, which we will then give to you to read in your own time. At a subsequent dialysis session, if you are willing to take part, we will ask you to sign a consent form to show you have considered the information provided, understand what the study involves for you, and that you are agreeable to proceed. You are free to withdraw from all or any part of the study at any time, without giving a reason. **The standard of your care that you receive will not be affected in any way if you decide not to participate in the study or if you start the study and then decide to withdraw at a later date.**

4. What will happen to me if I take part?

When you decide you wish to participate one of the research team will approach you for your consent. The study visits will take place on the same day of your dialysis session at the haemodialysis unit.

The following procedure will be for all 100 patients:

Demographic and medical history:

We will collect some information about you for example, your age, sex, occupation, height and weight. We will also review your medical records to confirm your suitability to participate in the next stage of the study.

Baseline Human Activity Profile Questionnaire: (15 minutes)

This questionnaire consists of 94 questions and seeks to determine the activities you currently do. This is a tick box questionnaire and the research nurse involved in the study will give you this to complete.

EQ-D5 Questionnaire (5 minutes)

This is a self-completing questionnaire comprising of the following 5 areas: mobility, self-care, your daily activities, pain/discomfort and depression.

Handgrip Strength measurement (2 minutes)

The purpose of this test is to assess your maximum strength in your hands and forearm. To do this we will ask you to hold a device and squeeze for 5 seconds to give us a reading.

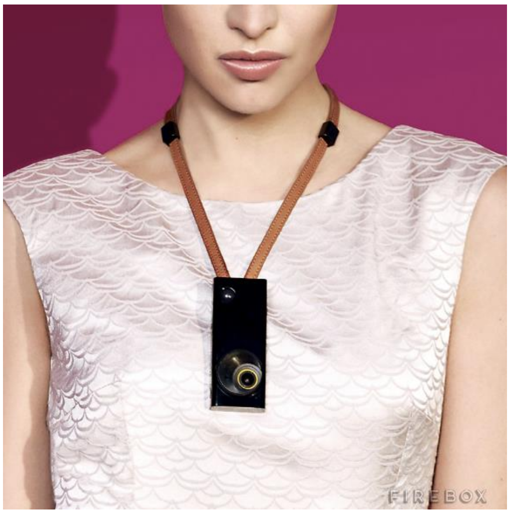
Once the above part is finished, we will ask up to 40 patients to participate in the observational part of the study. The following procedures will take place if you participate in this part:

Wrist worn accelerometer:

You will be given a small wrist worn motion sensor called an accelerometer. You will be expected to wear the accelerometer at all times during dialysis and non-dialysis days for 7 days in total.

<u>Wearable camera</u>

In addition to the accelerometer, you will be given a camera to wear around your neck for 7 days. This will help us determine what type of physical activity you do, and in what circumstances. Naturally, you will be free to take the camera off when you or others may feel uncomfortable or when you want to maintain privacy such as showering or dressing. **The camera does not record any sound, voices or conversations, so your privacy is assured in this regard.**



One of the research team will instruct you on how to use the devices. You will also be given an instruction hand-out to take home.

We can also send you an email or SMS (text) reminder to charge the wearable camera. The devices will be configured (scrambled) so that the data can only be accessed by members of the research team, thus blocking any access in case other participants and/or third parties inappropriately find the devices.

After 7 days and on a suitable dialysis day, you will return the camera and accelerometer. The images and data form these devices that you have collected will be put on to a computer. You will have an opportunity to view the images before any of the research team. You will also be welcome to delete any or all of the images without giving any reason.

Human Activity Profile Questionnaire (15 minutes)

You will again complete this questionnaire once the devices have been returned.

Device Acceptability Questionnaire (5 minutes)

This questionnaire consists of 13 questions and seeks to determine your experience in wearing the camera and accelerometer devices.

Semi-structured Interview (1 hour)

You will then be interviewed with one of the researchers to go through some of the images with you and talk about your daily activity levels. With your permission we would like to audio-record the interview to help us identify some of the common themes. Immediately after the interview, we will also ask you to tell us about your experiences wearing the accelerometer and camera.

Once the above procedures are finished, your participation in the study will end.

5. **What are the risks of taking part?**

We do not anticipate that participating in this research project will have any significant effect on your lifestyle. However, it is be possible that you may be asked about the wearable camera by members of the public. In this case we suggest that you say the following:

> '*I am volunteering for a research project. The device is a wearable camera and the images will be used to record my day-to-day activities- I would be happy to remove it if you would like me to'*

6. **Will the information about me collected for this study be kept confidential?**

   If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from the University of Oxford and Oxford University Hospitals NHS Trust to check that the study is being carried out correctly. These people will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside of the research site.

   Again, your confidentiality will be respected at all times. Data will be stored according the Data Protection Act (1998). All the data and images will be anonymised and stored on a password protected computer. Any researchers using the data will have been trained in ethical handling of such data. You will never be identified nor will your images be shown without written permission. However, data of illegal activities may to be protected by confidentiality and may be passed to law enforcement.

   The University of Oxford, as a Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm arising from the negligence of the University, or that of a collaborator in this research, and with that harm resulting as a direct consequence of your participation.

   If you choose to withdraw from the study, we would like to use any data that we have already gathered from you, but will seek your permission in this regard. All data will be stored securely and destroyed after 10 years.

7. **Expenses and payments**

   As you are already attending dialysis regularly and that you will be seen on your dialysis days, expenses for travel will not be covered.

8. **What will happen to the results of the research study?**

   We aim to publish the results of our study in peer-reviewed, publicly available journals. At the end of the study, we will also put posters up in the Haemodialysis unit describing the findings and prepare an article for publication in Viva, the magazine of the Six Counties Kidney Patients' Association.

9. **Who is sponsoring and funding the research?**

This research study has been devised and will be organised and carried out by the staff of the Oxford Kidney Unit (Professor Pugh, Ms Sutherland, and Mrs Thornley) the University of Oxford (Dr Newton, Dr Jones, Dr Foster, Dr Doherty, Ms Penfold and Mr Jones). The study is sponsored by the University of Oxford and is funded by the National Institute for Health Research (NIHR) Research Capability Funding.

10. **Who has reviewed the study?**

An independent group called the 'Research Ethics Committee' reviews all research in the NHS. This group serves to protect your safety, rights, wellbeing and dignity during the research process. This study has been reviewed and given a favourable opinion by the NRES Committee South Central -________________.

11. **Contact Information**

The Principal Investigator for this research is Dr Julia Newton. If you have any questions or queries please feel free to contact her directly using the details below or in writing at the address on the front page of this document.

Telephone: Email: Julia.newton@ouh.nhs.uk

Alternatively please contact Ms Sheera Sutherland (Research Nurse) who can be contacted via the Main Haemodialysis Ward of the Oxford Kidney Unit or on Sheera.Sutherland@ouh.nhs.uk

12. **If you wish to make a complaint**

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Principal Investigator, Dr. Julia Newton via email: Julia.newton@ouh.nhs.uk

Or you may contact the university of Oxford Clinical trials and Research Governance Unit (CTRG) office on 01865 572224 or the head of the CTRG, email ctrg@admin.ox.ac.uk

13. **To find out more about research in general**

If you wish to find out more about taking part in research in general please ask to read the 'Involve' booklets available on the Main Haemodialysis Unit or discuss matters with your own nephrology consultant. You may also wish to contact the Patients' Advice and Liaison Service at the John Radcliffe Hospital (01865 221473).

Many thanks for taking the time to read this leaflet!

Appendix 7 Observational Study- Informed consent form

Informed consent form version 1.0 11th June 2014

University of Oxford

Informed consent form for participants

Project title: Physical Activity and Chronic Kidney Disease: a Cross-sectional Study in Haemodialysis Patients Investigating Motivators and Barriers towards Exercise

July _____ 2014 Version 1.1 REC reference Number:

Principal Investigators: **Dr Julia Newton**

Please initial box

1. I confirm I have read and understood the participant information sheet dated July 2014, Version ____ for the above study and have had the opportunity to ask questions which have been answered fully and satisfactorily.	
2. I understand that my participation is voluntary and I am free to withdraw at any time without giving any reason, without my legal rights being affected.	
3. I understand that data collected during the study may be looked at by authorised individuals from the University of Oxford or Oxford University Hospital NHS Trust where it is relevant to my taking part in this research. I permit these individuals to access my records.	
4. I agree to wearing a wearable camera and wrist worn accelerometer and an audio taping of a semi-structured interview.	

5. I understand that I may request to have any or all of the digital images deleted at any time without giving any reason.	
6. I consent to the use of anonymised quotes in reports and publications and to pass anonymised data on to other organisations which may include commercial organisations.	
7. I agree to take part in the above study	

Name of participant…………………………………………….. Signature……………………………… Date……………….......

Name of person taking consent……………….…………… Signature……………………………….. Date……………………..

Principal investigator………………………….……………….. Signature……………………………….. Date……………………..

1 copy for participant; 1copy for principal investigator; 1copy for medical notes

Appendix 8: Feasibility Study-Research Ethics Committee Approval

NHS
Health Research Authority

East Midlands - Nottingham 1 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 you to start your study at NHS sites in England until you receive HRA Approval

29 April 2019

Ms Sheera Sutherland
Senior Research Nurse
Oxford University Hospitals NHS Foundation Trust
Oxford Kidney Unit, Main Dialysis Unit
Churchill Hospital, Old Road
Oxford
OX3 7LE

Dear Ms Sutherland

Study title:	**A structured exercise and educational intervention to increase physical activity in haemodialysis patients: a feasibility study**
REC reference:	**19/EM/0042**
Protocol number:	**FREC 2017/62**
IRAS project ID:	**247579**

Thank you for your letter of 14 March 2019, responding to the Committee's request for further information on the above research.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

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

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

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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

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

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

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

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

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		16 July 2018
GP/consultant information sheets or letters	2.0	08 July 2018
Interview schedules or topic guides for participants	1.0	29 August 2018
Interview schedules or topic guides for participants [Motivational Interviewing Topic guide]	1.0	18 January 2019
IRAS Application Form [IRAS_Form_24012019]		24 January 2019
IRAS Application Form [IRAS_Form_13032019]		13 March 2019
Letter from funder [Letter from funder]		29 September 2017
Letter from sponsor		20 September 2018
Non-validated questionnaire [Patient questionnaire]	1.0	18 January 2019
Participant consent form [Patient Consent Form]	1.6	07 March 2019
Participant consent form [Staff Consent Form]	1.2	07 March 2019
Participant information sheet (PIS) [Patient PIS]	2.5	07 March 2019
Participant information sheet (PIS) [Staff PIS]	1.3	07 March 2019
Referee's report or other scientific critique report		10 October 2018
Research protocol or project proposal [Protocol]	10.0	07 March 2019
Response to Request for Further Information		14 March 2019
Sample diary card/patient card [Educational booklet]	1.1	18 January 2019
Summary CV for Chief Investigator (CI) [CV]		15 October 2019
Summary CV for student		18 October 2018
Summary CV for supervisor (student research)		18 October 2018

Summary CV for supervisor (student research) [CV Prof M. Boulton]		18 January 2019
Summary, synopsis or diagram (flowchart) of protocol in non technical language	9.0	12 December 2018
Validated questionnaire [Human Activity Profile]	1.0	09 April 2018
Validated questionnaire [EQ53DL]		
Validated questionnaire [IPOS Renal]		
Validated questionnaire [Falls and fractures Questionnaire]		
Validated questionnaire [Borg RPE]		
Validated questionnaire [Client Service Receipt Inventory]	1.1	

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

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

HRA 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/

19/EM/0042	**Please quote this number on all correspondence**

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

Yours sincerely

Mr Murthy Nyasavajjala
Chair

Email:NRESCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures:	"After ethical review – guidance for researchers" *[SL-AR2]*
Copy to:	*Ms Kellie Tune*

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Ms Sheera Sutherland
Senior Research Nurse
Oxford University Hospitals NHS Foundation Trust
Oxford Kidney Unit, Main Dialysis Unit
Churchill Hospital, Old Road
Oxford
OX3 7LE

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

29 April 2019

Dear Ms Sutherland

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**A structured exercise and educational intervention to increase physical activity in haemodialysis patients: a feasibility study**
IRAS project ID:	**247579**
Protocol number:	**FREC 2017/62**
REC reference:	**19/EM/0042**
Sponsor	**FREC 2017/62**

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.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important 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 of the research management function for each organisation can be accessed here.

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 the devolved administrations of 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) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

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 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.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Ms Kellie Tune

E-mail: frec@brookes.ac.uk

Telephone: 01865485276

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 **247579**. Please quote this on all correspondence.

Yours sincerely

Sharon Northey
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Kellie Tune – Sponsor contact*

IRAS project ID	247579

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)		16 July 2018
GP/consultant information sheets or letters	2.0	08 July 2018
HRA Schedule of Events [HRA Schedule of Events]	2	12 February 2019
HRA Statement of Activities [HRA Statement of Activities]	2	18 February 2019
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Validated questionnaire [EQ53DL]		
Validated questionnaire [IPOS Renal]		
Validated questionnaire [Falls and fractures Questionnaire]		
Validated questionnaire [Borg RPE]		
Validated questionnaire [Client Service Receipt Inventory]	1.1	

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	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	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.
4.2	Insurance/indemnity arrangements assessed	Yes	The indemnity for the accelerometers lies with the study sponsor.
4.3	Financial arrangements assessed	Yes	The Statement of Activities confirms that the NHS site will not receive any funding.
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	Yes	No comments

IRAS project ID	247579

Section	Assessment Criteria	Compliant with Standards	Comments
	received for applicable studies		
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 and Wales

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.
There is one type of participating NHS Organisation completing all of the research activities as detailed in the study protocol. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales 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. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS or on the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net, or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor's position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
This is a single site study and the study Chief Investigator will, in addition, act as Principal Investigator (PI). Therefore no additional PI or Local Collaborator (LC) is required. GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

IRAS project ID	247579

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.
Use of identifiable patient records held by an NHS organisation to identify potential participants should be undertaken by a member of the direct care team for the patient. No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain an honorary research contract. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 9: Feasibility Study- Patient Information Leaflet

A structured exercise and educational training programme to increase physical activity in haemodialysis patients: a feasibility study

Patient Information Leaflet

Principal Investigator: Ms Sheera Sutherland

Centre for Movement, Occupational and Rehabilitation Sciences
Oxford Brookes University
Gipsy Lane
Headington
Oxford
OX3 0BP
15000724@brookes.ac.uk

We would like to invite you to take part in a research study. Before you decide, we want you to understand why the research is taking place and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Please feel free to ask us if any of the following information is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. **What is the purpose of the study?**

   Studies have shown links between physical activity and better health and longer life expectancy in the general population. Patients with chronic kidney disease have low fitness levels compared to their healthy counterparts. Physical activity has specific physical and mental health benefits for the dialysis population, improving fitness, walking distances, heart function, and quality of life; indeed national guidelines now recommend physical activity for all patients. In this study, we wish to assess whether a structured physical activity programme and educational booklet promotes haemodialysis patients to engage with physical activity. This study is a part of a PhD project.

2. **Why have I been invited to participate?**

   You have been invited to participate in this study because you are receiving regular haemodialysis treatment under the care of the Oxford Kidney Unit. We are aiming to recruit 20 dialysis patients to complete the Human Activity Profile questionnaire looking at your current physical activity levels and to complete the EQ-5D-3L and IPOS-Renal questionnaires to assess your health status. We will also ask you to complete falls and fractures questionnaire and a short mobility test. You will be given an educational booklet with information regarding physical activity outlining a chair-based exercise program that will be delivered prior to your dialysis treatment. You will be given input from a sports exercise instructor over a 6 week period. The study will last 6 months in total.

3. **Do I have to take part?**

   No. Only take part if you wish to do so. To help you decide, we will describe the study and go through this information sheet when you attend for dialysis, which we will then give to you to read in your own time. If you wish to discuss the study further, one of the research team will be happy to see you on one of your dialysis sessions. You may also discuss the study with your General Practitioner (GP). If you wish to take part, at a subsequent dialysis session we will ask you to sign a consent form to show you have considered the information provided, understand what the study involves for you, and that you would like to proceed. You are free to withdraw from the study at any time, without giving a reason. Your care will not be affected in any way if you participate, decide not to participate or withdraw from the study. Information collected will only be used for the purpose of research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

4. **What will happen to me if I take part?**

One of the research team will approach you for your consent. The study visits will take place on the same day as your dialysis session at the haemodialysis unit. The Oxford Kidney Unit will notify your GP that you are participating in the study and we will ask your GP to notify the Oxford Kidney Unit if there are any changes to your health that affect your participation in the research.

The following procedures will be for all 20 patients:

Baseline assessments:

<u>Demographic and medical history:</u>

We will collect some information about you for example, your age, gender, occupation, height and weight. We will also review your medical records to confirm your suitability to participate in the next stage of the study.

The following questionnaires will be completed within one week of consent:

<u>Baseline Self-report Human Activity Profile Questionnaire (HAP): (15 minutes)</u>

This tick box questionnaire consists of 94 questions and seeks to determine the activities you currently do.

<u>EQ-D5-3L Questionnaire (5 minutes)</u>

This is a self-completing short questionnaire comprising questions on the following 5 areas: mobility, self-care, your daily activities, pain/discomfort and depression.

<u>IPOS – Renal Questionnaire (10 minutes)</u>

This is self-completing questionnaire comprising of 11 questions assessing renal symptoms with other items for additional concerns.

Falls and Fractures Questionnaire (5 minutes)

A research nurse or member of the research team will help you fill out this short tick box questionnaire. We wish to know if you have had any falls or fractures in the last 6 months and your baseline mobility level.

Client Service Receipt Inventory Questionnaire (CSRI) (5 minutes)

You will be given as short tick-box questionnaire to collect information regarding other hospitals facilities you have visited including General Practitioner visits over the last 6 months. This will exclude your routine visits to haemodialysis.

Timed Up and Go (TUG) mobility assessment (1 minute)

We will ask you to take part in the Timed Up and Go mobility assessment. This will be done on one of your dialysis days just prior to starting your treatment. One of the members will ask you to sit in a chair with arm rests. Following a prompt from a member of the research team, you will need to stand up, walk for three metres which (will be marked on the floor), turn around and return to a seated position in the chair.

10 Metre Walk Test (10 minutes)

We will ask you to walk for 10 metres to assess you functional mobility and walking speed. If you need to use a mobility aid such as frame this will be fine. This test will be done prior to one of your dialysis days prior to starting your treatment. Following a prompt from a member of the research team, you will walk for 10 metres (which will be clearly marked on the floor).

Handgrip Strength measurement (1 minute)

The purpose of this test is to assess your maximum strength in your hands and forearm. To do this we will ask you to hold a device and squeeze for 5 seconds to give us a reading.

Routine bloods

As per your routine dialysis care, nurses take routine bloods from you every month to check your urea, creatinine, haemoglobin and your dialysis adequacy. We will look at your bloods between months 1-3 and at month 6. For this purpose of this study we will check your bloods to assess your dialysis adequacy. We will not need any additional samples from you.

Blood pressure measurements

As part of your dialysis care you usually have your pre and post dialysis blood pressure taken. We will take your blood pressure readings before and after your dialysis session as per your usual care during the intervention. This is to ensure you are safe prior to undertaking your exercises. We will use the blood pressure cuff that is already attached to your dialysis machine.

Wrist worn accelerometer:

You will also be given a small wrist worn motion sensor called an accelerometer. You will be expected to wear the accelerometer during dialysis and non-dialysis days for one week at the start of the study, month three and at month six. One of the research team will instruct you on how to use the accelerometer. The accelerometer will be fully charged and you will also be given an instruction hand-out to take home. Naturally, you will be free to remove the accelerometer when you feel it may be uncomfortable, however, patients who have used this device before in our previous studies have found it comfortable and is just like wearing a watch.

After wearing it for seven days (including at least one dialysis day), you will return the accelerometer. The data from the accelerometer that you have collected will be put on to an encrypted computer and analysed.

Following the above, the intervention part of the study will start.

Chair-based Exercise Programme

You will be receiving advice and support from an exercise trainer twice a week for 6 weeks to help you undertake the Chair-based exercise Programme. This will be delivered on one of your dialysis days prior to your dialysis session. The instruction of the exercises will take approximately 10-15 minutes per session. This will not shorten your dialysis session or delay your transport home. Due to the screening procedures and the exercise programme running within the clinic other staff and patients may be aware of your participation in the research. You will receive tailored feedback regarding your progress and be able to ask any questions. You will also be encouraged to continue with Chair-based exercises at home up to 3 times a week for 10-15 minutes per session. We will also ask you to tell us how hard you breathing is when you do the exercise. We will be asking you to select a number from this scale from 1 to 10. Each number represents the amount of effort that you can feel in your breathing.

Exercise Education Booklet

You will be given an education booklet which has advice on physical activity and instructions on the Chair-Based exercises.). The exercises are designed to help with balance, flexibility, endurance, fitness and strength. You will receive input from a sport exercise instructor. You will also receive feedback and support from nurses and the research nurses during the 6 week intervention. After the 6 weeks of instructor led support you will then be asked to continue with the exercises at home. You can do as much as you like but ideally at least 2 - 3 times a week.

At Month 3 (week 12):

After 3 months, we will ask you to complete the following activities:

Study Questionnaires

We will ask you to complete the questionnaires which you completed at the start of the study as detailed above.

Wrist worn accelerometer:

We will ask you to wear the wrist worn accelerometer for one week. After wearing it for 7 days (including at least one dialysis day), you will return the accelerometer. The data from the accelerometer that you have collected will be put on to an encrypted computer and analysed.

Acceptability and feasibility questionnaires (5 minutes):

We will ask you to fill out a short questionnaire regarding how you found the study and what worked well and what did not. Your feedback is important to us.

Short Semi Structured Interview (30 minutes):

Along with the study questionnaires detailed above, we would like to do a short interview with some participants. This is a chance for you to share your thoughts on how you found the study and to provide detailed feedback. This will take no longer than 30 minutes to complete. This will be done on one of your dialysis sessions in a side room to maintain privacy by one of the research team. The interviews will be audio recorded, transcribed and analysed. You can ask for a transcript once the interview has been transcribed and have the right to amend comments if you wish to do so. Once you are happy with the transcription, the audio recording will be destroyed, but the transcript will be kept for 10 years and destroyed thereafter.

Timed Up and Go (TUG) mobility assessment (1 minute)

We will ask you repeat this mobility assessment as detail above. This will be done on one of your dialysis days just prior to starting your dialysis treatment.

10 Metre Walk Test (10 minutes)

We will ask you to walk for 10 metres to assess you functional mobility and walking speed.

Handgrip Strength measurement (1 minute)

We will ask you to repeat your handgrip strength.

Month 3 will be the end of the main data collection period.

At Month 6 (Follow up and end of the study):

There will be a follow up after 6 months, where you will be given the study questionnaires which were given to you at the start of the study to complete. We will also ask you to repeat the Timed-Up and Go, 10 metre walk test and hand grip strength. We will also ask you to wear the accelerometer for one week,

Following the above and once you return the accelerometer after the 7 day period, your participation in the study will end. Once your data has been assessed we will provide you a letter with a summary of your results.

5. What are the risks of taking part?

Your General Practitioner (GP) will be informed of your participation in this study. We do not anticipate that participating in this research project will incur significant risks however; there is always risk of injury, such as, falls, dizziness, and shortness of breath when participating in any form of activity. The risks will be discussed with a member of the research team and the sports exercise instructor. If you experience any of these symptoms while participating in the exercise programme we ask that you stop and discuss this with a member of staff.

You may be concerned about the safety of engaging in exercise whilst being a dialysis patient. These risks may be related to the physical changes that occur as your body adapts to haemodialysis and if you have other co-morbid diseases such as diabetes. The risks are more likely to occur when you do inappropriate kinds of exercise when you overexert yourself. This is why we have specialists in sports and exercise medicine and rehabilitation physiotherapists as part of the research team. If you feel that you need further support in goal setting, we can also refer you to our clinical psychologist. Alternatively, additional support and advice from the National Kidney Advisor can be found on: https://www.kidney.org.uk/?gclid=EAIaIQobChMIqZjx2bPx3AIVqrftCh3YkAc-EAAYASAAEgJ_APD_BwE or via telephone on 0800 169 0936.

6. **Will the information about me collected for this study be kept confidential?**

   If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from the Oxford Brookes University and Oxford University Hospitals NHS Trust to ensure that the study is being carried out correctly. Your confidentiality as a research participant will be ensured throughout.

   Data will be stored according to the General Data Protection Regulation and Data Protection Act (2018). Any researchers using the data will have been trained in ethical handling of such data.

   Oxford Brookes University is the sponsor for this study based in Oxford, United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Oxford Brookes University will keep identifiable information about you for 10 years after the study has finished

   Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

   The Oxford Kidney Unit, Oxford University Hospitals NHS Foundation Trust will keep your name, date of birth and contact details confidential and will not pass this information to Oxford Brookes University. The Oxford Kidney Unit, Oxford University Hospitals NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely in a locked cupboard in a locked office at the Oxford Kidney Unit, Oxford University Hospitals NHS Foundation Trust for 10 years after the end of the study. Certain individuals from Oxford Brookes University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Oxford Brookes University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, date of birth, NHS number or contact details.

If you choose to withdraw from the study, we will seek your permission to keep and use any research data and demographic data you have already provided for the sole purpose of this study. When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Oxford Brookes University, as a Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm resulting as a direct consequence of your participation.

7. Expenses and payments

All study visits will take place during your regular dialysis session and hence, your expenses for travel will not be covered.

8. **What will happen to the results of the research study?**

We aim to publish the results of our study in peer-reviewed, publicly available journals. At the end of the study, we will also put posters up in the Haemodialysis unit describing the findings and prepare an article for publication in Viva, the magazine of the Six Counties Kidney Patients' Association. The results of this study will form part of a PhD thesis and made publically available. Patients will be made aware through unit newsletters and study summaries will be made available via the Six Counties Viva publication and the dialysis patient quarterly newsletter. Individual feedback will be given to you by the research nurse after the study has finished.

9. **Who is sponsoring and funding the research?**

This research study has been devised and will be conducted by staff of the Oxford Kidney Unit (Ms Sutherland, Professor Pugh) the University of Oxford (Dr Newton, Dr Doherty) and Oxford Brookes University (Professor Dawes and Professor Boulton and Dr Meaney) and Dr Rose Penfold (Harvard Chan School of Public Health). The study is sponsored by Oxford Brookes University and funded by Oxford NIHR BRC Clinical Research Preparatory Fellowship.

10. **Who has reviewed the study?**

An independent group called the 'Research Ethics Committee' reviews all NHS research. Nottingham 1 Research Ethics Committee has reviewed this study. This group serves to protect your safety, rights, wellbeing and dignity during the research process. This study has been reviewed and given a favourable opinion by the Faculty Research Committee in the Faculty of Health and Life Sciences at Oxford Brookes University

11. **Contact Information**

The Principal Investigator for this study is Ms Sheera Sutherland. If you have any questions please feel free to contact her directly using the details below or in writing at the address on the front page of this document.

Telephone: 01856 225813 Email: 15000724@brookes.ac.uk

Alternatively, please contact Mrs Karen Parsons (Research Nurse Manager) who can be contacted on 01865 225096 or email Karen.parsons@ouh.nhs.uk

12. If you wish to make a complaint

If you have questions about this study, you should contact the Principal Investigator, Ms Sheera Sutherland via email: 15000724@brookes.ac.uk or co-researcher Professor Helen Dawes; hdawes@brookes.ac.uk. In the event of concerns about the conduct of the research, please contact the Faculty Research Ethics Officer at frec@brookes.ac.uk If you have any complaints about your care, you may also wish to contact the Patients' Advice and Liaison Service (PALS) at the John Radcliffe Hospital (01865 221473).

13. Getting involved in other research

If you wish to find out more about other research at the unit please see the 'Involve' booklets available on the Main Haemodialysis Unit or discuss matters with your own nephrology consultant.

Many thanks for taking the time to read this leaflet!

Appendix 10: Feasibility study Patient consent form

PATIENT CONSENT FORM

A structured exercise and educational intervention to increase physical activity in haemodialysis patients: a feasibility study

March 7th 2019 Version 1.6 REC Number: 19/EM/0042 IRAS ID: 247579

Principal Investigator: Sheera Sutherland 15000724@brookes.ac.uk
Doctoral Supervisor: Professor Helen Dawes: hdawes@brookes.ac.uk

Participant ID:		**Date of Consent**	DD/MM/YYYY

Please initial box

1. I confirm that I have read the information sheet dated __/__/___ (version 2.5) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.		
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by the research team and individuals from Oxford Brookes University and from Oxford University NHS Foundation Trust, and from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.		
4. I understand that routine bloods taken as part of my haemodialysis care will be looked at by members of the research team.		
5. I understand that my study data will be handled, stored and destroyed in compliance with General Data Protection Regulation (2018).		
6. I agree to my General Practitioner being informed of my participation in the study and of any changes to my health that affect my participation in the research.		
7. I agree to an audio recording of a short semi structured interview.	Yes	No
8. I understand that the information collected about me may be used in an anonymous form to support other research in the future. It will not be possible for me to be identified by it.	Yes	No
9. I understand that confidentiality can only be maintained within legal limits.		
10. I consent to the use of anonymised quotes in reports and publications.	Yes	No
11. I agree to take part in this study.		

________________________	________________________	________________________
Name of Participant	*Date*	*Signature of Participant*
________________________	________________________	________________________
Name of Person taking Consent	*Date*	*Signature*

**1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes* (if participant is a patient).

REC: 19/EM/0042 IRAS: 247579 Patient Consent form V 1.6 March 7th 2019 Page 180 of 248

Appendix 11: Topic Guide Participant Interviews- Month 6

Participant ID:

Section 1. Your treatment.

A. What did you find most helpful about the educational booklet?

B. What did you find most difficult about the educational booklet?

C. What did you find most helpful with the sports exercise trainer?

D. What did you find most difficult with the sports exercise trainer? (Intervention group only)

E. What did you find most helpful with the Motivational Interviewing and tailored feedback?

F. What did you find most helpful with goal setting as part of the intervention.

Section 2. Questionnaires and outcomes

A. What was your experience in completing the quality of life questionnaires (IPOS, EQ-5D)?

B. What was your experience in completing the Physical Activity Questionnaire (HAP)?

C. How did you find taking part in this study? Are there any experiences or thoughts you wish to share?

Section 3. Accelerometers

A: Did you have any issues wearing the accelerometers?

If so – please describe?

Appendix 12: Falls and Fracture Questionnaire

Falls and Fractures Short Questionnaire

To be filled out by Research Nurse in discussion with the patient:

1) FALLS HISTORY

G) FALLS Assessment: Performed Yes☐ No☐ Already under falls☐ Referred medical falls clinic☐Referred therapy falls clinic☐ Referred non-FLS primary care	
No. of falls, slips, trips in last 12 months=	
Indoor Gait: Independent ☐Stick:1☐ or 2☐Frame☐ Wheel Chair☐ Bedbound☐	
Outdoor Gait: Independent ☐Stick:1☐ or 2☐Frame☐ Wheel Chair☐	
Any Indoor falls☐	**History of possible syncope: Probable☐ No☐**
Details of current Fall (contributory/ landed on)	
Need help getting up after falling☐	**Fear of falling☐** Balance/gait problems☐
Confusion / wandering☐	**Abnormal Cardiovascular☐**
Urinary incontinence☐ Visual problems☐	**At risk medications for falling☐**
Times nocturia (polyuria)=	Foot pain: Never☐Sometimes☐ Often☐Most time☐
Previous referral to falls☐ DK☐	Date last seen ....
Previous referral to strength/ balance☐ DK☐	No. Hrs/wk of recommended exercise done in the last month before fracture =

FRACTURE HISTORY

2) Have you broken any bones in adulthood? Yes □ No □

If yes, which ones starting with the most recent

Which bone(s)	Which Year	After a fall / slip /trip
		Yes□ No□
		Yes□ No□
		Yes□ No□
		Yes□ No□

RISK FACTORS

Have either of your parents ever broken a hip? Yes□ No□ Don't know□

If yes, what age were they? ……Years

Appendix 13: IPOS Renal Questionnaire

IPOS – Renal Patient Version

www.pos-pal.org

Patient name : ....

Date (dd/mm/yyyy) : ....

Patient number : .... (For staff use)

Q1. What have been your main problems or concerns over the past week?

1. ....
2. ....
3. ....

Q2. Below is a list of symptoms, which you may or may not have experienced. For each symptom, please tick the box that best describes how it has affected you over the past week?

	Not at all	Slightly	Moderately	Severely	Overwhelmingly
Pain	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Shortness of breath	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Weakness or lack of energy	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Nausea (feeling like you are going to be sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Vomiting (being sick)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Poor appetite	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Constipation	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Sore or dry mouth	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Drowsiness	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Poor mobility	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Itching	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Difficulty sleeping	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Restless legs or difficulty keeping legs still	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Changes in skin	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Diarrhoea	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Please list any other symptoms not mentioned above, tick the box to show how they have affected you over the past week?

1.______________________	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
2.______________________	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

Over the past week:

	Always	Most of the time	Sometimes	Occasionally	Not at all
Q3. Have you been feeling anxious or worried about your illness or treatment?	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
Q4. Have any of your family or friends been anxious or worried about you?	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
Q5. Have you been feeling depressed?	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
Q6. Have you felt at peace?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Q7. Have you been able to share how you are feeling with your family or friends as much as you wanted?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Q8. Have you had as much information as you wanted?	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
Q9. How much have you been bothered by problems with your memory over the last 7 days?	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐
Q10. Has your memory affected your ability to work or interact with family or friends?	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

	Problems addressed/ No problems	Problems mostly addressed	Problems partly addressed	Problems hardly addressed	Problems not addressed
Q11. Have any practical problems resulting from your illness been addressed? (such as financial or personal)	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐

	None at all	Up to half a day wasted	More than half a day wasted
Q12. How much time do you feel has been wasted on appointments relating to your healthcare, e.g. waiting around for transport or repeating tests.	0 ☐	1 ☐	2 ☐

	On my own	With a friend/ family	With Staff member
Q13. How did you complete this questionnaire?	☐	☐	☐

If you are worried about any of the issues raised on this questionnaire then please speak to your doctor or nurse

Appendix 14: Chair Based Exercise Booklet

Oxford University Hospitals
NHS Foundation Trust

Chair Based Exercises for Strength and Balance

Information for renal dialysis patients

Produced in collaboration with

Moving Medicine

Oxford Kidney Unit

When you first start haemodialysis you may feel tired and lack energy. You may also have a change in your appetite and find it difficult to enjoy the things you once did. However, haemodialysis treatment should not stop you from being physically active.

How will exercise help me?

Being active is good for your health, mood, mental health and wellbeing.

What is the Chair Based Exercise Programme?

Designed by experts, the Chair Based Exercise Programme (CBE Programme) is a set of exercises, lasting up to 6 weeks, which can help develop your fitness, strength, mobility and balance.

What does joining this exercise programme mean for me?

We will explain the exercises to you when you come to the dialysis unit. The CBE Programme is safe, easy to follow and can be carried out in the comfort of your own home.

It is recommended that you do the exercises up to 3 times a week, at a time that suits you. If you have any questions about the exercises, please contact your dialysis nurse, consultant or rehabilitation therapist.

How do I keep safe when exercising?

Your safety while exercising is important. You should exercise according to your capabilities.

- Don't overdo it.
- Start slowly and build up steadily.
- Use a stable chair.
- Keep your back straight.

Before you start the programme you will be seen by someone in the renal team, who will assess your suitability to exercise.

Exercising with a Tesio

If you have a Tesio line in your chest for dialysis you will have been told whether you are still safe to continue with normal day to day physical activities.

If you have any discomfort in the area around your Tesio, please contact the vascular access nurses, let your dialysis nurse know when you come to dialysis or phone the renal unit.

Exercising with an arterio-venous fistula (AVF)

If you have an AVF, you can still exercise. Exercising is good for your circulation, blood flow and keeping you healthy.

Where can I do the exercises?

Anywhere. These exercises were developed to be carried out in the comfort of your own home, either before or after dialysis, but you can do them anywhere that has suitable space and is safe.

The exercises in this booklet start off easy and become more challenging. The exercises will become easier over time.

Please discuss any issues or concerns you have with your nurse, consultant or rehabilitation therapist.

You could ask a family member or friend to join you when you exercise. This can make it more fun, as having someone with you is a great way to exercise.

Can I set goals?

Setting yourself small goals or target to achieve will often help you to exercise. Like anyone going to the gym for the first time, the rehabilitation therapists will look at what is realistic and set small goals for you to achieve. These really can be anything that you want. It is up to you! It may simply be that you want to strengthen your legs so you can stand for longer; that you enjoy the social side of exercise; or that you wish to be healthier and lose weight.

Can I do too much?

Yes, if you don't listen to your body. If you are not used to exercising it is best to begin gently and build up gradually. Your muscles or joints may feel a bit achy and stiff a few hours after the first exercise session, but this should get better in a few days. Please talk about this with your nurse or rehabilitation therapist.

Will I feel tired?

Exercise very often helps to reduce fatigue. However, to begin with you may feel more tired or you may be tired as a result of the exercise you have done. This is quite normal and the tiredness usually improves as you get used to your new level of activity. This tiredness may not be the same as the fatigue you experience with your condition.

What if I feel unwell?

You should not exercise if you feel unwell.

You should **stop exercising** if you experience any of the following:

- chest pain
- shortness of breath that stops you from talking
- dizziness.

Dizziness and shortness of breath are symptoms you may experience during and after haemodialysis. It is good to know which symptoms are associated with haemodialysis and which are associated with exercise.

Please contact your GP if these symptoms continue.

You should wait until you feel better before re-starting the exercises. Speak to your nurse or rehabilitation therapist. They will let you know when you should start the programme again.

Walking

Walking to the shops or even to the end of the street is a good way of increasing your activity levels. Going for a walk for 5 to 10 minutes each day on the days you don't dialyse and even on your dialysis days will give you lots of benefits.

If you use a walking aid, such as a walking stick, continue using this as normal. You can increase the amount of time walking as you get more confident.

Tips for walking

Always wear comfortable shoes.

When you walk, make sure that:

- your shoulders are relaxed
- you look ahead and not at the ground
- your heel lands on the ground first and you push off with your toes
- you walk at a comfortable pace.

Remember these top tips:

Endurance: When you exercise your breathing may become faster. This is normal, but you should still be able to talk.

Strength and balance: When you exercise always use a steady chair to hold on to.

Warm up and flexibility: Before you exercise, always warm up and cool down afterwards. A few minutes of walking is an ideal way of doing this. Stretching is also good.

How to use this booklet

All the exercises in this booklet will help improve your strength, mobility and fitness levels.

Look at the photographs and read the instructions. You will be taught how to do the exercises by the rehabilitation therapists. If you are unsure what to do, just speak to them. They'll be happy to help.

How much should I do?

Ideally you should try to practice these exercises every other day. Do as much as you feel you can.

You may prefer to practice in smaller activity chunks, for example, arm exercises in one session and leg exercises in the next and so on.

The most important thing is to start small and build up gradually.

If one of the exercises causes a sharp pain or discomfort, then stop that exercise, but carry on with the others. Tell your rehabilitation therapist when you come in for the next session.

CHAIR BASED EXERCISES

(Toe raises)

(Heel raises)

1. Toe and heel raises

Sit on a chair.

- Place both feet flat on the floor.
- Keeping your heels on the floor, lift your toes as high as you can. Hold for 1 second and then lower them back down. Repeat 10 times.
- Then raise your heels so your toes are on the floor. Hold for 1 second and then return to normal position. Repeat 10 times.
- Then alternate between toes and heels. Repeat 10 times, at a steady and even pace.
- Increase the number of repetitions when you feel more confident.

2. Heel taps

Sitting on a chair.

- Place both feet flat on the floor.
- Move your foot forwards to tap your heel on the floor. Return to the start position. Repeat with the same leg 10 times.
- Then do the same with the other foot.
- Once you have done 10 for each foot, do another 10 but alternate your feet at an even pace.
- Increase the number of repetitions when you feel comfortable to do so.

Too much?

✓ Reduce the number of repetitions and build up gradually.

Need more?

✓ Increase the number of repetitions.

3. Leg ups

Sitting on a chair.

- Place both feet flat on the floor.
- Holding onto the side of the chair, raise one leg and hold for 1 second. Then lower your leg to the ground. Repeat 10 times with the same leg.
- Do the same with the other leg; raise the leg, hold for 1 second and lower. Repeat 10 times.
- When you have done both legs, alternate between the left and the right leg. Repeat 5 times for each leg.

You might find this exercise starts to make you feel a bit warmer and breathe a little heavier. You should still be able to hold a conversation.

4. Thumb exercises – ducks

Sitting on a chair.

- Place both feet flat on the floor.
- Hold your arms out to the side of your body, with your palms facing forward.
- Rotate your thumbs in a circle in one direction 10 times. Change the direction and repeat 10 times.

5. Hand exercises – playing piano

Sitting on a chair.

- Place both feet flat on the floor.
- Hold your arms in front of you, so that they bend at the elbow.
- Move your fingers one by one like a 'finger wave', or like you are playing the piano. Move your arms in and out at the same time.
- When you have done 10 repetitions, rotate your hands so your palms are facing upwards and repeat the same movements as you did before.

6. Wrist rotations

Sitting on a chair.

- Place both feet flat on the floor.
- Sit comfortably in your chair and bring your hands up to shoulder height.
- Rotate your wrists in one direction 10 times and then in the other direction another 10 times.

If you feel you need to do more, increase the number of repetitions up to a maximum of 20.

7. Steeples

Sitting on a chair.

- Place both feet flat on the floor.
- Put your palms together in front of you.
- Then move your arms to your sides, lifting your elbows upwards (see pictures below). Then bring your palms together again.
- Each time you bring your palms together is 1 repetition. Do 10 repetitions to start with and remember to pace yourself.

Too hard?

✓ Reduce the number of repetitions and build up gradually.

Need more?

✓ Increase the number of repetitions up to 20.

8. Pointing forward

Sitting on a chair.

- Place both feet flat on the floor.
- Point one arm forward and then rest on your lap.
- Repeat with the other arm.
- Do 10 repetitions for each arm.

9. Reaching across

Sitting on a chair.

- Place both feet flat on the floor.
- Start with both hands resting on your lap. Raise one arm, stretch across your chest and point. Then relax your arm back to your lap. Repeat with the other arm.
- Alternate your arms and do 10 repetitions for each arm.

10. Raised arm extensions

- Sit with your hands in your lap.
- Raise one arm and point your finger to the ceiling. Then stretch over your head a few inches further. Hold this position for 1 second.
- Relax and drop your arm to the start position. Repeat with the other arm.
- Do 10 in each direction.

11. Swimming

- Alternately rotate your arms forward, as if you were doing front crawl, but in small circles. Repeat the movements 10 times (5 each arm).
- When you have completed the forward movements, repeat the arm movements backwards (like back crawl).

If you feel you can do more, increase the repetitions. Remember to keep a steady pace and look forward when completing this exercise. This will help you keep your balance and focus.

12. Standing exercises – tip toes

Stand and hold on to the back of the chair.

- Raise yourself up on the balls of your feet (so your heels are off the ground). Hold for 1 second and then return to starting position.
- Repeat 10 times.

If you feel you can do more later on then increase the repetitions up to 20.

13. Standing exercises – side marches

- Stand facing to the left, but hold on the back the chair for balance. Raise and lower your legs alternately, as if marching on the spot. Repeat 10 times in one direction.
- When you have completed your first 10, turn to the other side and repeat another 10.

If you feel you can increase repetitions, do so at a steady pace.

14. Squats

- Hold the back of the chair for support.
- With your legs shoulder width apart, bend your knees so you squat down, as far as you can go. Hold for 1 second and then rise to standing position.
- Repeat 10 times.

When you feel more comfortable, increase the number of repetitions or how low you can squat.

15. Standing exercises – reverse lunges

- Hold the back of the chair for support. With your legs apart, bring one leg back as far as you can.
- As you bring your leg back, bend your front leg. Make sure you keep your knee in line with your toes.
  Do small lunges to start with.
- Hold for 1 second, then bring your leg back to its start position.
- Repeat with the other side and continue to alternate the lunges.
- Do 10 for each leg.

16. Stand to sit

This exercise may be difficult at first but will become easier with practice. Follow the pictures and instructions:

Stand in front of the chair.

- Slowly bend down and place your elbows on your knees.
- Hover in this position (see picture to left) for 1 second. Count down from 5 and slowly lower yourself to a sitting position on the chair.

- Once seated and when you are ready, slowly bend forward. Push up on your legs and return to a standing position.

~~(picture to the left)~~

- Once in the stand position, repeat the sequence again. Repeat 5 times.

Not quite there yet?

✓ Make it easier by starting with a higher chair.

Need more?

✓ Do more repetitions, up to 10.

17. Walking to running whilst sitting

- Alternate the raising and lowering of your legs in time with your arms, just like you are walking but in a sitting position.
- Start off slowly, as if you are walking, and do 10 repetitions.
- When you feel ready, increase the speed to a gentle 'trot'. When you feel more confident increase the speed to 'running'. Slow down if you feel you need to, or if you get out of breath.

Date	Number of repetitions														
1 Toe and heel raises															
2 Heel taps															
3 Leg ups															
4 Thumb exercises – ducks															
5 Hand exercises – playing piano															
6 Wrist rotations															
7 Steeples															
8 Pointing forward															
9 Reaching across															
10 Raised arm extensions															
11 Swimming															
12 Standing exercises – tip toes															
13 Standing exercises – side marches															
14 Squats															
15 Standing exercises – reverse lunges															
16 Stand to sit															
17 Walking to running whilst sitting															

Date	1 Toe and heel raises	2 Heel taps	3 Leg ups	4 Thumb exercises – ducks	5 Hand exercises – playing piano	6 Wrist rotations	7 Steeples	8 Pointing forward	9 Reaching across	10 Raised arm extensions	11 Swimming	12 Standing exercises – tip toes	13 Standing exercises – side marches	14 Squats	15 Standing exercises – reverse lunges	16 Stand to sit	17 Walking to running whilst sitting
Number of repetitions																	

Date	1 Toe and heel raises	2 Heel taps	3 Leg ups	4 Thumb exercises – ducks	5 Hand exercises – playing piano	6 Wrist rotations	7 Steeples	8 Pointing forward	9 Reaching across	10 Raised arm extensions	11 Swimming	12 Standing exercises – tip toes	13 Standing exercises – side marches	14 Squats	15 Standing exercises – reverse lunges	16 Stand to sit	17 Walking to running whilst sitting
Number of repetitions																	

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14 Squats																
15 Standing exercises – reverse lunges																
16 Stand to sit																
17 Walking to running whilst sitting																

Moving Medicine

Produced by the Moving Medicine Team, September 2018

Adapted for Renal Dialysis patients by Sheera Sutherland at the Centre for Movement, Occupational Rehabilitation Sciences (MOReS) and in the CLEAR Unit, Oxford Brookes University.

Part of the feasibility pilot by Oxford University Hospitals, to improve levels of activity in hospitals, commissioned by Public Health England and funded by Sport England.

Many thanks to Professor Patrick Doherty (University of York), Professor Helen Dawes (Oxford Brookes University) and Dr Andy Meaney (Oxford Brookes University), who assisted with the design and advised on the contents of the exercise programme.

All photos taken with consent: Many thanks to Katie Winter, Bruna Oliveira and Fran Ronan for their assistance.

If you need an interpreter or would like this information leaflet in another format, such as Easy Read, large print, Braille, audio, electronically or another language, please speak to the department where you are being seen. You will find their contact details on your appointment letter.

Author: Sheera Sutherland
September 2019
Review: September 2022
Oxford University Hospitals NHS Foundation Trust
www.ouh.nhs.uk/information

OMI 58081P

Appendix 15: Borg Rate of Perceived Exertion

Rating of Perceived Exertion Scale(CR-10)

Instructions given to participants:

0	**Nothing at all**
0.5	**Extremely light (Just noticeable)**
1	**Very light**
2	**Light**
3	**Moderate**
4	**Somewhat hard**
5	**Hard**
6	
7	**Very hard**
8	
9	
10	**Extremely hard (almost maximal)**
	Maximal

"________________(name), during the exercise test we want you to pay close attention to how hard the exercise is. In particular we want to know how hard you are breathing. I'll be asking you to select a number from this scale from 1 to 10. Each number represents the amount of effort that you can feel in your breathing. The words are there to help you choose a number. Try not to underestimate or overestimate your feelings of exertion. Although there is no right or wrong answer, It is important that you are as accurate as possible. So, while you are resting, looking at the scale, how would you describe your breathing now? (Pause)

Appendix 16: EQ-5D-3L™ Participant responses by dimension and age group

(a) Baseline EQ-5D-3L™

		Age group							
		18-29	30-39	40-49	50-59	60-69	70-79	80+	Total
Mobility	Level 1	**1**	0	0	0	1	1	0	3
	Level 2	0	0	1	1	3	3	1	9
	Level 3	0	0	0	0	0	0	0	0
Self-care	Level 1	1	0	0	0	3	3	0	7
	Level 2	0	0	0	0	3	1	1	5
	Level 3	0	0	0	0	0	0	0	0
Usual activities	Level 1	1	0	0	0	1	1	0	3
	Level 2	0	0	1	1	3	2	1	8
	Level 3	0	0	0	0	0	0	3	3
Pain/Discomfort	Level 1	1	0	1	0	1	3	0	6
	Level 2	0	0	0	1	3	1	1	6
	Level 3	0	0	0	0	0	0	0	0
Anxiety/ Depression	Level 1	1	0	1	0	3	4	1	10
	Level 2	0	0	0	1	1	0	0	2
	Level 3	0	0	0	0	0	0	0	0

(b): Month 3 EQ-5D-3L™

		Age group							
		18-29	30-39	40-49	50-59	60-69	70-79	80+	Total
Mobility	Level 1	**1**	0	0	0	**1**	3	0	5
	Level 2	0	0	**1**	2	2	2	1	8
	Level 3	0	0	0	0	0	0	0	0
Self-care	Level 1	1	0	1	1	1	4	1	9
	Level 2	0	0	0	1	2	1	0	4
	Level 3	0	0	0	0	0	0	0	0
Usual activities	Level 1	1	0	0	0	1	3	1	6
	Level 2	0	0	0	2	2	2	0	6
	Level 3	0	0	1	0	0	0	0	1
Pain/Discomfort	Level 1	1	0	1	0	1	2	1	6
	Level 2	0	0	0	2	3	2	0	7
	Level 3	0	0	0	0	0	0	0	0
Anxiety/ Depression	Level 1	0	0	0	0	2	3	1	6
	Level 2	1	0	1	2	1	1	0	6
	Level 3	0	0	0	0	1	0	0	1

(c) Month 6 EQ-5D-3L™

		Age group							
		18-29	30-39	40-49	50-59	60-69	70-79	80+	Total
Mobility	Level 1	**1**	0	0	0	**1**	4	0	6
	Level 2	0	0	**1**	2	3	0	1	7
	Level 3	0	0	0	0	0	0	0	0
Self-care	Level 1	1	0	1	0	1	4	1	8
	Level 2	0	0	0	2	3	0	0	5
	Level 3	0	0	0	0	0	0	0	0
Usual activities	Level 1	1	0	0	0	1	4	1	7
	Level 2	0	0	1	2	3	0	0	6
	Level 3	0	0	0	0	0	0	0	0
Pain/Discomfort	Level 1	1	0	1	0	1	2	1	6
	Level 2	0	0	0	2	1	2	0	5
	Level 3	0	0	0	0	2	0	0	2
Anxiety/ Depression	Level 1	0	0	0	0	2	3	1	6
	Level 2	0	0	1	2	1	1	0	5
	Level 3	1	0	0	0	1	0	0	2

The EQ-5D-3L™ comprises the following dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: Level 1: no problems, level 2: some problems, and level 3: extreme problems.

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