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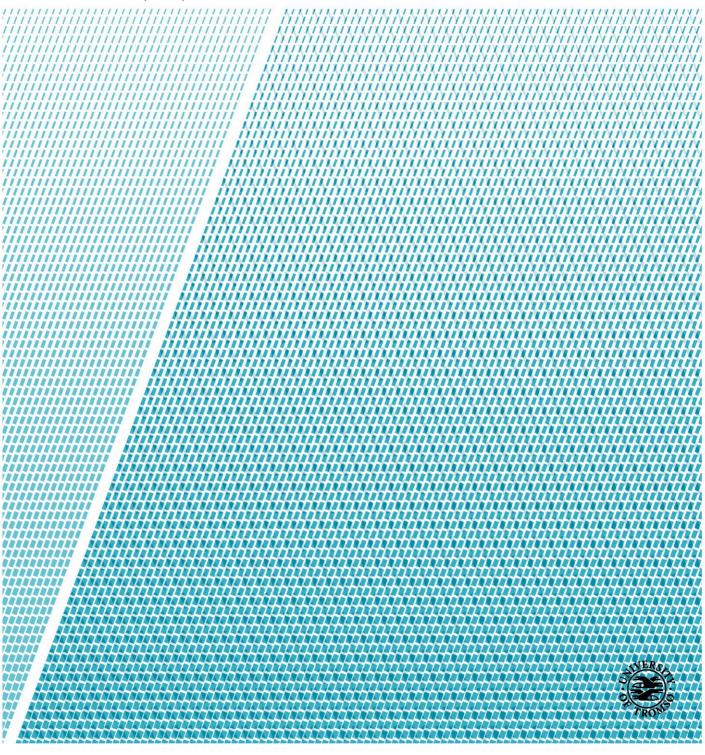
THE ARCTIC UNIVERSITY OF NORWAY

A survey of physical activity in dialysis patients in Northern Norway.

An observational study **Kjell-Gunnar Vangen** Master's thesis in Medicine (MED 3950), class of 2014.

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Preface

This paper has been quite a journey to write. An interesting, fun and challenging journey indeed. The process began fall 2017, and this paper has been part of my life ever since. It is fun to look back at all the work that has been put into this paper, because I can truly say the result is one of my biggest achievements during my academic career. This achievement would not be possible without help from people around me, especially my supervisor Marit Dahl Solbu has been outstanding during this process. Always responding fast and kindly to any question of mine, she has guided me through the process from day one. I sincerely thank her for all help with the paper, but also her reassurance when I came across obstacles. Thank you!

I would also mention my assistant supervisor Randolf Hardersen and Doctoral Research Fellow at School of Sport Science Edvard Hamnvik Sagelv for their contributions during this paper. I would like to thank Landsforeningen for nyresyke og transplanterte (LNT) for their financial support.

The purpose of this paper was to get valuable insight and knowledge about physical activity and health-related quality of life in dialysis patients. Hopefully, this paper can contribute to a higher focus on this patient group and to kickstart future studies. All with the aim of making a positive difference in dialysis patients' lives.

Kjell Gurner Vangen

Kjell-Gunnar Vangen Bodø, 31.05.2019

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Abstract

Background: Patients in advanced stages of chronic kidney disease (CKD), especially patients treated with dialysis, have reduced physical capacity. The main objective of this project was to study and compare the degree of physical activity (PA) in patients in haemodialysis (HD) and peritoneal dialysis (PD) in Nordland, Troms and Finnmark. To our knowledge this is the first study to include accelerometer recordings of patients in both HD and PD.

Methods: An observational study was conducted during 15. November to 15. December 2018. Patients were recruited in hospitals and dialysis satellites by mainly nephrologist and dialysis nurses. Each patient participated voluntarily and signed a written consent. The study consisted of a self-administered questionnaire about PA and health-related quality of life, and accelerometer recordings for seven days for objective measurements of PA. **Results:** Thirty patients out of 181 on chronic dialysis participated in the study, whereas 22 in HD and 8 in PD. Twenty-eight percent of all invited patients consented and were included in the study. Median wear time for ActiGraph accelerometer was significantly higher (P < 0,05) in the HD group with 9194,5 (8501-9733) minutes compared to PD 7509 (6400-9134) minutes. Seven out of 22 HD patients (31,8%) and five out of eight PD patients (62,5%) reached the recommended weekly goal of \geq 150 minutes moderate-to-vigorous physical activity (MVPA). Only one patient had an active lifestyle in terms of average steps daily (≥ 7500), three patients classified to somewhat active (5000-7499 steps/day), whereas 26 were categorised as sedentary. Haemoglobin was significantly associated with daily MVPA at or above vs. below median (OR 0,39 (95% CI 0,15-0,99) per 1 g/dL increase; P = 0,047). Most patients reported that they had never been informed by their nephrologist about the potential benefit of being physically active, but a desire to be more active was commonly found.

Conclusion: Results from this study indicate that dialysis patients have a low level of PA based on average daily MVPA and step count, compared to healthy people. We found no significant differences between patients on the two different dialysis modalities. A high haemoglobin level was associated with less daily MVPA. There seems to be a potential for increased level of PA in dialysis patients, and efforts should be made by health care personnel to get more patients to reach the recommended levels of PA.

IV

Abbreviations

APD	Automatic Peritoneal Dialysis
AV	Arteriovenous
CAPD	Continuous Ambulatory Peritoneal Dialysis
CKD	Chronic Kidney Disease
CVC	Central Venous Catheter
ESRD	End-Stage Renal Disease
GFR	Glomerular Filtration Rate
HD	Haemodialysis
HRQOL	Health-Related Quality of Life
IPAQ	International Physical Activity Questionnaire
KDGIO	Kidney Disease Improving Global Outcomes
KDQOL	Kidney Disease and Quality of Life
MVPA	Moderate to vigorous Activity
PA	Physical Activity
PD	Peritoneal Dialysis
RRT	Renal Replacement Therapy
WHO	World Health Organization

1 Background

Patients in advanced stages of chronic kidney disease (CKD), especially patients treated with dialysis, have reduced physical capacity. The causes are complex. A high share of patients in chronic dialysis have comprehensive comorbidity, often cardiovascular disease, diabetes mellitus and frequent infections (1). Many patients on dialysis are prescribed and use numerous drugs, making them susceptible for side effects that may impair quality of life. CKD includes retention of uraemic toxins that affect other organs (cardiovascular system, bone marrow, endocrine organs, cognitive functions) and the disease is also associated with subjective symptoms such as nausea, impaired quality of sleep, depression and reduced general well-being (2, 3). Finally, dialysis treatment itself is associated with several adverse effects and a high risk of complications. Moreover, the treatment is time consuming and exhausting for patients over time. Patients undergoing treatment with dialysis have reduced exercise tolerance compared with age-matched sedentary controls (4). There are also indications that patients undergoing dialysis have difficulties being physically active, and therefore may often have a sedentary lifestyle. The reasons behind the low amount of physical activity (PA) is not fully known, but the above-mentioned factors may contribute to a low activity lifestyle.

1.1 Definition of chronic kidney disease (CKD) and end-stage renal disease (ESRD)

According to the Kidney Disease: Improving Global Outcomes (KDIGO, 2012) CKD is defined as abnormalities of kidney structure or function, present for >3 months, with implications for health (5). The period of three months is set to distinguish between acute kidney diseases and CKD. CKD is diagnosed if one or more of the following criteria are present >3 months; markers of kidney damage and/or decreased glomerular filtration rate (GFR). Albuminuria is often used as marker of kidney damage, being an indicator of increased glomerular permeability and/or dysfunction of proximal tubular reabsorption. KDGIO guidelines recommend CKD classified into stages based on measurements of GFR and albuminuria (5). By applying categories of GFR, CKD can be staged from category G1 (normal/high, i.e. GFR >90 ml/min/1.73 m²) to G5 (GFR <15 ml/min/1.73 m², or kidney failure)(5). End-stage renal disease (ESRD) is generally acknowledged as kidney failure treated with renal replacement therapy (RRT) (1).

1.2 Treatment of ESRD

ESRD is generally treated with dialysis or renal transplantation, both included in the term RRT (6). Kidney transplantation has been shown to be the most desired and cost-effective treatment for suitable patients with ESRD (7). Dialysis is divided in peritoneal dialysis (PD) and haemodialysis (HD).

1.2.1 Peritoneal dialysis (PD)

The principles of PD are based on the use of the peritoneal membrane as the dialyzing surface. Waste and excess fluids are removed from the vascular system, through the peritoneal capillary blood, into the dialysis solution instilled in the peritoneal cavity through a catheter(8). The dialysis solution contains an osmotic agent, usually glucose, creating the osmotic gradient that moves fluid from the capillaries to the peritoneal cavity, while solute removal is the result of diffusion and convective transport over the membrane (6). Most PD patients use one form of continuous dialysis, implying that the dialysis solution is always present in the peritoneal cavity except during the out- and in-flow of the fluid. In continuous ambulatory PD (CAPD) the solution is exchanged 4-5 times a day, usually by the patient, whereas a machine takes care of fluid exchanges in automatic PD (APD), mainly during the night. Thus, PD is the most common modality of home dialysis. Most patients carry out the treatment themselves, whereas other patients need additional help from homecare personnel (assisted PD). Treatment with PD allows patients to participate in normal daily activities between the exchanges of the peritoneal fluid.

1.2.2 Haemodialysis (HD)

Haemodialysis is an extracorporeal treatment based on a dialyzer with a semipermeable membrane. HD requires a vascular access, either an arteriovenous (AV-)fistula or a central venous catheter (CVC), to allow blood to be transported from the patient through the dialyzer, where the exchange of uremic toxins, fluids and electrolytes is performed (8). The

principle of HD involves diffusion and convection of solutes across the dialyser membrane. Diffusion refers to the movement of solutes from higher concentrations in the blood to the lower concentrations in the dialysate fluid, whereas convection is the mass transport of fluid and solutes driven by a higher hydrostatic pressure in the blood compartment, generated by the blood pump of the dialysis machine (8). The treatment usually takes place 2-5 times per week at a hospital centre or in a dialysis satellite unit in sessions of 3-5 hours (9). HD requires patients to travel to treatment and use a considerable amount of time during each session, which is demanding for the patient. However, home HD treatment is also available for adherent and motivated patients.

1.2.3 Kidney transplantation

Kidney transplantation is associated with better observed mortality and morbidity rates, quality of life and participation in activities than dialysis (7, 9, 10) and therefore is the preferred RRT in patients with ESRD. Due to the high prevalence of comorbidity in ESRD, as well as to the need for life-long therapy with immunosuppressive drugs, all patients considered for kidney transplantation must go through a thorough evaluation to rule out malignant diseases, chronic infections and extensive cardiovascular disease that must be treated before transplantation, or that may rule out transplantation as a treatment of choice. Also, non-adherent patients are not eligible for transplantation. We should aim for early referral of patients who need kidney transplantation, and who do not have known contraindications, to an evaluation program to assess if they are suitable for the treatment. In kidney transplantation, the source of the graft may be either a living donor, which is preferred due to an even better prognosis, or a deceased donor (11). In Norway the waiting list for organs is relatively short, indicating that most patient eligible for transplantation eventually are transplanted within 1-2 years (12). Thus, in Norway patients on long term dialysis in general are older and have more comorbidity than patients on the waiting list for transplantation.

1.3 Physical activity and kidney disease

The positive effects of PA in the general population is well documented. The World Health Organisation (WHO) concludes that participation in regular PA has been shown to reduce the risk of coronary heart disease and stroke, diabetes, hypertension, colon cancer, breast cancer and depression in the general population (13). Studies have also shown that PA is positively correlated with psychological wellbeing, weight control, building and maintenance of healthy bones, muscles and joints (14). Regardless of the positive effects of PA, some data show that 31-32% of the world's adult population do not meet the minimum recommendations for PA (15, 16). Current recommendations suggest moderate PA for 150 minutes a week or 75 minutes' vigorous PA during a week in bouts of minimum 10 minutes, or an equivalent of moderate-to-vigorous intensity activity. For example, 30 minutes of moderate-to-vigorous physical activity (MVPA) 5 times a week is sufficient for people between 18-64 years old (13). This also applies to people over 65 years old.

1.3.1 Existing knowledge and knowledge gaps regarding physical activity in ESRD.

Even if some observational studies have shown that the level of PA among patients on dialysis is low, results from observational studies (17-19) and small intervention studies have demonstrated that increased physical exercise in this patient group is associated with better outcome(20, 21), in terms of proxy measures as arterial stiffness and health-related quality of life (HRQOL). One systematic review has shown that aerobic exercise made an improvement in physical fitness, muscular strength and quality of life in ESRD patients (21). In 2017 a retrospective cohort study concluded that high levels of PA was associated with favourable results in HRQoL scale scores, including frailty, disability and exhaustion (18). Therefore, some do think that patients on dialysis should be recommended the same amount of PA as people > 65 years (22).

To counsel the patients and to implement targeted intervention more knowledge about the type and quantity of PA applied by patients in this group is necessary. Most of the published observational studies on quantification of PA have used questionnaires. Today we know only of two small studies in which activity monitors were used to assess the type and amount of PA in patients in HD treatment (23, 24). We do not know of equivalent studies on patients in PD treatment, and therefore we do not have data that compare the two groups of patients. As far as we know, no activity measurements within patients in ESRD in HD or PD treatment has ever been carried out in Scandinavia.

1.3.2 Methods to assess physical activity

1.3.2.1 Questionnaires

The use of questionnaires in studies regarding PA and health-related quality of life are broad. Many earlier studies have used standardised questionnaires due to their easy-to-use properties, economically favourable and acceptably validated qualities. Scoring manuals allow the results to be compared to other studies. Well renowned questionnaires do have weaknesses because information is self-reported from the patients, and therefore allow subjective interpretations of questions, communication barriers, and overestimating/underestimating to happen. Overestimating PA, especially in moderate intensity, are shown in different countries (24). There are also studies that show a weak relationship between self-reported PA in questionnaires and objectively measured PA with heart rate monitor and movement sensor (24). Therefore, self-reported data should be interpreted with caution.

1.3.2.2 IPAQ

IPAQ is a questionnaire designed to classify individuals in activity categories related to current recommendations for PA (16). The questionnaire is validated in 12 countries, mainly in populations between 18-65 years old in diverse settings, with acceptable measurement properties (25). The short form consists of seven questions about PA during the last seven days, with questions about amount of activity and intensity, walking and time spent sitting. IPAQ short form has been tested and used in many international studies (26). The IPAQ short form has previously been used to assess PA in patients with CKD not requiring dialysis and in patients with CKD undergoing haemodialysis (27, 28).

1.3.2.3 KDQOL-SF 1.3

KDQOL-SF is a self-reporting instrument to assess particular concerns of people with kidney disease and dialysis (23). The Norwegian translated questionnaire has thirty-three questions related to the kidney disease, including symptoms, effect of kidney disease on daily life, burden of kidney disease, work status, cognitive function, sexual function, sleep, social support, dialysis staff encouragement and patient satisfaction (29, 30).

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KDQOL-SF have been used in international studies of HRQOL in ESRD patients (30), and the reliability of the Danish version has been tested in Denmark with the same internal consistency as the original U.S English version (31).

1.3.3 Accelerometers

Accelerometers are useful in collecting body movement objectively and may so contribute with information about total amount, intensity, duration and frequency of PA (32). Thus, the use of accelerometers has lately become more regular in epidemiologic and clinical studies. Accelerometers are motion sensors that measure movement accelerations in one or more directions to calculate movement in the subject wearing them. Today, we often use electronic uniaxial (usually vertical plane) and triaxial accelerometers (anteroposterior, mediolateral and vertical directions). The electronic motion sensors consist of piezo-resistive or piezo-electric sensors. Piezo-resistive accelerometers require an external power source due to registration of accelerations by change in resistance of silicon resistors, which is then transformed to a voltage proportional to the amplitude and frequency of the acceleration. This will also allow them to respond to constant acceleration such as gravity (33). Piezo-electric accelerometer will not respond to constant gravity as they generate an electric charge in response to a mechanical force. However, they will not be dependent on an external power supply to operate (33). Some accelerometers have additional features such as the ability to measure heart rate, lighting, body temperature etc.

2 Beneficial value of the study

It is presumed that the level of PA of patients in dialysis is significantly lower than recommended. Some studies have shown favourable effects of a higher PA level in this group of patients. However, we know little about the actual activity level of dialysis patients in general, and in Northern Norway in particular, which we want to assess in this study. We believe this is essential and basic knowledge to better implement targeted and effective measures to increase the amount PA and therefore increase quality of life while reducing morbidity in this patient group. Therefore, we claim our project has an obvious beneficial value.

3 Hypotheses and aims of the study

3.1 Hypotheses

Our hypothesis is that the general level of activity in dialysis patients, assessed using an accelerometer, is low; lower than the general population within the same age group. We also hypothesise that patients in PD have a higher level of activity compared to patients in HD. Finally, we believe that the degree of comorbidity has a negative influence on the amount of PA exercised in this group of patients.

3.2 Aims of the study

In the present project, we aimed to:

- examine if registration with the accelerometer is a suitable method for studying PA in dialysis patients.
- study the degree of PA of patients in HD and PD in Nordland, Troms and Finnmark.
- To map out biological factors that are associated with the amount of PA in dialysis patients.
- To study potential factors that limit the amount of PA carried out by patients in HD and PD.

4 Material and methods

4.1 Ethics

This is an observational study where PA was measured through an unharmful and painless method. Participation in the study was based on written informed consent from all patients included. The Data Protector Officer of involved institutions have approved the protocol.

The Regional Committee for Medical and Health Research Ethics has evaluated the protocol and concluded that the Health Research Act does not apply due to the scope and design of the project. Therefore, their approval was not necessary.

4.2 Study population

The study is an observational pilot study aimed to measure PA objectively, and to collect information about the quality of life in prevalent dialysis patients treated with either HD or PD in Northern Norway. Northern Norway consists of three counties (Finnmark, Troms and Nordland), cover an area of 112 973 square kilometres and have 486 001 inhabitants (01.01.2018) (34). There are four hospital trusts (Finnmarkssykehuset, Universitetssykehuset Nord-Norge (UNN), Nordlandssykehuset, Helgelandssykehuset) in Helse Nord's regional health authority. The two main hospital dialysis centres are in Bodø and Tromsø, for HD and PD. These centres initiate HD-treatment and PD-treatment in Northern Norway. Specialists in nephrology are also located in Sandnessjøen (Helgelandssykehuset), Kirkenes (Finnmarkssykehuset) and Harstad (UNN). Furthermore 15 dialysis satellite units, situated in local hospitals as well as in primary care centres, contribute with HD (35).

Patients in HD treatment were invited to participate when they arrived at their treatment centre, either by a project partner or collaborating doctor or nurse. Patients established in PD were invited to participate during a regular visit to the hospital, or per letter or telephone by a project collaborator/partner. All eligible participants interested in the project received written information. Project partners made sure the written information was understood, and we obtained a written consent from all included patients. Participants gave their consent to the collection of data mentioned below, and to project partners to access their patient records to collect relevant background information, and to the collection of follow-up project relevant for this study.

4.2.1 Inclusion and exclusion criteria

All patients >18 years old, able to give their written consent and who had been on treatment with HD or PD > 3months and received follow-up by a nephrologist in Nordland, Troms or Finnmark were eligible for the study.

Exclusion criteria were;

- Non-cooperative patients

- Admittance to hospital during the last 4 weeks due to acute illness (patients may be included in the study 4 weeks after discharge from the hospital)
- Patients considered by a nephrologist as not suitable due to a high load of physical and/or mental comorbidity
- Patients unable to walk

4.3 Health-related quality of life and physical activity questionnaires

Immediately after the receipt of their written consent, each patient was given a selfadministered questionnaire. The questionnaire was composed with the use of questions from the following validated questionnaires; KDQOL-SF[™] 1.3 (Norwegian short form) (29) and IPAQ (Norwegian short form) (16).

Data from KDQOL SF-questions were scored from 0-100, where a higher score reflects a better quality of life, in following domains; physical functioning, role limitations due to physical health problems, role limitations due to emotional health problems, emotional well-being and energy/fatigue.

Data from IPAQ questions were summarized to quantify self-reported PA into three levels; High (equivalent to \geq 1-hour moderate/vigorous activity daily), moderate (equivalent to half an hour of \geq moderate/vigorous intensity PA on most days) and low (not meeting any of the criteria of moderate or high levels of PA). In addition, we composed questions to study what the patient acknowledges as barriers towards participating in more PA. These questions were scored in four categories ("no barrier", "low barrier", "moderate barrier", "high barrier") to give an indication of the challenges our patients must face. The questionnaire used in the study is included in the appendix (Appendix 1).

4.4 Objective assessment of physical activity

Objective measurements of PA were collected with ActiGraph GT3X accelerometer, which is among the best validated devices (32, 36) and has recently been used in The Tromsø Study 2015-2016. The ActiGraph GT3X is a piezo-electric device that is small (4.6 x 3.3 x 1.5 cm), weighing 19 grams and use sample rate 30-100Hz. The battery life is up to 25 days. During the study, the subjects placed the ActiGraph on their right hip with 100Hz sampling rate for 8 days with a recording time of 7 full calendar days.

We used the ActiLife v6.13.3 software to extract data from ActiGraph monitors. Data were extracted into 10 seconds EPOCH. EPOCH are essentially raw data that have been filtered and summed up into chunks of data. The raw data can then be viewed in time-defined chunks of 10, 15, 30 or 60 seconds, and so on. Dividing raw data into EPOCH data is necessary to use algorithms to produce outputs. Wear-time validation was performed using the Choi 2011 algorithm; 1) zero-count threshold during a non-wear time interval, 2) 90-min time window for consecutive zero/nonzero counts, and 3) allowance of 2-min interval of nonzero counts with the up/downstream 30-min consecutive zero counts window for detection of artifactual movements (37). Sedentary bouts were defined from a minimum length of 10 minutes, with minimum count value 0 and maximum count value 99 in the ActiGraph. Average time per sedentary bouts during a period is given in minutes. Freedson Adult VM3 algorithm uses all three of ActiGraph's axes to calculate motion and was used to calculate minutes of light activity (< 2690 counts per minute), moderate to vigorous activity (MVPA ≥ 2691 counts per minute). Light activity and MVPA are also measured in percent of total time. ActiGraph measured the daily number of steps, and we classified subjects into three categories based on average daily step count: sedentary (< 5000 steps/day), somewhat active (5000-7499 steps/day), or active (\geq 7500 steps/day) (38).

4.5 Data collection

We collected the following data from patient records:

- Demographical data (age, gender, marital status)
- Type and duration of RRT
- Travel distance and time spent for travelling to dialysis centre/nephrologist
- Comorbidity (Carlson's comorbidity index)
- Current drug use
- Smoking (never smoked, previous smoker, current smoker; pack years)
- Height and dry weight at inclusion

 Laboratory test (blood samples measured in timeframe +/- 4 weeks from inclusion): Haemoglobin, leucocyte count, albumin, ionised calcium, phosphate, parathyroid hormone, bicarbonate, creatinine, carbamide, HbA1c, cholesterol. For patients on HD, we used predialytic values.

4.6 Statistical Analysis

Statistical analyses were performed using SPSS version 25 for Windows. Frequencies and percentages were calculated using descriptive statistics. Data are given in median (interquartile range). To show comparison between groups, the nonparametric independent samples test Mann-Whitney U test was used. Chi-Square test was used for between-group comparisons of dichotomous variables, and these are expressed in percentages. Univariate correlation was performed for the variables; age, body mass index (BMI), diabetes, number of drugs, haemoglobin, albumin and creatinine, and *r* values are listed with Spearman correlation coefficient. Logistic regression analysis was used to check for predictors for higher activity. The following predictors were included in models: age, BMI, diabetes, number of drugs, haemoglobin, albumin and creatinine. The level of significance was set at *P* < 0,05.

4.6.1 Power calculation

We recognise this pilot project as a descriptive survey of PA of dialysis patients in Northern Norway Regional Health Authority. PA measurement has never previously been accomplished using this method in a comparable cohort. Therefore, precise power calculations cannot be done. Study of factors associated with the amount of activity are secondary objectives. At the time of inclusion, the total number of patients in HD summarised to 134, whereas 42 patients were on PD in the region.

5 Results

5.1 Study population

The selection of participating patients is shown in Figure 1. Of 42 patients on PD and 139 HD patients, 74 were not invited to participate in the study, for various logistic reasons, or because they fulfilled one or more of the exclusion criteria. A total of 37 patients consented to participate in the study, but seven were excluded due to dialysis vintage < 3 months (n=1), acute illness (n=3) or withdrawal of consent to participation (n=3), resulting in a total of 30 patients in the study. Twenty-eight percent of all asked patients participated in the study and were analysed.

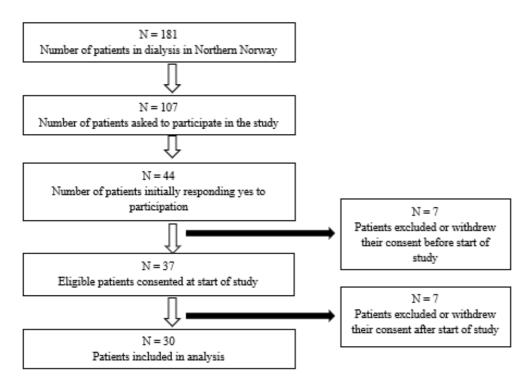


Figure 1: Flowchart of patients included in study.

The characteristics of the HD patients and PD patients in the study are shown in Table 1. Median age, gender distribution, marital status, percentage of transplantation candidates, number of medications, comorbidities, BMI and laboratory data were all similar between the HD-patients and PD-patients. The distance to dialysis centre in kilometres was significantly higher in the PD-patients group (P < 0,05).

Characteristics	HD patients (n=22)	PD patients (n=8)	Р
Age (years)	69 (55,5-78,5)	64 (61,3-76)	0,945
Male (%)	15 (68,2%)	5 (62,5%)	0,77
Marital status			0,43
Single	2 (9,1%)	1 (12,5%)	
Widowed or divorced	4 (18,2%)	0 (0%)	
Married/domestic relationship	16 (72,7%)	7 (87,5%)	
Duration of treatment (months) ¹	25 (13-43,5) ¹	16,5 (6,3-27,8)	0,168
Transplantation candidate – yes (%)	13 (59,1%)	6 (75%)	0,424
Number of drugs	12,5 (10-17,3)	13 (11,5-15)	0,621
Distance to dialysis centre (km) ⁹	16 (6-65) ⁷	255 (75,9-362,5) ²	0,01
Comorbidities			-
Diabetes - yes (%)	9 (40,9%)	1 (12,5%)	0,144
Heart attack - yes (%) ¹	3 (13,6%) ¹	1 (12,5%)	0,901
Congestive heart failure - yes (%)	4 (18,2%)	0 (0%)	0,195
COPD - yes (%) ¹	3 (13,6%) ¹	0 (0%)	0,259
Ulcus ventriculi/duodeni - yes (%)	4 (18,2%)	1 (12,5%)	0,712
BMI (kg/m ²)	25,9 (23,1-30,4)	29,2 (25-30,1)	0,534
Laboratory			
Haemoglobin (g/dL) ¹	10,9 (10-11,8)	11,5 (10,3-13,9) ¹	0,328
Leucocytes (x 10^9/mL) ¹	5,8 (4,9-6,6)	6,5 (5,4-10) ¹	0,211
Albumin (g/L) ¹	41 (39-42,1)	40 (38-41,5) ¹	0,258
Ionized Calcium (mmol/L) ²	1,2 (1,08-1,21) ¹	1,2 (1,08-1,28) ¹	0,376
Phosphate (mmol/L) ²	1,6 (1,4-2,3)	1,7 (1,35-2,15) ²	0,806
PTH (pmol/L) ²	42,6 (27,3-66,5)	28,1 (14,9-71,8) ²	0,401
Creatinine (µmol/L) ¹	711 (571,5-867,8)	651 (440-712) ¹	0,271
Carbamide (mmol/L) ¹	20 (15,4-22,6)	20,1 (18,5-22) ¹	0,784
HbA1c (mmol/mol) ⁵	37,0 (29,3-59,3) ²	36,0 (33,5-39,5) ³	0,683
Cholesterol (mmol/L) ⁸	3,7 (2,9-4,2) ³	3,8 (3,1) ⁵	0,415

Data are shown in median (interquartile range) and number (percent). Numbers in ^{xx} indicates missing cases.

5.2 Physical activity

5.2.1 Self-reported recordings

Table 2 shows the results for self-reported PA and HRQOL for both patient groups. There were no significant differences between the groups in self-reported PA or SF-questionnaire domains. For role limitations due to physical health, between-group difference reached borderline significance (p=0,053) No patients performed vigorous training during the last week, and no patients were scored in the high physical category by IPAQ.

Physical activity	HD patients (n=22)	PD patients (n= 8)	Р
IPAQ PA categories	[((- <i>)</i>	0,820
- Low	15 (68,2%)	7 (87,5%)	- ,
- Moderate	1 (4,5%)	0	
- High	0	0	
- Missing	6 (27,3%)	1 (12,5%)	
Days during last week with vigorous activity?			0, 896
- None	17 (77%)	6 (75%)	
- 1 or more days	`o ´	`O ´	
- Missing	5 (23%)	2 (25%)	
Days during the last week with moderate activity?	, <i>,</i> ,	. ,	0,86
- None	13 (59,1%)	5 (62,5%)	,
- 2 days	1 (4,5%)		
- 4 days	1 (4,5)		
- 5 days	1 (4,5)		
- Missing	6 (27,3%)	3 (37,5%)	
Days during the last week with 10 minutes walking?			0,455
- None	7 (31,8%)	4 (50%)	-
- 1 day	2 (9,1%)		
- 2 days	2 (9,1%)		
- 3 days	3 (13,6%)		
- 4 days	1 (4,5%)		
- 5 days	1 (4,5%)	1 (12,5%)	
- 7 days	1 (4,5%)	1 (12,5%)	
- Missing	6 (27,3%)	2 (25,0%)	
Time spent sedentary during a normal day?			0,527
 No of patients responding in minutes 	8 (36,4%)	5 (62,5%)	
- How many minutes?	420 (435)	300 (150)	0,222
 Do not remember 	8 (36,4%)	2 (25%)	
- Missing	6 (27,3%)	1 (12,5%)	
KDQOL-SFTM 1.3 domains (0-100)			
Physical functioning	50 (42,5-67,5) ¹⁷	65 (22,5-92,5) ⁶	0,516
Physical role functioning	0 (0-12,5) ¹⁷	75 (0-100) ⁷	0,053
Emotional wellbeing	80 (73-84) ¹⁶	86 (58-97) ⁶	0,590
Emotional role functioning	41,7 (16,7-66,7) ¹⁶	66,7 (0-66,7) ⁷	0,734
Energy/fatigue	37,5 (30-50) ¹⁶	47,5 (11,2-70) ⁶	0,590

Table 2: Self-reported physical activity (PA) of HD patients and PD patients.

Data are shown in median (interquartile range) and number (percent). Numbers in ^{xx} indicates valid cases.

5.2.2 Accelerometer recordings

All participants wore their accelerometer during the study. Range for wear time: 5h 9min to 7 days). Median wear time for ActiGraph accelerometer was significantly higher (P < 0,05) in the HD group compared to PD (Table 3). In total, participants contributed with ActiGraph recordings spread out over a total of 206 days, 137 in the HD group and 39 in the PD group, with a total wear time of 176 full days. There were no further significant differences in the ActiGraph measurements between the HD and the PD patients. Total MVPA time and MVPA as percent of wear time were not significantly different between the two groups. Time in light activity have the lowest non-significant P-value (P = 0,070). In total, 7 out of the 22 HD patients (31,8%) 5 out of 8 PD patients (62,5%) reached the recommended goal of \geq 150 minutes MVPA a week during the study.

Table 3: ActiGraph registered wear time and physical activity (PA).

Table 5. Actionaph registered wear time ar	iu physical activity (17	יןר.	
ActiGraph	HD patients (n = 22)	PD patients (n = 8)	Р
Wear Time Accelerometer (min)	9194,5 (8501-9733)	7509 (6400-9134)	0,024
Daily Average of Sedentary Bouts (min)	676,2 (565,1-770,4)	680,1 (631,3-788,9)	0,475
Daily Average of Sedentary Breaks (min)	742,4 (653,2-837,2)	710,3 (641-787,5)	0,344
Time in light activity (min)	8596,4 (7285-9185,3)	9145,3 (8709,2-9918,3)	0,070
 Percent in light activity 	98,8% (2,2%)	98,4% (1,6%)	0,945
Time in MVPA total (min)	98,9 (37,6-203,5)	157,7 (51,4-197,2)	0,534
 Percent in MVPA 	1,2% (2,2%)	1,6% (1,6%)	0,945
 Subjects with ≥ 150 min MVPA weekly 	7 (31,8%)	5 (62,5%)	0,129
Average MVPA per Day (min)	13,3 (5,4-29,1)	22,5 (8,1-28,2)	0,504
Average Steps per Day	1972,5 (1160,3-3673)	2687,3 (1265-3798)	0,730

Data are shown in median (interquartile range) and number (percent). Abbreviations: MVPA – Moderate to vigorous activity

Figure 2 shows that only one patient who was treated with dialysis had an active lifestyle in terms of average steps daily (≥ 7500), three patients classified to somewhat active (5000-7499 steps/day), whereas 26 were categorised as sedentary. In total, >7500 steps per days ("active") were recorded for 10 days, 5000-7500 steps ("somewhat active") for 22 days, whereas number of steps per day were classified as sedentary for 174 of the 206 accelerometer recording days.

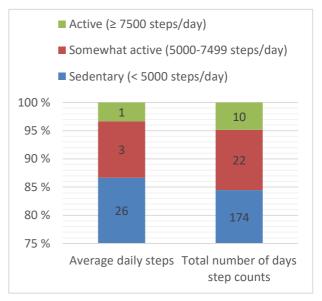


Figure 2: Frequency of patients with average daily steps and total number of days with step counts qualified to categories.

5.2.3 Correlation coefficients

In Table 4 , Spearman correlation coefficients between covariates believed to affect physical condition and average steps per day, as well as average daily MVPA, are shown. There were no significant correlations. However, there is a borderline non-significant negative correlation between haemoglobin and the dichotomous variable of daily average of MVPA above median (r = -0,359, P = 0,56).

Table 4: Correlations

Variable	r – steps per day above median.	Р	r – daily MVPA above median.	Ρ
Age years	- 0,320	0,085	- 0,359	0,052
BMI kg/m ²	0,062	0,746	0,100	0,598
Diabetes yes	- 0,283	0,130	- 0,236	0,209
No drugs	- 0,101	0,597	- 0,167	0,379
Haemoglobin g/dL	- 0,276	0,147	- 0,359	0,056
Albumin g/L	- 0,091	0,639	0,021	0,915
Creatinine µmol/L	- 0,058	0,766	-0,049	0,799

Univariate correlations (r=Spearman's rho) of baseline variables with the dichotomous variables average steps per day above median and average daily moderate to vigorous activity (MVPA) above median combined for HD and PD patients.

In a multivariable logistic regression analysis, haemoglobin was significantly associated with the dichotomous variable average daily MVPA at or above vs. below median (OR 0,39 (95% Cl 0,15-0,99) per 1 g/dL increase; p = 0,047). None of the other variables in the model (age, BMI, diabetes, number of drugs, albumin, creatinine) were significantly associated with any of the two outcome variables.

5.2.4 Knowledge about barriers against physical activity

Figure 3 shows that 16 patients reported that they had not been informed by their nephrologist about the importance of PA (13 patients did not respond to the question). Nineteen patients claimed that they wanted to be more physically active than they were at the time of

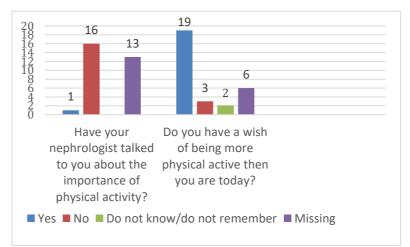


Figure 3: Information about physical activity and number of patients wanting to be more active.

registration, whereas three stated that they did not wish they were more active (two patients responded "do not know"; six did not respond).

Figure 4 shows that complications from comorbidities was the barrier/obstacle 12 patients considered to be moderate/high. Time used on dialysis treatment, complications from dialysis treatment and complications from their kidney disease were the next on the list.

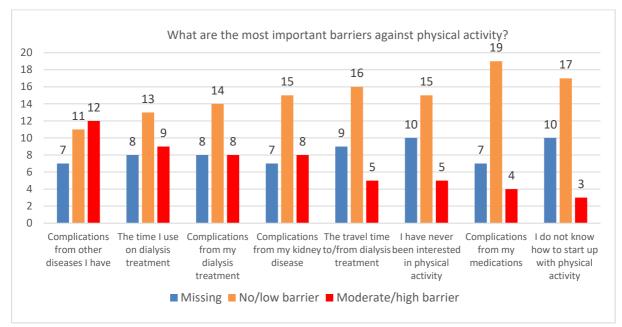


Figure 4 Survey of barriers related to amount of physical activity.

6 Discussion

In the present study we assessed PA and HRQOL among patients in HD and PD dialysis. We measured PA with a questionnaire and an accelerometer worn during a week, and according to our knowledge, this has never been done previously in HD and PD patients simultaneously.

6.1 Physical activity in dialysis patients and differences in HD and PD

The results of this study did not show any significant differences between HD and PD patients in the amount of self-reported and objectively measured PA. For HRQOL scores only role limitations due to physical health were significantly higher among PD patients compared to patients in HD. This may indicate that our group of HD patients have more severe physical health obstacles to overcome in terms of filling their role in everyday life. PD patients may experience fewer health problems that interfere with them doing what is expected from others or themselves. However, this is only one domain in the SF-questionnaire, and we found no significant differences between the groups in other domains. Moreover, selfreported, subjective data should be interpreted with caution. Numerically, both the average daily MVPA and the average number of steps performed by PD patients exceeded the measurements done in patients on HD. However, the differences did not reach statistical significance. The lack of between-group differences may be due to the low sample size and selection bias. The objective measurements, using an accelerometer, gives an indication that dialysis patients mostly perform light PA, and are more restrictive in moderate to vigorous PA This is an interesting finding, because 30 minutes MVPA a day 5 times a week or 150 minutes MVPA a week is the recommended amount of PA also in dialysis patients. Vigorous training may be too comprehensive to conduct for many patients in these groups, but a focus on moderate activity may be needed.

6.2 Selection of patients and other study limitations

Although the number of asked patients were 107, only 30 subjects participated in the study, 22 HD and 8 PD patients. This is a relatively small number of subjects, below the number we expected. There may be many reasons for that. First, the study was carried out in multiple centres, varying in size and staff. HD satellites are typically run by skilled dialysis nurses only, whereas in hospitals both nephrologists, nephrology trainees and dialysis nurses are directly involved in patient treatment. All the centres were informed orally and by written material about the aims and scope of the project. However, the actual project period was short, and limited spare time in a busy clinical setting, as well as the lack of at least one dedicated project collaborator at each site, probably affected patient information and recruitment. Also, PD patients in the region have a long distance to the dialysis centre, and therefore infrequent visits. Therefore, some eligible patients were not informed and invited to participate, or they were recruited too late. Furthermore, as one of the exclusion criteria was open to individual clinical judgement ("Patients considered by a nephrologist as not suitable due to a high load of physical and/or mental comorbidity"), it could not be ruled out that the various health workers (doctors and nurses, respectively) would influence the recruitment by evaluating this criterion differently.

Second, in the recruiting process there may have been a spread of negative mentality between patients in the same dialysis unit, and this may be a partial reason why a lower number of patients than expected joined our study. Third, some patients expressed that their main reason for rejecting study participation, was that revealing their low PA level made them feel uncomfortable. However, a low attendance rate is not uncommon in clinical studies. Based on the baseline characteristics presented in Table 1, which is similar to the mean values provided in the Norwegian Renal Registry, we believe that our cohort was fairly representative for eligible patients (12). The characteristics of included HD and PD patients, respectively, were similar, except a significantly longer median distance to the nearest dialysis centre for PD patients. This was expected since some of patients are treated with PD are offered this treatment modality mainly due to a long distance to the dialysis centre.

6.3 Comparison of physical activity to other studies on dialysis patients

According to our knowledge, few other studies on dialysis patients have assessed PA using an accelerometer, and most are only conducted on HD patients. However, a study from Japan with 202 eligible HD patients wearing an uniaxial accelerometer for seven days showed a median (interquartile range) daily steps of 3925 (2287-6244)(39). This is a considerably higher number of steps compared to the findings in our study. In the Japanese study, median age of the included patients was 64 (57-72) and 52% were women. Our HD study population consisted mostly of men, and this may be a factor potentially explaining the difference in step counts. In terms of comorbidity, 38,6% of the subjects had diabetes mellitus, which is similar to our percentage.

A study conducted on 19 HD patients aged \geq 18 and < 65 years with a triaxial accelerometer worn 12 hours daily for four days showed a mean ±SD of daily steps 5648 ± 2870 (40). This Brazilian study also showed a higher number of steps taken compared to our study. However, an important difference compared to our study was a lower mean age of the subjects (47,5 ± 12,5 years). Furthermore, the percentage of diabetes was considerably lower in the Brazilian study (10,5% of the subjects) compared to our study.

In another study from Brazil, ActiGraph GT3X was used to register PA in 79 HD patients for one full week. Whereas 22 patients (35,5%) in this study achieved \geq 150 minutes MVPA per week (41). In our study, seven out of the 22 HD patients (31,8%) managed to get \geq 150 minutes MVPA in total during the study. The methods are quite similar between the studies and this may indicate that MVPA registered in our study is representative for HD patients. However, because we do not have many studies to compare our results with, and since all observational studies so far suffer from low numbers of participants, both differences and similarities should be interpreted with care. Moreover, differences in daily step count may be affected not only by exercise patterns, but also by logistic differences such as differences in availability of transportation etc.

6.4 Comparison of physical activity with other patient groups

This study focused on differences between HD and PD patients, and we did not have any control group. However, our results may be compared to historical data published in the literature. By comparing our data to measurements made in a general population, the impact from a serious chronic disease on PA may be illustrated. On the other hand, it is also of interest to compare the results from dialysis patients with similar measurements done in patients with other chronic conditions, such as heart failure.

An American study conducted in 2018 with accelerometer measurements of PA among 182 patients with heart failure, used the same device, ActiGraph GT3X, as we did for 7 full days of measurement, with a minimal wear time of 4 days in total and 10 hours daily to be included in the results (42) However, they applied the Freedson 1998 et al cut points, that uses the vertical axis of movement alone to calculate time in different activity categories, whereas we used Freedson Adult VM3 cut points with three axes in our study. Regardless of the methodological differences, it is interesting to compare groups in terms of average minutes daily of MVPA and steps. Participants in our study had median (interguartile range) average MVPA per day (min) 13.3 (5,4-29,1) patients in HD and 22.5 (8,1-28,2) patients in PD. However, mean SD average daily minutes of MVPA in patients with heart failure classified as New York Heart Association (NYHA) class I was 13.0 (9.4), 12.4 (11.9) in NYHA class II and only 6.4 (6.8) in NYHA class III and IV (42). Although our measurements are listed as medians, and the results in the heart failure study are given as means, we get the impression that time is spent on MVPA in HD and PD patients in Northern Norway is comparable to MVPA in this group of American heart failure patients with the least symptom load (NYHA class I). This was somewhat unexpected as patients on chronic dialysis are recognised as a group with a high burden of symptoms. However, there may be several reasons for this discrepancy. Cultural differences in PA habits in the population may play a

role, but the fact that our study included a smaller number of subjects than the heart failure study, and a selection bias towards healthier patients may be the most important factors. However, for indication purposes we think it is a suitable comparison.

6.5 Comparison of physical activity with healthy people

A study conducted in Norway, with focus on self-reported PA and objectively measured PA, i.e. data from The Tromsø Study, gives us a valid basis for comparison of our patient group to the general population with regards to average daily MVPA and steps. The objective PA data was collected with ActiGraph GT1M during 7 consecutive days with 15-second epochs and a minimum of 10-hour activity daily for at least 3 days to be included in the analysis. Women (n = 136) achieved mean daily average MVPA of 37,6 minutes, and men 36,8 minutes (43). Compared with our results, we saw a considerably higher amount of MVPA in the healthy cohort. This difference was expected. In terms of steps daily, women in the healthy cohort had a mean of 8727 steps daily and men 8109 (43). Comparison with the median steps in our study shows that there is a big difference between daily step count among dialysis patients and persons from the general population. This may indicate that dialysis patients have a potential to move more during the day.

6.6 Possible predictors of physical activity

In our aim to map out biological factors that may be associated with the amount of PA, we only found a borderline non-significant small negative correlation of -0,359 (P = 0,056) between haemoglobin and average MVPA. However, our study was small and not powered to assess predictors of PA, and therefore the results of this study should be interpreted with caution. However, whether biological factors are associated with PA is an important question that needs to be assessed in larger studies with less missing data.

6.7 Attitudes and barriers

Factors and barriers that limit PA were an interesting area of our survey. Our patients gave a clear indication that nephrologists working with them did not focus on the importance of PA. Only one patient reported that he/she had been informed about this from his/her nephrologist, and 16 had not. Although 13 of the 30 included patients did not respond to

this question, we believe that this is an area where nephrologists and other health professionals can – and should - improve. The fact that as many as 19 patients expressed a wish to become more active underlines the need for improvement in this area. Diseases other than kidney disease was the factor most frequently ranked by the participants as a moderate/high barrier to PA. This may indicate that many patients on chronic dialysis struggle with co-morbidities that are limiting in terms of exercising. Dialysis patient populations are complex and may need a broad approach to help them become more physically active. The results of our study can be used in a constructive way as a reminder to us that we are dealing with patients who want, but do not necessarily manage or know how to become more physical active. A combination of better information and motivation from health workers in contact with dialysis patients may contribute to a higher percentage of the patients understanding the benefits of PA and getting the right tools to start. Another suggestion is to offer activities specifically suited for patients on dialysis. We do clearly see from our study that patients want to be more active, so starting up training groups for dialysis patients may be an interesting interventional study in the future. In this regard, the long time spent on treatment as well as considerable travel distances to the dialysis unit may be challenging; these factors were also mentioned by a number of patients as a barrier to PA.

6.8 The use of accelerometer measurements in dialysis patients

We do believe that ActiGraph registration a suitable method for studying PA in dialysis patients. We did not receive negative feedback from the subjects wearing them, and the devices were considered user friendly with instructions that were easy to understand. Patients were instructed to wear the device for one week, and therefore median wear time in minutes HD 9194,5 (8501-9733) and PD 7509 (6400-9134), was satisfactory. Only one subject had a wear time <4 days, which is often seen as an exclusion criterion in other studies. The fact that registrations are poor for upper limb movements makes the ActiGraph devices less useful in patients with walking disabilities, such as patients who have had limb amputations. However, despite this limitation, we believe that ActiGraph is well suited to use in future studies on PA in this group.

7 Conclusion

Our main objective was to study the degree of PA of patients on HD and PD in Northern Norway, and, as far as we are aware of, an accelerometer was used for the first time to measure activity in both HD and PD patients. Study results indicate that dialysis patients have a low level of PA based on average daily MVPA and step count, compared to healthy persons. We found no significant differences between patients on the two different dialysis modalities, but small group sizes limit firm conclusions. A high haemoglobin level was associated with less daily MVPA. Most patients reported that they had never been informed by their nephrologist about the potential benefit of being physically active, but a desire to be more active was commonly found. Barriers to PA included comorbidities and time spent on treatment. We believe there is potential to raise awareness of PA in health workers being involved in dialysis treatment, and to increase PA levels in dialysis patents. We hope this study can be used as a catalysator for future observational and interventional studies on PA in patients on dialysis.

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Appendix

Appendix 1: Questionnaire

Spørreskjema til deltakerne i studien «Kartlegging av fysisk aktivitet hos dialysepasienter i Nord-Norge – en observasjonsstudie»

Dette spørreskjemaet handler om hvordan du ser på din egen helse, hvordan du vurderer din egen fysiske aktivitet og hvilke forhold som eventuelt hindrer deg fra å være mer aktiv. Sammen med aktivitetsmålingen vi gjør i denne studien, bidrar dine svar til å og oss mer kunnskap om sammenhengen mellom dialysebehandling og fysisk aktivitet hos personer som har langt kommet kronisk nyresykdom.

Du trenger ikke å svare på alle spørsmålene på én gang, men det er fint om du er ferdig med å fylle ut skjemaet før du skal levere ActiGraph tilbake.

Hvis du er i tvil om ordlyden i spørreskjemaet eller har andre spørsmål eller kommentarer, kan du kontakte dialyselegen eller –sykepleieren du vanligvis forholder deg til, så formidler de kontakt til prosjektmedarbeiderne.

Takk for at du svarer på spørsmålene!

Studie-ID:

.....

Skjema mottatt

.....

Sted/dato Prosjektmedarbeider

1. 9	Stort sett, vil du si at din helse er:			
1 l	Itmerket 2 Meget god	3 God	4 Nokså god	5 Dårlig
2. 9	Sammenliknet med for ett år siden, hvor 	dan vil du si at	t din helse stort sett er	nå?
1 N	Nye bedre nå enn for ett år siden		2 Litt bedre nå enn for	ett år siden
3 C	omtrent den samme som for ett år siden		4 Litt dårligere enn for	ett år siden 🗌
5 N	Aye dårligere enn for ett år siden			
	De neste spørsmålene handler om aktivi din helse slik at den begrenser deg i utfør			
AK	TIVITETER	Ja, begrense meg mye	er Ja, begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a.	Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i			
	anstrengende idrett			
b.	Moderate aktiviteter som å flytte et bord, støvsuge, gå en tur eller drive med hagearbeid			
c.	Løfte eller bære en handlekurv			
d.	Gå opp trappen flere etasjer			
e.	Gå opp trappen en etasje			
f.	Bøye deg eller sitte på huk			
g.	Gå mer enn to kilometer			
h.	Gå noen hundre meter			
i.	Gå hundre meter			
j.	Vaske eller kle på deg			

4. I løpet av de siste 4 ukene, har du hatt noen av følgende symptomer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	Ja	Nei
a. Du har måttet redusere tiden du har brukt på arbeid eller andre gjøremål		
b. Du har utrettet mindre enn du har hadde ønsket		
c. Du har vært hindret i å utføre visse typer arbeid eller gjøremål		
d. Du har hatt problemer med å gjennomføre arbeid eller andre gjøremål (f.eks. fordi det krevde ekstraanstrengelser)		

5. I løpet av de siste 4 ukene, har du hatt noen av følgende symptomer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som f.eks. å være deprimert eller engstelig)?

	Ja	Nei
a. Du har måttet redusere tiden du har brukt på arbeid eller andre gjøremål		
b. Du har utrettet mindre enn du har hadde ønsket		
c. Du har hatt utført arbeid eller andre gjøremål mindre grundig enn vanlig		

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

Ikke i det hele tatt	Litt	En del	Муе	
7. Hvor sterke kroppslige s	merter har du h	natt i løpet av de siste 4	ukene?	
Ingen Meget svake	Svake	Moderate	Sterke	Meget sterke

8. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste fire ukene. For hvert spørsmål vennligst velg det svaralternativ som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste fire ukene har du:

	Hele tiden	Nesten hele tiden	Mye av tiden	En del av tiden	Litt av tiden	lkke i det hele tatt
a. Følt deg full av tiltakslyst						
b. Følt deg veldig nervøs						
c. Vært så langt nede at ingenting kunne muntre						
deg opp						
d. Følt deg rolig og harmonisk						
e. Hatt mye overskudd						
f. Følt deg nedfor og trist						
g. Følt deg sliten						
h. Følt deg glad						
i. Følt deg trett						

9. Hvor RIKTIG eller GALT er hver av de følgende påstandene for deg?

	Helt riktig	Delvis riktig	Vet ikke	Delvis galt	Helt galt
a. Min nyresykdom forstyrrer for mye i livet mitt					
b. Jeg bruker for mye av tiden min på nyresykdommen min					
c. Det er frustrerende å beskjeftige seg med nyresykdomme min	en				
d. Jeg føler meg som en belastning for min familie					

	Ikke plaget	Litt	Noe	Муе	Veldig
mye	i det hele tatt	plaget	plaget	plaget	plaget
a. Ømme muskler					
b. Brystsmerter					
c. Kramper					
d. Hudkløe					
e. Tørrhud					
f. Kortpustethet					
g. Svimmelhet eller nesten besvimelse					
h. Mangel på appetitt					
i. Utkjørt eller utbrent					
j. Nummenhet i hender og føtter					
k. Kvalme eller brekninger					
(Besvares kun av pasienter i hemodialyse): I. Problemer med dialysetilgangen (fistel, graft, kateter)					
(Besvares kun av pasienter i peritoneal dialyse): m. Problemer med kateterinngangen?					

10. I løpet av de siste 4 uker, hvor mye har du vært plaget av følgende (Sett kryss i én boks på hver linje)

11. Noen personer er plaget av nyresykdommen i det daglige liv, mens andre ikke er det. Hvor mye plaget er du av din nyresykdom innen hvert av de følgende områder? (Sett i én boks på hver linje)

	Ikke plaget i det hele tatt	Litt plaget	Noe plaget	Mye plaget	Veldig mye plaget
a. Begrensninger i hvor mye du kan drikke					
b. Kostrestriksjon					
c. Din evne til å klare arbeid i huset					
d. Din evne til å reise					
e. Din avhengighet av leger og annet helsepersonell					
f. Stress og bekymring forårsaket av din nyresykdom					

12. Hvor ofte de siste 4 uker har du... (Sett kryss i én boks på hver linje)

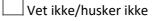
	lkke i det hele tatt	Litt av tiden	En del av tiden	Mye av tiden	Nesten hele tiden	Hele tider
a. Våknet om natten og hatt problemer med å sovne igjen						
b. Fått den mengden søvn						
som du trenger						
c. Hatt problemer med å holde deg våken om dagen						

13. a. Hvor mange dager i løpet av den siste uka har du drevet med meget anstrengende fysiske aktiviteter som tunge løft, gravearbeid, aerobics eller sykle fort? Tenk bare på aktiviteter som varer minst 10 minutter i strekk

dager per uke
ingen (gå til spørsmål 14.a)

13.b. På en vanlig dag hvor du utførte meget anstrengende fysiske aktiviteter, hvor lang tid brukte du da på dette?

timer	minutter



14. a. Hvor mange dager i løpet av den siste uka har du drevet med middels anstrengende fysiske aktiviteter som å bære lette ting, sykle eller jogge i moderat tempo eller mosjonstennis? Ikke ta med gange, det kommer i neste spørsmål.

L	dager per uke
	ingen (gå til spørsmål 15.a)

14.b. På en vanlig dag hvor du utførte middels anstrengende fysiske aktiviteter, hvor lang tid brukte du da på dette?

timer		minutter		Vet ikke/husker ikke

15. a. Hvor mange dager i løpet av den siste uka gikk du minst 10 minutter i strekk for å komme deg fra ett sted til et annet? Dette inkluderer gange på jobb og hjemme, gange til buss, eller gange som du gjør på tur eller som trening i fritiden

____ dager per uke ____ ingen (gå til spørsmål 16)

15.b. På en vanlig dag hvor du gikk for å komme deg fra et sted til et annet, hvor lang tid brukte du da totalt på å gå?

timer	minutter	Vet ikke/husker ikke

16. Dette spørsmålet omfatter all tid du tilbringer i ro (sittende) på jobb, hjemme, på kurs, og på fritiden. Det kan være tiden du sitter ved et arbeidsbord, hos venner, mens du leser eller ligger for å se på TV.

I løpet av den siste uka, hvor land tid brukte du vanligvis totalt på å sitte på en vanlig hverdag?

timer III minutter III Vet ikke/huske			timer			minutter		Vet ikke/huske
---------------------------------------	--	--	-------	--	--	----------	--	----------------

ikke

17. Har nyrelegen noen gang snakket med deg om viktigheten av å være fysisk aktiv?								
Ja Nei	Vet ikke/huske	er ikke						
18. Har du et ønske om å være mei	⁻ fysisk aktiv enr	n du er i dag?						
Ja Nei	Vet ikke							
19. Hvis du svarte "ja" på forrige spørsmål, hvilke forhold tenker du er dine viktigste hindre for fysisk aktivitet?								
	lkke et hinder	Litt hinder	Middels stort hinder	Stort hinder				
a. Tiden jeg bruker	_							
på dialysebehandlingen								
b. Tiden jeg bruker på å reise								
til og fra dialysebehandlingen								
c. Plager jeg får av								
dialysebehandlingen								
d. Plager jeg får av								
medisiner jeg tar								
e. Plager jeg får av								
nyresykdommen								
f. Plager jeg får av								
andre sykdommer jeg har								
g. Jeg har aldri tidligere vært								
interessert i fysisk aktivitet								
h. Jeg vet ikke hvordan jeg								
skal komme i gang								

Annet:

.....

20. Til deg som behandles med hemodialyse: Kunne du tenke deg:

	Ja	Nei	Vet ikke
a. Å trene mens du får dialysebehandling?			
b. Å trene før dialysebehandlingen?			

21. Til deg som behandles med peritoneal dialyse: Kunne du tenke deg:

	Ja	Nei	Vet ikke
a. Å trene i gruppe på sykehuset der du går til kontroll, sammen med andre som behandles med PD?			
b. Å trene i gruppe på mitt hjemsted?			

22. Har du andre innspill om forhold som med bedre tilrettelegging kunne ha bidratt til at du var mer fysisk aktiv?

.....

.....

23. Hvor mange kilometer er det fra ditt hjem til ditt dialysesenter (evt. det sykehuset der du går til PDkontroll)?

kilometer

24. Når du skal til dialyse eller dialysekontroll, hvilket klokkeslett reiser du vanligvis hjemmefra?

Klokken:			

25. Hvilket klokkeslett er du vanligvis hjemme igjen?



26. Har du andre kommentarer til undersøkelsen eller til temaet fysisk aktivitet ved dialyse?

.....

.....

Tusen takk for at du tok deg tid til å svare på spørsmålene!

Appendix 2: Information to patients and written consent FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKT

«En undersøkelse av fysisk aktivitet blant dialysepasienter i Nord-Norge»

BAKGRUNN OG FORMÅL MED PROSJEKTET

Hos mange personer som behandles regelmessig med dialyse, bidrar både nyresykdommen og behandlingen til at de er mindre fysisk aktive enn andre. Forskning tyder likevel på at fysisk aktivitet kan være gunstig for fysisk helse og livskvalitet også hos personer i dialyse. Det finnes ingen tidligere forskningsstudier av fysisk aktivitet blant personer som er i behandling med dialyse i Nord-Norge. Vi vil med dette spørre deg om du vil være med på den aller første.

Hensikten med studien er å undersøke om økt fysisk aktivitet har sammenheng med økt livskvalitet. For å undersøke dette vil vi gjennomføre en spørreundersøkelse med spørsmål rundt dine aktivitetsvaner. Vi vil også be deg om å gå med en aktivitetsmåler i sju dager for å måle mengden fysisk aktivitet i denne perioden.

Forskningsstudien kom i stand som et studentprosjekt ved medisinutdanningen, UiT Norges Arktiske Universitet. Den er utformet av leger og studenter ved Universitetssykehuset i Nord-Norge/UiT og Nordlandssykehuset Bodø. Vi har også viktige samarbeidspartnere blant nyrelegene ved Finnmarkssykehuset og Helgelandssykehuset. Videre støttes prosjektet økonomisk av Landsforeningen for Nyresyke og Transplanterte (LNT).

HVA INNEBÆRER DET Å DELTA?

Dersom du samtykker til å delta, vil du få utdelt et spørreskjema med spørsmål rundt dine aktivitetsvaner og din livskvalitet. Det er ønskelig at du svarer så godt du klarer på flest mulig av spørsmålene.

Videre vil du gå med en liten aktivitetsmåler rundt høyre hofte i sju dager. Dette er en liten databrikke som festes ved høyre hofte og som kun vil registrere hvor mye du beveger deg. Brikken registrerer ikke hva du holder på med eller hvor du er. Sammen med brikken leverer vi ut en god beskrivelse av hvordan den skal festes og brukes. Vi vil avtale nærmere med deg hvor og hvordan du aktivitetsmåleren blir utdelt og tilsvarende hvor og hvordan du skal levere den inn igjen. Bruk av ActiGraph vil forekomme i tidsrommet mellom 15. november - 15.desember.

For å få et best mulig bilde av det fysiske aktivitetsnivået hos personer i dialyse, og hva som eventuelt begrenser aktiviteten, ønsker vi å registrere noen opplysninger om din sykdom (type nyresykdom, medisiner du bruker, hvilke andre sykdommer du har og enkelte blodprøvesvar) og dialysebehandling (type dialysebehandling, hvor lenge du har vært i behandling, reiseavstand og –tid til dialysen eller nyrelegen). Opplysningene ønsker vi å hente fra din medisinske journal. Vi vil be om ditt samtykke til innsyn i journalen for å finne disse spesifiserte opplysningene.

MULIGE FORDELER OG ULEMPER

Deltagelse vil innebære noe tidsbruk for deg i utfyllingen av spørreskjemaet. Det vil også ta litt tid å betjene aktivitetsmåleren (av/på under dusj/bad o.l). Aktivitetsmålerne som brukes i studien, vil ikke medføre ubehag eller smerter, og vil kunne sammenlignes med et belte når den er i bruk.

Kunnskapen vi får fra denne studien vil kunne bidra til å forbedre framtidige anbefalinger om fysisk aktivitet blant personer som behandles med dialyse.

HVA SKJER MED INFORMAJSONEN OM DEG?

All informasjon som innhentes om deg i denne forskningsstudien, vil kun bli brukt for å besvare de spørsmålene vi har skissert over (se «Bakgrunn og formål med prosjektet» over). Data som innhentes, vil samles og lagres på en sikker måte, i samsvar med nasjonale forskrifter og slik det kreves av Personvernombudet ved hvert av de fire involverte helseforetakene. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten der ditt ID-nummer er konstruert, og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når denne publiseres.

Studien har vært vurdert av Regionale komiteer for medisinsk og helsefaglig forskning avdeling Nord (REK Nord), som ikke har stilt spesielle krav til forskningen.

FRIVILLIG DELTAKELSE

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke om deltakelse. Dersom du ønsker å delta i studien, ber vi om at du undertegner samtykkeerklæringen på siste side. Dersom du har spørsmål til studien kan du kontakte: Kjell-Gunnar Vangen, Medisinstudent Universitetet i Tromsø, Tlf: xxxxxxx

Marit Dahl Solbu, overlege og spesialist i nyresykdommer, Universitetssykehuset Nord-Norge, Tlf: xxxxxxxx

Du kan også stille dine spørsmål til din nyrelege eller dialysesykepleier, som kan formidle spørsmålet videre til oss.

SAMTYKKE TIL DELTAKELSE I FORSKNINGSSTUDIE:

«En undersøkelse av fysisk aktivitet blant dialysepasienter i Nord-Norge»

Jeg har fått muntlig og skriftlig informasjon om forskningsstudien.

.....

Lege/sykepleier bekrefter å ha informert om studien (sted/dato/navn/underskrift)

Jeg samtykker herved til å delta i studien. Mitt samtykke omfatter også innhenting av medisinske opplysninger som er nødvendige for dette forskningsprosjektet fra min pasientjournal.

.....

•••••

Sted/dato

Signatur, prosjektdeltaker

Navnelapp

GRADE

Reference: Barcellos FC, S	Study design: systematic review.		
			Level of la
			evidence
			GRADE High
Aim of study	Patients and Methods	Resultater	Discussion/comments/check-list
	Patients and wethous Population:	Literature search:	1. Is the review based on a focused
	CKD patients.	We retrieved 5489 articles in searches, 486	guestion that is adequately formulated
for and appraise	ord patents.	duplicated articles were excluded initially. 5003	and described? YES.
	The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) statement for the conduct of meta-analyses of	articles examined for eligibility, 4861 were	 Were eligibility criteria for included and
	intervention studies was followed.	excluded based on the title or abstract. 142	excluded studies predefined and
exercise		potentially eligible studies full text were	specified? YES
interventions on	Inclusion criteria:	evaluated. 59 fulfilled inclusion criteria and	 Did the literature search strategy use a
	Eligibility criteria were randomized controlled trials (RCT) evaluating any type of exercise intervention, including advising for physical activity	included in the review. 2858 randomized	comprehensive, systematic approach?
		participants overall within these 59 studies.	YES
	Only studies with adults (218 years) were selected.		Were titles, abstracts, and full-text
The strongest evidence		Selected trails:	articles dually and independently
Ŭ l	Exclusion criteria:	Number of participants ranging from 11 to 297.	reviewed for inclusion and exclusion to
	Studies on the acute effects of exercise (intervention lasting <8 weeks) and/or quasi-experimental studies were excluded.	38 studies (67%) with sample size less than 50	minimize bias? YES
improving physical		participants. Three studies uses a healthy control	5. Was the quality of each included study
	Literature search:	group in addition to a CKD control group. Six trails	rated independently by two or more
		lasted over a year, most other lasted from 8 to 24	reviewers using a standard method to
	results with searches of the Cochrane Central Register, and clinical trials registry databases. Conference proceedings abstracts also were	weeks. Twenty-eight of the 59 studies were	appraise its internal validity? YES
The benefits of exercise	handsearched (American Society of Nephrology from 2003 to 2014, European Renal Association–European Dialysis and Transplant Association	published after 2009.	Were the included studies listed along
in dialysis patients are	from 2002 to 2014 and World Congress of Nephrology from 2001 to 2012).		with important characteristics and
well established,		Assessment of the quality of studies:	results of each study? YES
supporting the	Data extraction:	Allocation: 23 studies had adequate	Was publication bias assessed? YES
prescription of physical	The articles identified in the literature search were screened by two independent extractors (F.C.B and M.B) who were blinded to authorship.	randomization and concealment of the allocation	Was heterogeneity assessed? (This
activity in their regular	The initial screening was based on only titles and abstracts. After that, the full text of potentially eligible articles was evaluated. Data	sequence was describes in only 14 RCTs.	question applies only to meta-
	extraction of selected RCTs was performed by two independent reviewers (F.C.B and M.B). Discrepancies between the two extractors were	Blinding: process of participants, care providers	analyses.) NOT APPLICABLE
	discussed until consensus was reached.	and assessors was described in six studies. Three	
earlier stages of CKD		studies blinded outcomes.	Discussion:
· · · · · · · · · · · · · · · · · · ·	Primary outcomes:	Dropout rates: 41 of 59 studies reported dropout	Strength:
	1. Physical fitness: aerobic capacity, muscular strength;	rates. 32 had dropout rate between 0-30%.	- Systematic review
	Health-related quality of life (measured through well-established, reliable and validated instruments);	Intention-to-treat analysis: Ten studies.	 Strict exclusion criteria.
	Cardiovascular dimensions: heart rate variability (HRV) index, mean RR, mean standard deviation of normal-to-normal intervals (SDNN),	Adherence to interventions: Nine RCTs reported	 Many articles reviewed.
assessing long-term	pulse wave velocity (PWV) and arterial stiffness;	on compliance, which was from 70-89%.	Findings in accordance with meta-
	 Nutritional measures: body composition (visceral fat, waist circumference and leg lean mass), body mass index, waist circumference); 		analysis for the Cochrane Collaboration,
charalse protocorror	5. Depression;	Overview of the most important findings:	by Heiwe and Jacobsen, published in
	6. Systemic inflammation: interleukin 6, C-reactive protein.	- Consistent evidence of the positive effects of	2011, and updated in 2014.
remains to be		aerobic exercise on physical fitness, muscular	Authors discuss the possible benefits of
	Secondary outcomes:	strength and quality of life in ESRD patients.	engaging exercise in earlier stages of CKD,
	 Blood lipids: total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides; Progression of CKD: determined as glomerular filtration from serum creatinine and/or cystatin C and/or radioisotope tracing 	 Evidence regarding exercise effects on other health outcomes and/or in earlier stages of 	and the problem that many articles did not
Drazii	Progression of CKD, determined as giomerular intration from serum creatinine and/or cystatin c and/or radioisotope tracing	CKD are weaker and heterogenous.	include subjects in these stages.
Year of data collection	Assessment of risk of bias:	 Heart rate variability – six of the seven studies 	mendue subjects in these stages.
	Assessment of make of Mass. The quality of RCTs was judged by selection bias (method of recruitment, proper method of randomization at baseline, concealment of	assessing HRV found significant improvements	
Source Forth	The quarky of kets was judged by selection bias (method of recreating, proper method of andomatomatomatomatomatomatomatomatomatomat	in this variable after exercise.	
	blinded administrator and blinded patients) and attrition bias (level of adherence to the intervention, completeness of follow-up and use of		
	intention-to-treat analysis). Each item was rated by assigning a judgment of high, low or unclear risk of material bias.		
	· · · · · · · · · · · · · · · · · · ·		

	d S, Davidson W, Ford G, Kiland K, Manns B. Effects of exercise training on physical impairment, arterial stiffness and h	ealth-related quality o	f life in patients with chron	ic kidney disease: a	Study design: RCT			
study. Int Urol Nephrol. 2011;43(4):1133-41.					Level of evidence		
						GRADE	High/moderate	
Aim of study	Patients and Methods		Results				Discussion/comments/check-list	
Patients with chronic kidney	Study design:		en EX and CT was statistica)2peak	Checklist		
disease (CKD) have impaired	Prospective randomized controlled study		95% CI 0.92, 6.26; P = 0.01		0.003)		scribed as randomized, a randomized trial, a trial, or an RCT? Prospective randomized controlled	
performance in physical tasks, ower health-related quality of	Ten patients were randomized to 12 months of exercise (EX) and 10 to standard care (CT). We compared the	95%CI4.34,17.59;P =	0.003) and AI(-11.7%;95%	CI-18.79, -4.61; P =	0.003).	trail.	that, of an RCT? Prospective fandomized controlled	
ife and high cardiovascular	difference between the two	Main results:				crun.		
morbidity and mortality.	groups in physical impairment (VO2peak and endurance time [ET]), arterial stiffness (augmentation index [AI]) and		this study are that 1 year of	of supervised aerob	2. Was the method o	of randomization adequate (i.e., use of randomly		
Moderate intensity exercise has	health-related guality of life (EuroQol EQ-5D and Short Form-36 guestionnaires) (all measured at baseline and 12		mproves physical impairme		generated assignmer			
been shown to provide	months).	patients with predialy						
ardiovascular and metabolic					3. Was the treatmen	nt allocation concealed (so that assignments could not		
enefits in healthy individuals	Population:	Incidence/RR/risk red	luction/aRR			be predicted)? YES		
and patients without CKD. Long-	Eligible patients were invited to attend an information session outlining all aspects of the study before agreeing to		een EX and CT at 12 month		-			
erm exercise training is	participate. Following completion of baseline exercise testing, subjects were randomly assigned to exercise in		O2/kg/min; 95% CI 0.92, 6				cipants and providers blinded to treatment group	
ecommended as a vital	addition to standard care (EX) or standard care alone (CT) using a computer generated randomization list and		95% CI 4.34, 17.59; P = 0.0	003) and augmentat	ion index	assignment? CANNO	DT DETERMINE.	
component in the management	sequentially numbered, sealed envelopes.	(AI) (-11.7%; 95% CI -	18.79, -4.61; P = 0.003).					
of a number of chronic diseases.		Others and they				5. Were the people a group assignments?	assessing the outcomes blinded to the participants'	
This randomized controlled pilot project examined the effects of	Inclusion criteria: Medically stable sedentary patients with Stage III–IV CKD (GFR 15–60 ml/min/1.73 m2) were recruited from	Other results: The evercise modality	/ most commonly chosen i	n the FX group was	valking	Broup assignments?	165	
exercise in predialysis CKD	outpatient Nephrology clinics in the Calgary Health Region.		bed training frequency was			6. Were the groups	similar at baseline on important characteristics that	
patients.	outputere reprinting a mean mere cargory incaren region.		ssions, with a median wee				es (e.g., demographics, risk factors, co-morbid	
Conclusion	Exclusion criteria:		ere no significant changes f				(0, 0,)	
This study suggests that long-	Patients were excluded if any of the following had occurred within the month prior to enrolment: acute	in EX or CT.						
erm exercise training improves	cardiorespiratory disease (acute coronary syndrome, congestive heart failure or severe pneumonia), uncontrolled					7. Was the overall drop-out rate from the study at endpoint 20% or		
physical impairment, arterial	diabetes (plasma glucose[20 mmol/l or\4 mmol/l on at least two occasions) or uncontrolled hypertension (systolic	Other factors with po	tential to alter exercise cap	pacity, arterial stiffn	ess and	of the number alloca	ated to treatment? YES	
stiffness and health-related	blood pressure[180 mmHg or diastolic blood pressure[110 mmHg on at least two occasions), persistent		and diastolic blood pressur			 Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower? NO 		
quality of life in patients with	hyperkalaemia (K[5.5 mmol/l) or musculoskeletal abnormalities precluding or exacerbated by exercise.		um haemoglobin, albumin,					
predialysis CKD. A larger		phosphorus) showed	no significant differences b	between the two gr	oups.			
randomized trial is required to	Method:	0:17			or I.c.v		//	
examine the impact of exercise	Forty-five eligible patients were invited to attend the study information sessions, and 20 agreed to participate, with					 Was there high adherence to the intervention protocols for each treatment group? YES, 80% for supervised sessions and 20% for hom 		
on markers of cardiovascular risk and quality of life in predialysis	10 randomized to exercise in addition to standard care (EX) and 10 to standard care alone (CT).		nce is unknown. Although d not reach statistical signi			sessions.	cs, 80% for supervised sessions and 20% for nome	
CKD patients.	Outcome:		ent was demonstrated in th		clinically	505510115.		
Country	The primary study outcome was the difference in physical impairment between EX and CT at 12 months. Physical	Important improvem	ent was demonstrated in t	ie Ex group.		10. Were other interventions avoided or similar in the groups (e.g.,		
Canada	impairment was assessed by measuring exercise capacity (VO2peak) and endurance time (ET).					background treatme		
Year of data collection	Secondary outcomes included arterial stiffness and health-related quality of life.					-		
2010						11. Were outcomes a	assessed using valid and reliable measures,	
	Variables:					implemented consist	tently across all study participants? YES.	
	The training program was of 1-year duration, combining supervised and home-based exercise. Supervised training							
	consisted of twice-weekly in-centre sessions throughout the study period and included choice of treadmill,	Table 1 Patient physical characteristics at baseline	Variable	Value*			report that the sample size was sufficiently large to be	
	stationary cycle and elliptical trainer. Home training (walking) was initiated in the second month and progressed				X (n = 10)		erence in the main outcome between groups with at	
	over 3 months to a frequency of 3 days/ week. Exercise prescriptions were individualized, with an initial intensity of		Age (years) Gender (female/male)		4 (55, 73)	least 80% power? No	O, this is a pilot study.	
	40–60% of VO2peak and duration of 5–20 min. Exercise duration was increased by 5–10% weekly (to a maximum of 60 min), and patients used heart rate monitors. (Polar) and rations of perceived evertion. (12–15 on the Borg PPE		Cause of CKD (diabetes mellitus/total)	6/10	/10	13 Were outcomes	reported or subgroups analysed prespecified (i.e.,	
	60 min), and patients used heart rate monitors (Polar) and ratings of perceived exertion (12–15 on the Borg RPE scale) to guide exercise intensity.		BMI (kg/m ²) Abdominal girth (cm)		7.5 (25, 32) 01 (86, 110)		alyses were conducted)? YES.	
	search to going exercise intensity.		Systolic blood pressure (mmHg) Diastolic blood pressure (mmHg)	145 (125, 160)	40 (130, 150) 7.5 (70, 80)	a chance before and	.,	
	Stastical analysis:		GFR (ml/min/1.73 sq m)	28 (22, 34)	7 (20, 41)			
	As this was a pilot study, no sample size calculation was completed. Subject characteristics were described using		VO _{2peak} (ml O ₂ /kg/min) Endurance time (min)		5.8 (10.9, 17.4)	14. Were all random	ized participants analysed in the group to which they	
	descriptive statistics and expressed as median values. The difference between the measurements obtained at	* Values are median (25%, 75%)	Augmentation index (%)		9 (25, 42)		ned, i.e., did they use an intention-to-treat analysis?	
	baseline and 12 months in each group was found to have a normal distribution and comparison of the difference	1.049				YES.		
	between the two groups was analysed using the unpaired t-test. A P-value of <0.05 was considered statistically							
	significant. Analysis was intention to treat.					Strength:		
							p, mostly significant results and only two people	
	Approvals:					dropped out during 1	1 year.	
	The study protocol was approved by the University of Calgary Conjoint Health Research Ethics Board, and written							
	informed consent was obtained from each participant.					Weakness:		
						pmall population. No	ot used gold standard for measuring arterial stiffness.	

Reference: Kang SH, Do JY, Jeong HY, Lee SY, Kim JC. The Clinical Significance of Physical Activity in Maintenance Dialysis Patients. Kidney and Blood Pressure Research.			Study design: Cohort					
			Level of evidence IIb					
			GRADE Moderate					
Aim of study	Patients and Methods	Results	Discussion/comments/check-list					
Evaluate the	Study design:	Total number of participants	Was the population well defines? Yes, they were recruited from 27 clinics in Korea.					
effects of	Retrospective cohort study.	in inactive (N=728),						
physical activity		intermediate (N=520) and	Are the groups recruited from the same population? Yes, they are recruited from					
on various	Population:	Active (N=363) groups.	Korea in clinics treating CKD-patients.					
aspects in Asian	Study participants were recruited from 27 hospitals or dialysis centres in Korea (n = 1611) from a	Number of participants in HD	D					
dialysis	previous study. between July and December 2012. The participants were divided into 3 groups		Are the population representative for a defined population? Yes.					
patients.	according to the degree of regular exercise: Inactive group, Intermediate group, and Active group.	(364 – 22,6%).						
Conclusion	A total of 2737 participants who underwent dialysis were included.		Are those who evaluated the results blinded? Uncertain, do not say in the paper.					
High physical		The proportions of patients						
activity was	Exclusion criteria:		e Was it a prospective study? No					
associated with	Participants were <u>excluded</u> from the present study if they met the following criteria: age < 20	of each component						
favorable results	years (n = 12), hospitalization during the previous 3 months except for vascular access problems		$_{ m Y}$ Did a high enough amount of people in the cohort get follow-up? (Attrition bias/follow					
for most HRQoL	(n = 351), dialysis duration < 6 months (n = 164), inability to walk with or without an assistive	increased. The presence and	up-bias) Uncertain.					
scale scores,	device (n = 79), lack of laboratory findings (n = 117), refusal to participate (n = 254), or inability to	numbers of disabilities						
including frailty,	communicate with interviewers (n = 149). As a result, 1611 participants were ultimately included	decreased as physical activity	y Is the follow-up time adequate? Uncertain.					
disability, and	in this study.	increased.						
exhaustion, in			Are confounding factors analysed during the study? Yes.					
Korean dialysis	Method:	The number of participants						
patients. Patients	Demographic and laboratory data collected at enrolment included the following: age, sex, body	with a history of fall during	Do you believe in the results? Yes.					
on dialysis should	mass index (BMI; kg/m2), DM, CAD, cerebrovascular disease (CVD), dialysis vintage (years),	the last 12 months was 149						
be encouraged to		(20.5%) in the Inactive group,	p, Can the results be transferred to the general population? No.					
increase their	(mg/dL), calcium (mg/dL), phosphorus (mg/dL), total cholesterol (mg/dL), intact-parathyroid	88 (16.9%) in the						
physical activity,	hormone (i-PTH; pg/mL), and high sensitivity CRP (hs-CRP; mg/dL).	Intermediate group, and 48						
which may		(13.2%) in the Active group.	Discussion:					
improve their	Assessment of HRQoL was assessed by Kidney Disease Quality of Life (KDQOL)-SF 1.3 Korean		Strength:					
prognosis.	version. Disability was evaluated using 4 questions regarding activities of daily living (ADLs).	Physical component scale	High number recruited patients. Other studies have shown many of the same results.					
Country	Exhaustion was measured using 2 questions from the Center for Epidemiological Studies	· · ·						
Korea	Depression Scale. Physical activity was defined as the presence of regular exercise during leisure							
Year of data	time for the past 3 months. Frailty was defined using modified criteria including components of	activity increased.	recommendation of physical activity among dialysis patients.					
collection	slowness, poor endurance, physical inactivity, and unintentional weight loss.							
July – December		The survival rate for all-cause						
2012	Statistical analysis:	· · ·						
	The data were analysed using the statistical software SPSS version 21. The level of statistical							
	significance was set at P < 0.05.	v						
		93.5% in the Inactive group.	medications that may affect physical activity; opioids, antihistamine and					
	Approvals:		antidepressants.					
	The hospitals ethics committee approved the study protocol. The study was conducted in							
	accordance with the principles originating from det Declaration of Helsinki.							

Defense and L.D.	Pelester M. Mill Odunes E.A. Olaha M. Still M. S.	Churd	destas es	- Manual				
	., Robertson N., Niyi-Odumosu F.A., Clarke A.L., Bishop N.C., S	Study design: cross sectional						
representations, p	physical activity and depression in chronic kidney disease. Jou	urnai of kenal Care 45 (2), 74-82.		of evidence				
			GRADE)E	Moderate			
Aim of study	Patients and Methods	Results			Discussion/comments/check-list			
Explore the	Study design:	Seventy respondents, 60% male, with a mean age of		Checklist				
relationship	Cross-sectional study.	60±16years, took part in the study.			research question or objective in this paper clearly stated? YES			
between					study population clearly specified and defined? YES			
physical	Population:	Physical activity:			participation rate of eligible persons at least 50%? NO, 43%			
activity,	A total of 164 patients were approached, of these, 100	- 35% of participants were sedentary.			the subjects selected or recruited from the same or similar populations			
depression	patients consented, but 30 did not return the survey	 39% of participants were «minimally active» 			g the same time period)? Were inclusion and exclusion criteria for being			
and illness	booklet and were withdrawn from the study.	 26% of participants met the active category. 			udy prespecified and applied uniformly to all participants? YES			
representatio		- Median level of physical activity per week was 1386 MET-			ample size justification, power description, or variance and effect estimates			
ns in CKD.		min, which meets the category «minimally active».		provide				
Conclusion	Inclusion criteria:				analyses in this paper, were the exposure(s) of interest measured prior to			
Facets of illness	 Diagnosis of CKD and not on dialysis. Male as female and 12 warm as been 	Depression severity:			ome(s) being measured? NO			
representations	 Male or female aged 18 years or above. Manual Manual and able to give informed approximation. 	- 63,2% of participants scored «minimal depression»			timeframe sufficient so that one could reasonably expect to see an			
U U	 Were willing and able to give informed consent for aturdy participation 	- 17,6% of participants scored «mild depression»			ion between exposure and outcome if it existed? NO			
relationships	study participation.	- 11,8% of participants scored «moderate depression»			osures that can vary in amount or level, did the study examine different			
with levels of	 Were able to complete the measures in English. 	 7,4% of participants scored «severe depression» 			the exposure as related to the outcome (e.g., categories of exposure, or e measured as continuous variable)? CANNOT DETERMINE			
physical activity.	Method:	Association of illness representations with levels of physical			e exposure measures (independent variables) clearly defined, valid,			
Country	70 patients (43% participation rate) with CKD but not	activity:			and implemented consistently across all study participants? YES			
United Kingdom	requiring dialysis from a UK renal outpatient clinic	- Positive correlation between personal control and level of			exposure(s) assessed more than once over time? NO			
Year of data collection	completed the Revised Illness Perception Questionnaire	physical activity (r = .288, p = .034).			e outcome measures (dependent variables) clearly defined, valid, reliable,			
August 2016-	(IPQ-R), Beck Depression Inventory (BDI-II) and Short-Form	physical activity (1 = .200, p = .034).			lemented consistently across all study participants? NO			
January 2017	International Physical Activity Questionnaire (IPAQ-SF).	Regression analysis:			e outcome assessors blinded to the exposure status of participants? NOT			
January 2017	Demographic information was obtained via medical	 Timeline cyclical (a subscale of the IPQ-R relating to 		APPLICA				
	records. The participants were given a study survey	patient beliefs about the nature of their illness) was a			s to follow-up after baseline 20% or less? NOT APPLICABLE			
	booklet to take away, complete and return within 10 days.	significant predictor (Beta =423, p = .008).			y potential confounding variables measured and adjusted statistically for			
	All participants provided informed consent.				pact on the relationship between exposure(s) and outcome(s)? ? NOT			
		Moderation and mediation analyses: Moderation analysis		APPLICA				
	Statistical methods:	was conducted with levels of physical activity (IPAQ-SF) as						
	Data analysis were performed using IBM SPSS statistics for	the dependent variable, timeline cyclical as the independent		Discussion				
	Windows, version 24.	variable and severity of depression (BDI-II) as the moderator		Strength: co	relations between personal control and levels of physical activity are			
		variable.			ith one meta-analysis, a systematic review with meta-analysis and			
	Descriptive statistics were used on patients characteristics.	Severity of depression was neither a moderator nor a		cardiovascul	ar disease research studies. Furthermore, timeline cyclical dimension			
	Correlation and regression analyses were conducted to	mediator of illness representations and levels of physical		predicted lev	els of physical activity are parallels with a study conducted on CVD			
	determine the relationship of illness representations with	activity (b= .021,BCaCl [082,.008],p =.33).		patients.				
	levels of physical activity. Moderation and mediation							
	analyses were performed to investigate the role of			Weakness:				
	depression in any relationship between illness				seven domains of CSM were statistically significant. Self-report measures			
	representations and physical activity levels.			are prone to	recall bias. Small sample size.			

Reference: Hagstromer M, Oja validity2006.	P, Sjostrom M. The International Physical Activity Questionnaire (IPA	Q): A study of concurrent and construct	Study design: Cross-sectional Level of evidence
validity2000.			GRADE Moderate
Aim of study	Patients and Methods	Results	Discussion/comments/check-list
	Study design:	Forty-six volunteers, 92% response,	
-	A cross-sectional study was performed, comparing measures of PA	age range 19-62, participated in the	 Was the research question or objective in this paper clearly stated? YES
was developed to measure	by the long, self-administered, last 7 day version of the IPAQ with	study, 22 men.	 Was the study population clearly specified and defined? CANNOT
health-related physical	those obtained by a log book and an activity monitor for concurrent		DETERMINE
activity (PA) in populations.	validity, and with aerobic fitness and body composition for	Age (years) 40.7 ± 10.3 Height (cm) 171.0 ± 8.9 Weight (kg) 70.4 ± 10.3 Body mass index (kg m ⁻²) 24.0 ± 2.4	Was the participation rate of eligible persons at least 50%? YES
	construct validity.	Body mass index (kg m ⁻¹) 224.0 ± 2.4 Body fat (%) 26.6 ± 2.1 Aerobic fitness (ml O ₂ kg ⁻¹ min ⁻¹) 37.7 ± 9.8	4. Were all the subjects selected or recruited from the same or similar
has been tested extensively		Values are expressed as mean ± standard deviation.	populations (including the same time period)? Were inclusion and
and is now used in many	Population:	No significant gender differences	exclusion criteria for being in the study prespecified and applied
international studies. The	A total of 50 healthy volunteers (24 men) living in the Stockholm	regarding age, BMI or time spent in	uniformly to all participants? YES
purpose of the present study	metropolitan area of Sweden participated in the study. Four	different intensities of PA measured	Was a sample size justification, power description, or variance and effect
was to further evaluate the	subjects (two men) were excluded from the analyses due to	with the accelerometer.	estimates provided? NO
concurrent and construct	incomplete log book activity recordings or failure to test aerobic		For the analyses in this paper, were the exposure(s) of interest measured
validity of the self-	fitness. The remaining 46 subjects had a higher level of education	IPAQ versus the activity monitor:	prior to the outcome(s) being measured? NO
administered, last 7 days,	than the average Swedish population, as indicated by the high	Reported time spent in vigorous-	Was the timeframe sufficient so that one could reasonably expect to see
long form version of the	prevalence of university education.	intensity PA and total amount of PA	an association between exposure and outcome if it existed? NOT
IPAQ in a Swedish sample of		from the iPAQ were significantly	APPLICABLE
adult men and women.	Inclusion:	correlated with the time spent I	8. For exposures that can vary in amount or level, did the study examine
	Healthy volunteers	vigorous-intensity PA from the MTI	different levels of the exposure as related to the outcome (e.g.,
Conclusion	A dealer de	activity monitor (p=0.55, P < 0.001).	categories of exposure, or exposure measured as continuous variable)? CANNOT DETERMINE
Results from the present	Method:	It was not a significant correlation	
	On day 1 the participants were invited to the clinic and were provided with detailed instruction on how to use the activity	between reported moderate PA by	 Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study
version, self-administered,	monitor and how to fill in the activity log book. Data on	IPAQ and the MTI activity monitor.	participants? YES
last 7 days IPAQ instrument	anthropometric and demographic characteristics were collected.	TRACtand the With activity monitor.	10. Was the exposure(s) assessed more than once over time? NO
has acceptable validity properties for assessing	Starting on day 2 the participants wore the activity monitor for	Not significant absolute difference	11. Were the outcome measures (dependent variables) clearly defined,
different domains of PA, PA	seven consecutive days and filled in the log book at the end of each	between reported time for total PA	valid, reliable, and implemented consistently across all study
intensities and total PA in	day. On day 8 the subjects returned to the clinic, filled in the IPAQ	from IPAW and measured time with	participants? YES
healthy adults.	and performed an aerobic fitness test.	MTI activity monitor.	12. Were the outcome assessors blinded to the exposure status of
nearchy address			participants? NOT APPLICABLE
Country	Statistical analyses:	IPAQ versus the log book:	13. Was loss to follow-up after baseline 20% or less? NOT APPLICABLE
country	All statistical analyses were performed using the Statistical Package	Significant correlation between	14. Were key potential confounding variables measured and adjusted
Sweden	for the Social Sciences for Windows, version 10.0.	calculated MET-h per day from PA log	statistically for their impact on the relationship between exposure(s) and
Year of data collection	The characteristics of subjects and outcomes from the IPAQ, log	book and IPAQ (p=0.77, P<0.001).	outcome(s)? NOT APPLICABLE
	book and activity monitor are described as mean ^ standard		
2005	deviation (SD).	Significant relationship between three	Discussion
	Non-parametric Spearman correlation coefficient(r) used to assess	of four domains from IPAQ and log	Strength:
	the relationship between MET-h week-1 from IPAQ data and MTI	book; "work PA, p=0.64; home/garden	 No missing data.
	counts, log book outcomes, aerobic capacity and BF (%). Bland-	PA p=0.47; leisure-time PA p=0.58".	 MTI activity measurements were performed for the same time period as
	Altman method used to provide an indication of systematic and	Time spent sitting were also significant	the questionnaire. This gives no reason to believe that the respondents
	random error and heteroscedasticity of data. Variables used for the	p=0.75, P<0.05.	did not refer to the same day when answering the questionnaire.
	Bland–Altman analysis were weekly time spent in moderate and		Weakness:
	vigorous activity according to IPAQ versus MTI and the weekly total	Aerobic fitness	 Uniaxial activity monitor – known to underestimate PA levels in specific
	amount of PA (MET) according to IPAQ versus the logbook. The	Weak positive correlation with total	activities.
	level of significance was set at P , 0.05.	amount of PA and time spent in	 Self-reported questionnaires overestimates of high-intensity activities are
		moderate-intensity PA from IPAQ	known, while underestimating light-moderate intensity activities.
	Approvals:	p=0.21, P<0,05). No significant	 Cut-off points for vigorous and moderate PA obtained from experimental aturds. Different set off exists have been supported error experimental
	The ethics committee of Huddinge University Hospital approved the	-	study. Different cut-off points have been suggested more recently.
	study protocol and the subjects provided written informed consent.	and time spent in vigorous activity	
		from IPAQ.	

	opes AA, Bragg-Gresham JL, Kurokawa K, Map.	es DL, Akizawa T, et al. Health-relat	ed quality of life am	ong dialysis patients o	on three conti	nents: The Dialysis	Outcomes and	Practice Pa	tterns Study.	Kidney Inte	ernational.			n: cross sectional observational				
2003;64(5):1903-10.										Level of III								
													evidence GRADE	Moderate/low				
Alian of study.	Patients and Methods												GRADE	Discussion/comments/check-list				
Aim of study The goal of the study	Study design:	A total of 7378 patients were inclu	ded in the applycer	2406 in Europe, 209		esults	ator HROOL da	ta wara oht	tained from a	norovimate	Ju SOM of th	e elizible	Checklist					
was to document	Cross-sectional observation study.	patients. Average age 59.4 years.	· · ·	; 2406 in Europe, 206	/ in Japan and	2005 In United St	ales. HRQUL da	ala were obl	lamed from a	pproximate	ery 60% of th	ie eligible		Was the research question or objective in this p	aper			
international	We examined data from the Dialysis	patients. Average age 55,4 years, 1	7,570 mares.										1.	clearly stated? YES	Juper			
differences in HRQOL	Outcomes and Practice Patterns Study	Results. In all generic HRQOL subs	ales natients on al	three continents had	much lowers	cores than their re	espective nonu	lation norm	values Patier	nts in the II	Inited States	had the	2	Was the study population clearly specified and				
among dialysis	(DOPPS), a prospective, observational.	highest scores on the mental healt												defined? YES				
patients and to	international study of haemodialysis	United States or Europe, but they				,	- P P	· · · · · · · · · · · · · · ·				3 III LIIC	3.	Was the participation rate of eligible persons at	t least			
identify possible	patients.	office states of Europe, but they	siso reported the Br	catest barach of kian	cy 015c05c. 01	eran, enese amere	inces remained	- even areer	aajasting tot	possible co	mounders.			50%? YES, 60 %				
explanations of those		Table 1: Almost all comorbid condi	tions were most co	mmon among the US	patients and	east common amo	ong the Japane	se patients, e	except diabet	tes which w	as least con	nmon among	4.	Were all the subjects selected or recruited fron	n the			
differences.	Population:	ro-DOPPS patients. Highest annual income most common among Japanese patients, least common in Euro-DOPPS patients. Unemployment and disability most common in US												same or similar populations (including the same	e time			
Conclusion	It was performed a cross-sectional analysis	in o on o particular ingress and income most common anong apparese parents, rest common in 200 on in proteins, one populate and assume most common in our												period)? Were inclusion and exclusion criteria f	or			
On all three continents,	of DOPPS data from the United States, five					being in the study prespecified and applied unit												
ESRD and	countries in Europe (France, Germany, Italy,	Table 2: HRQOL scores show Japan	ese patients score l	best physical functioni	ing. Mental co	mponent summar	y and mental h	ealth were s	significantly h	igher for pa	atients in US	compared to		to all participants? NO, recruited from three dif	ferent			
haemodialysis	Spain, and the United Kingdom), and Japan.	Europe. Japanese patients reporte	d the greatest burd	en of kidney disease.										continents with cultural differences. Population	n was			
profoundly affect		Table 1. Mean demographic rest	alts, comorbid conditions, and c	linical and socioeconomic variable	5		Table 2. Unadjusted	I and adjusted by the	th related condition of t	in direction	674			similar.				
HRQOL. In the United	Method:	Characteristic	Europe	Japan	United States			-DOPPS	th-related quanty of I Jars		res United	States	5.	Was a sample size justification, power descripti	on, or			
States, the effects on	Random samples of 20 to 40 haemodialysis	Sample size number	2406	2087	2885	HRQOL Measure	Unadjusted	Adjusted	Unadjusted	Adjusted*	Unadjusted	Adjusted*		variance and effect estimates provided? NOT				
mental health are	patients were selected from each facility. At	Age years Male %	59.9 57.9	58.4* 62.6*	59.6 52.8* 39.0*	SF-36 Physical functioning			(I. ^m)	(0. ^m	a) -	42.7		APPLICABLE				
smaller than in other	study entry a medical questionnaire	Black % Comorbidities %	1.6	0.0		Role (physical)	46.9 34.4 57.9	45.0 37.2 56.4	65.3 ^b 48.7 ^b	60.3* 46.5* 61.4*	40.8* 31.7 59.0	42.7 ^e 37.6 57.1	6.	For the analyses in this paper, were the exposu				
countries. Japanese	completed by the nurse coordinator in the	Coronary artery disease Congestive heart failure	28.7 24.1	18.7° 5.6°	48.3° 43.9°	Bodily pain General health	36.9	56.4 36.1 34.7	48.7° 64.8° 43.4° 41.8° 53.0° 70.1° 53.6°	40.7*	40.7*	41.02		of interest measured prior to the outcome(s) be	eing			
haemodialysis patients	dialysis unit provided information about the	Other cardiac problem Hypertension	24.1 36.2 72.5	23.9° 56.1°	34.6 83.7 ^b	Physical component summa Vitality Social functioning	41.9	34.7 42.4 62.2	41.8° 53.0°	40.0 ⁴ 50.8 ⁴	33.1° 42.9	33.4° 43.4 63.5	-	measured? NO.				
perceived that their	patients and the practice pattern of the	Poripheral vascular disease Cerebrovascular disease	22.0 13.2	10.9 ^a 11.8	24.3 16.8*	Role (emotional)	62.1 46.1		70.1° 53.6'	69.2 ⁶ 48.7	42.9 62.1 51.8 67.3		/.	Was the timeframe sufficient so that one could				
kidney disease imposes	facility. Within 60 days of completion of the	Diabetes (primary or contributing) Lung disease	19.3 10.7	25.4* 1.2*	24.3 16.8° 44.4° 12.2 9.2 1.1° 8.9°	Mental health Mental component summar	59.9 43.2	60.8 44.1	63.5 ^o 44.8 ^o	61.8 44.0	67.3* 46.6*	68.2 ^b 47.6 ^p		reasonably expect to see an association betwee exposure and outcome if it existed? NOT APPLI				
a greater burden, but	medical questionnaire, the study	Cancer (other than skin) HIV/AIDS	9.0 0.2 5.2 5.4	5.1° 0.0	9.2	KDQOL Symptoms, problems	69.9	70.4	75 <i>.8</i> *	73.8	71.1	72.5		For exposures that can vary in amount or level.				
their physical	participants filled out a patient questionnaire, which included the questions	Gastrointestinal bleeding Neurological disease	52	3.3* 3.5* 2.2*	8.9	Effects Burden	57.3 35.4	57.9 36.8	67.7° 28.6°	66.7° 27.6°	71.1 62.5 ⁹ 40.8 ⁹	72.5 63.1 42.4	0.	the study examine different levels of the exposi-				
functioning was		Psychiatric disorder Recurrent cellulitis	23.9 6.2		11.P 22.6 10.0 27.5	Work status Cognitive functioning Quality social	25.2 73.6	28.5 74.3 77.2 66.7	44.8 ⁶ 81.7 ⁶	73.8 ^o 66.7 ^b 27.6 ^b 33.0 ^o 80.0 ^b	20.0 ^b 77.2 ^b	27.0 78.0 ⁶		related to the outcome (e.g., categories of exposi-				
significantly higher.	of the Kidney Disease Quality of Life Short Form (KDQOL-SFTM). Scores on all eight	Dyspnea Primary cause of ESRD %	18.9	1.9° 2.4°	27.5*	Quality social Sexual functioning	77.0 67.7	77.2 66.7	60.9° 65.2	60.6*	75.9 60.7*	76.0 60.5		or exposure measured as continuous variable)?				
Different distributions of socioeconomic	subscales of the SF-36 were examined.	Diabetes Giomerulonephritis	13.8 16.2	22.4 54.7	36.6	Sleep Social support	57.1 73.0	58.1 73.0	75.8 67.7 28.8 44.8 81.7 60.9 65.2 63.2 72.4 78.9 77.1 8 59 77.1 8 59	61.2" 72.0 79.3 76.2" 63.3	20.0 ⁰ 77.2 ⁶ 75.9 60.7 ⁶ 58.3 73.1	27.0 78.0 60.5 59.9 74.1 78.0 69.2 63.7		CANNOT DETERMINE				
factors and major	Demographic and comorbidity data were	Openetronic parties Hypertension Other	10.5	3.6 19.3	36.6 11.9 28.9 22.6	Staff encouragement Satisfaction	82.8 71.3	80.5 68.9	78.5° 77.1°	79.3 76.2*	70.5	78.0° 69.2	۹	Were the exposure measures (independent var	iables)			
comorbid conditions	abstracted from patients medical records at	Hematocrit % (mean and SD)	32.5 (5.2)	30.1 (4.2) ⁶	32.9 (4.7)	Average KDQOL	62.4	62.7	65.9	63.3	62.9	63.7		clearly defined, valid, reliable, and implemente				
could explain little of	their entry into the study; age, gender, race,	Years on dialysis %	22.6 37.2	11.0	29.3 41.9	*Adjusted for patient character *P < 0.0001 vs. Euro-DOPP *P < 0.05 vs. Euro-DOPPS	s and the second s							consistently across all study participants? YES	-			
this difference in	primary cause of ESRD, haematocrit,	4-6	16.1	28.3 20.6 14.1	16.7	7 < 0.0 % Euro DOFF3							10.	Was the exposure(s) assessed more than once	over			
physical functioning.	number of years on dialysis, complications	>11	10.4 13.7	14.1 26.0	16.7 7.3 4.8		feans of norm-based se			- 14 K				time? NO				
Other possible factors.	of ESRD, annual household income,	Complications of ESRD % Carpal tunnel syndrome	7.6	11.0* 14.9*	5.3* 1.9	Table 3. N	Euro-DOPP		standard deviation u Japan	nits, from general	-population data) United	States	11.	Were the outcome measures (dependent varial	bles)			
such as quality of	employment status, and 15 comorbidities.	Antyloidosis (B ₂ microglobulin) Parathyroidectomy Annual household income (US \$)	7.6 7.3 8.3	14.9° 4.2°	1.5° 4.0°	HRQOL Measure		-	Unadjusted	Adjusted*	Unadjusted	Adjusted*		clearly defined, valid, reliable, and implemente	d			
dialysis and related		Annual household income (US \$) <\$5000 \$5000-\$10,000	16.6	63	15.8]	Physical functioning Role (physical)	-1.52	-1.65	-1.13*	-1.34 ^b -1.05	-1.52	-1.48' -0.98'		consistently across all study participants? YES				
health care, deserve	Statistical methods:	\$10,000-\$20,000	29.2 30.0 18.3	26.8	27.4 26.1	Role (physical) Bodily pain General health	-1.22 -0.57 -1.31	-0.63	-1.04° -0.43°	-0.52	-0.46*	-0.56	12.	Were the outcome assessors blinded to the exp	oosure			
careful study.	Simple means and frequencies for the crude	\$20,000-\$40,000 \$40,000-\$75,000	18.3 4.8 1.1	6.3 26.8 27.6 19.7 9.5 10.2	15.8 27.4 26.1 20.0 8.5 2.1	General health Vitality Social functionine	-1.31 -0.95 -0.97	-1.65 -1.14 -0.63 -1.37 -0.94 -0.97	-0.95 ^b -0.62 ^b -0.79 ^c	-1.06 ^b -0.71 ^b -0.80 ^e	-1.16 -0.46 ^a -1.29 -0.77 ^b -0.83 ^a	-0.56 -1.27 ^e -0.76 ^e -0.76 ^e		status of participants? NOT APPLICABLE				
	baseline scores. Linear mixed models were	>\$75,000 Employment status* %				Role (emotional)	-0.97 -1.20 -0.63	-0.97 -1.12 -0.57	-0.79 -0.83 ^b -0.50 ^c	-0.80° -0.96° -0.57	-0.83* -0.80* -0.46*	-0.76* -0.61* -0.41*	13.	Was loss to follow-up after baseline 20% or less	s? NOT			
Country	used to take into account possible	Employed Disabled	26.8 20.0	53.3° 4.0*	16.8° 36.6°	Mental health *Adjusted for patient charac *P < 0.0001 vs. Euro-DOPP		-0.37	-0.50*	-0.57	-0.46*	-0.41*		APPLICABLE				
USA, France, Germany,	influences on the comparisons of HRQOL	¹ P value < 0.05 vs. Europe ¹ P value < 0.000 vs. Europe				⁹ P < 0.0001 vs. Euro-DOPP ⁴ P < 0.05 vs. Euro-DOPPS	s							Were key potential confounding variables measured				
Italy, Spain, United	scores among continents, including the	-r value < 0.000 vs. Europe												and adjusted statistically for their impact on the				
Kingdom and Japan.	effects of demographic characteristics,													relationship between exposure(s) and outcome	e(s)??			
Year of data collection	comorbidities, cause of ESRD, haematocrit,													YES.				
2003	time on dialysis, employment status, and												D:	russion				
	annual household income. Sensitivity													cussion ength:				
	analyses were conducted to investigate the choice of adjustment variables.													engtn: Many subjects, high response rate.				
	We also used the linear mixed models to													When they studied the characteristics of non-				
	determine adjusted HRQOL scores and to													respondents, it showed no clinically important b	ias			
	compare average values among the													respondents, reanowed no enricarly important o				
	continents, taking into account clustering at												Wez	akness:				
	the facility level. Mixed models were also													Healthier patients were more likely to complete	the			
	used to compare simple means among the													questionnaire, which might have biased the sam				
	continents, adjusting for facility clustering.													toward healthier respondents.				
	All statistical analyses were performed with													Self-administered questionnaire –				
	SAS, version 8.2.													over/underreporting.				