# Pre-emptive rehabilitation to prevent dialysisassociated morbidity

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
19/03/2018		☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
20/03/2018		Results		
Last Edited		Individual participant data		
27/03/2019	Urological and Genital Diseases	<ul><li>Record updated in last year</li></ul>		

### Plain English summary of protocol

Background and study aims

Chronic kidney disease is a long-term condition where the kidneys don't work as well as they should. Dialysis treatment to replicate some of the kidney's functions may be necessary in advanced cases. Chronic kidney disease and dialysis often lead to frequent hospital admissions, and are associated with increased lethargy (tiredness), muscle wasting, reduced independence and poorer quality of life. Increased exercise, improved nutrition, and education before patients start dialysis can help maintain independence and improve health on starting dialysis. This study aims to investigate whether regular exercise, good nutrition and education, commencing before dialysis starts and continuing for the first 6 months of dialysis, leads to greater improvements in exercise ability, independence, and quality of life, than usual care.

#### Who can participate?

Patients aged 18 and over who are expected to start dialysis within the next 12 months

#### What does the study involve?

All participants attend an appointment for exercise tests to measure muscle function and exercise ability, scans to measure muscle mass, and to complete questionnaires to assess appetite and quality of life. Participants are then randomly allocated to the treatment group or usual care group. The treatment group involves a 10-week exercise and education programme. Each session lasts for 2 hours, with an hour of exercise followed by an education session that aims to help participants to cope better with dialysis. Participants are given an individual exercise and care plan to follow. The exercise and education sessions continue once per month until starting dialysis, and for the first 6 months of dialysis. Participants in the usual care group continue with usual clinic appointments and dialysis. The assessments done at the start of the study are repeated at several timepoints throughout the study, before and after starting dialysis. Results from these assessments are compared between the groups to assess whether this treatment is better than usual care at maintaining independence and quality of life in patients starting dialysis.

What are the possible benefits and risks of participating? Not provided at time of registration Where is the study run from?

- 1. Royal Derby Hospital (UK)
- 2. Nottingham University Hospitals City Hospital Campus (UK)

When is the study starting and how long is it expected to run for? March 2016 to June 2020

Who is funding the study? Kidney Research UK

Who is the main contact? Fiona Willingham

## Contact information

## Type(s)

Scientific

#### Contact name

Miss Fiona Willingham

#### **ORCID ID**

https://orcid.org/0000-0003-2764-7173

#### Contact details

Department of Nutrition and Dietetics Derby Teaching Hospitals NHS Foundation Trust Derby United Kingdom DE22 3NE

## Additional identifiers

Protocol serial number

35594

# Study information

#### Scientific Title

Pre-emptive rehabilitation to prevent dialysis associated morbidity (PREHAB-2): a study to assess the impact of exercise, nutritional intervention and multidisciplinary education upon outcomes in patients approaching and commencing dialysis

### Acronym

PREHAB-2

## **Study objectives**

Chronic kidney disease and dialysis often lead to frequent hospital admissions, and are associated with increased lethargy, muscle wasting, reduced independence and poorer quality of life. Previous work from our unit shows that increased exercise, improved nutrition, and

education, before patients start dialysis, can help maintain independence, and improve health on starting dialysis.

This project aims to investigate whether regular exercise, good nutrition, and education, commencing before dialysis starts and continuing for the first 6 months of dialysis, leads to greater improvements in exercise ability, independence, and quality of life, than usual care.

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

East Midlands - Derby Research Ethics Committee (REC), 04/10/2017, ref: 17/EM/0290

#### Study design

Randomised; Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Physical

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Renal failure

#### **Interventions**

Patients expected to start dialysis within the next 12 months will be invited to take part. Patients who agree to take part will be asked to sign a consent form. All participants attend an initial assessment appointment, for exercise tests to measure muscle function and exercise ability, scans to measure muscle mass, and to complete questionnaires to assess appetite and quality of life. Participants are then randomly allocated to the treatment group or usual care group.

The treatment group involves a 10-week exercise and education programme. Each session lasts for 2 hours, with an hour of exercise, followed by an education session, which aims to help participants to cope better with dialysis. Participants will be given an individual exercise and care plan to follow. The exercise and education sessions continue once per month until starting dialysis, and for the first 6 months of dialysis.

Participants in the usual care group continue with usual clinic appointments and dialysis.

The assessments done at the beginning of the study are repeated at several timepoints throughout the study, before and after starting dialysis. By comparing results from these assessments between the groups, we can assess if this treatment is superior to usual care in maintaining independence and quality of life in patients starting dialysis.

#### Intervention Type

Other

### Primary outcome(s)

Functional and exercise capacity, determined by the Incremental Shuttle Walk Test; Timepoint (s): End of the study

#### Key secondary outcome(s))

- 1. Objective changes in functional capacity, determined by increased muscle mass, strength and function, will be assessed using the short physical performance battery test, single repetition maximum for leg extension and bicep curl, and one minute sit to stand, will be measured at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis 2. Objective and subjective changes in nutritional status will be measured using a combination of validated methods, including weight, body mass index (BMI) and percentage weight change, mid upper arm circumference, handgrip strength, dietary intake and appetite assessment, and subjective global assessment of nutritional status will be assessed at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis
- 3. Subjective changes in functional and exercise capacity, determined by patient perception of functional capacity using the Duke Activity Status Index (DASI) questionnaire, and exercise self-efficacy score will be measured at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis
- 4. Subjective improvement in quality of life, determined by DASI questionnaire, Patient Activation Measure, Renal Distress Thermometer, FACIT-Fatigue Score, Hospital Anxiety and Depression Scale (HADS), and nested qualitative interview studies will be measured at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis
- 5. Changes in body composition will be measured using DEXA scans and muscle ultrasound scans at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis 6. The presence of oxidative stress and assessment of cardiovascular risk will be measured from levels of advanced glycation end products (AGEs) via skin autofluorescence at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis

## Completion date

30/06/2020

# **Eligibility**

### Key inclusion criteria

- 1. Male and female aged 18 years and above
- 2. eGFR less than 15mls/min
- 3. Rate of change in eGFR indicates that dialysis will be initiated within 12 months from commencing the study
- 4. Attending the low clearance clinic
- 5. Patient has opted for dialysis
- 6. Patient is able to exercise

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

Αll

#### Key exclusion criteria

- 1. Patient is not predicted to require dialysis within 12 months of commencing the study
- 2. Patient has chosen conservative care rather than opting for dialysis
- 3. Severe physical impairment and/or significant comorbidity that makes exercise impossible or unsafe, defined by exercise-induced angina, inability to walk less than 50 metres, or dyspnoea with effort
- 4. Insufficient command of English to provide informed consent or comply with the testing protocol and exercise and education component (if results indicate the intervention to be beneficial, future studies will include provision for such patients)
- 5. Patient is pregnant (therefore is unable to undergo Dual X-Ray Absorption (DEXA) Scan)

#### Date of first enrolment

01/04/2018

#### Date of final enrolment

31/03/2019

## Locations

## Countries of recruitment

**United Kingdom** 

England

# Study participating centre Royal Derby Hospital (lead centre)

Uttoxeter Road Derby United Kingdom DE22 3NE

## Study participating centre

Nottingham University Hospitals City Hospital Campus

Hucknall Road Nottingham United Kingdom NG5 1PB

# Sponsor information

## Organisation

Derby Teaching Hospitals NHS Foundation Trust

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

Kidney Research UK (KRUK); Grant Codes: AHPF\_004\_20160729

#### Alternative Name(s)

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

**United Kingdom** 

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Other

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes