Dr Sharlene Greenwood
Consultant Renal Physiotherapist

The Renal Unit
Unit 6 KCH Business Park
London, SE5 9RS

Direct Tel: 0203 299 6725
Direct Fax: 0203 299 6940

Patient Information Sheet V1.0 8th of January 2018

---

1. Study title

Exercise Training and Progression of Chronic Kidney Disease: A Randomised Controlled Feasibility Study. The GFR-Exercise Feasibility Study.

2. An invitation

You are being invited to take part in a research study. Joining the study is entirely up to you. Before you decide, it is important for you to understand why the research is being done and what it will involve. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

3. What is the purpose of the study?

Chronic kidney disease (CKD) affects 1 in 17 adults in the UK. CKD is described as progressive loss of function of the kidneys over a period of months or years, regardless of the original kidney disease. Non-drug related treatments that can potentially slow down the decline of kidney function and delay end stage kidney failure, and associated costly and life altering treatment options such as three times per week haemodialysis or a kidney transplant, are urgently needed. We would like to find out if exercise training could be used to slow down the progression of kidney disease. We will assess this with measured glomerular filtration rate clearance (kidney function measurement). The main objective of this current proposed study is to determine if it is feasible to recruit, randomise and retain participants in this type of study.

4. Why have I been invited?

You have been invited to take part in the study because you have been diagnosed with Chronic Kidney Disease Stage 3 – 4, which means that you have reduced kidney function. This is the stage of Chronic Kidney Disease we are interested in investigating.

5. Do I have to take part?

Taking part in this research is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be able to keep this information sheet and think about taking part. You are free to discuss the information with anyone you wish including your family and friends. If you agree, we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

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

If you agree to take part, the doctor, research nurse or physiotherapist will explain the proposed study and the various things that this will involve for you. He/She will explain any possible risks or complications that may occur. He/She will give you this information sheet and will ask you to sign the accompanying consent form so that you can be enrolled into the study.

Following consent, you will have your first (baseline) tests. This visit will take a maximum of five hours. From 10.00pm the night before the test, stop drinking anything containing caffeine including tea, coffee and Coke. A light breakfast is recommended on the morning of the test, with fruit juice or water. Continue to drink water at the rate of a glass an hour on the morning of the test.

During this visit you will:

- Complete a review of your medications.
- Be asked questions about any pain or illness you have had since starting the study.
- Have your height, body mass, and waist and hip circumferences measured.
- Have the health of your heart and blood vessels assessed.
  - o You will be asked to lie down.
  - o Your heart rate will be recorded.
  - o Your blood pressure will be recorded by inflating a cuff on your arm.
  - o To assess the stiffness of your blood vessels, a cuff will placed on your neck and at the top of your leg near your groin
- You will be tested for body composition using a bioelectrical impedance machine.
  - o Whilst lying down we will attach an electrode to one of your feet and to your hand, this is not painful and the electrode will feel cold.
- You will have the strength of your knee straightening muscles assessed using a dynamometer machine.
  - o You will sit on a fixed chair and have a strap positioned around the lower part of your leg.
  - o You will then be asked to straighten your knee as hard as you can, and a measurement will be recorded.
  - o You will complete this procedure a total of three times.
- You will then sit on a stationary exercise bike to do a cardiopulmonary fitness test.
  - o You will wear a strap around your chest, an inflating blood pressure cuff on your arm, and a mask over your nose and mouth (that will not restrict your breathing).
  - o You will exercise on the bike for approximately 20 minutes.
  - o Every minute the exercise will feel slightly harder.
  - o You will continue exercising until you reach your maximum effort or until you wish to stop.

- You will also be asked to complete a questionnaire assessing habitual physical activity, quality of life, and will be asked to wear an accelerometer device (a small square device that clips onto your clothing).

- You will then visit the radiology unit nearby to have a contrast enhanced ultrasound done of your kidneys to assess the health of the small vessels.
  - o You will be asked to lie down.
  - o You will then receive an injection of a small amount of contrast substance that allows the very small vessels of the kidney to be seen.

o An ultrasound probe will be passed over the skin above where the kidneys are located, and an image will be stored and analysed.

You will then visit the Nuclear Medicine Department to have the function of your kidneys measured. The procedure is performed by nuclear medicine technologists, who will need to obtain your height and weight. A small amount of radioactive Cr51 EDTA is injected into your bloodstream. The technologists then calculate the rate at which it is removed by the kidneys. The nuclear medicine technologist will arrange to take blood samples at 2, 3 and 4 hours after the injection. During and after the test you can carry on with your normal activities. You can eat and drink as normal. There are no restrictions to activities after the test. There have been no adverse reactions recorded for this test but you may have some bruising around the injection site. This test involves using radioactive materials and so has the usual risks associated with ionising radiation. The amount of radiation used is roughly equivalent to that which you receive from natural background radiation in about 4 days. This adds very slightly to the risk of, for example, developing a cancer. However, as one in three of us will develop a cancer at some stage during our lives, the added risk is very small. The risk may be considered greater if you are pregnant and you should inform the Nuclear Medicine Department if you are pregnant or you think you might be pregnant, or are breastfeeding.

The ultrasound of the kidney will be re-assessed at 12 months. All other measures will be re-assessed at 6 and 12 months.

Up to twenty patients will be asked to attend a one-off visit to talk about their experience of the study, and what it is like to live with a condition like chronic kidney disease. Every effort will be made to combine this with another clinic appointment. If this is not possible, transport will be arranged up to a maximum of £30.00 return.

This study involves two groups. After the baseline test, you will be allocated by chance to a usual care plus exercise training group, or a usual care group. If you are allocated to the exercise group, you will attend 3 one-hour sessions per week of exercise training and will be supervised in small groups by a trained physiotherapy assistant in a hospital gym-setting, and be encouraged to do a further one unsupervised session per week at home.

7. What do I have to do?

A full schedule of the tests and visits we will be asking you to undertake is shown in the table below.

Table 1: Schedule of Tests and Visits

Study Visits	**Visit 1 / Baseline**	**Weekly Supervised Exercise** *Patients Randomised to the Usual Care Plus Exercise Group*	**Month 6**	**Month 12**
Informed Consent and registration.	Yes		Yes	Yes
Medical history, height, weight, blood pressure, pulse rate, medications, waist and hip circumference	Yes		Yes	Yes
Blood Test for kidney function using using chromium-51 labeled ethylenediamine tetraacetic acid (^{51}Cr-EDTA)	Yes		Yes	Yes
Urine Test (Albumin to Creatinine ratio and Protein to creatinine ratio)	Yes		Yes	Yes
Pulse Wave Velocity	Yes		Yes	Yes
Body composition assessed using a bioelectrical impedance machine				
Cardiopulmonary Testing (VO_2peak) assessment	Yes		Yes	Yes
International Physical Activity Questionnaire and Quality of Life Questionnaire	Yes		Yes	Yes
GTX Accelerometer to be worn for 2 weeks				
Knee extension (straightening of the knee) assessment	Yes		Yes	Yes
Contrast ultrasound of the kidneys	Yes			Yes
Interviews to talk about the study experience (up to 20 participants)				Yes (if asked to take part)
Supervised Exercise		Yes		

We will also review your clinical notes and medical history as part of the study. This information will be strictly confidential.

8. What are the alternatives for me if I do not decide to take part?

This study is not providing any additional treatment, therefore, if you chose not to take part, you will continue to receive your normal treatment and follow up in clinic.

9. What are the possible benefits of taking part?

The main benefit is to help improve care for future patients.

10. What are the possible disadvantages and risks of taking part?

The risk of a serious illness from participating in this study is very low. There have been no cases reported of chromium-51 labeled ethylenediamine tetraacetic acid (^{51}Cr-EDTA) causing kidney damage at the low dose which will be used in the study.

If you do agree to take part in this study, there will be additional time involved. To minimize your inconvenience, wherever possible, all assessments and interviews will be scheduled around your routine clinic appointments. We will award you £5.00 food voucher during the kidney function test appointment, and in the unlikely event that we cannot arrange the interviews to be conducted around your clinic visits, we will book transport up to a maximum of £30.00 return. In order for you to be able to attend the exercise classes on the 3 days of the week, if you are randomised to the exercise group, a maximum of £5.00 per session will be allocated to you to cover local public transport costs.

11. What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time; and if you would like to do so; please speak to your study physiotherapist or doctor.

Your decision to withdraw from the study will not affect the care you receive.

If you were to become unwell and loose the capacity to make your own decision, you will be withdrawn from the study. This means any information gathered for this study before this point will be anonymised and used for the study. You would not be asked to perform any further assessments.

If you withdraw your consent;

- Information collected about you may be used if you are happy with this.
- You can withdraw consent for all information collected to be destroyed where this is possible
- We would like to keep in contact with you through your doctor or GP so that we can know about your progress.

12. What if new information becomes available?

As we are creating a new health application, if new information becomes available, we will keep you informed throughout the duration of the study.

13. What happens when the research study stops?

When the study is over, we will send you a summary of the results and will be happy to discuss this with you further if you wish.

14. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer any of your questions. The contact details for the GFREx study Principal Investigator is: **Dr Sharlene Greenwood, 0203 299 6725**.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office are below:

King's College Hospital Patient Advisory and Liaison Service (PALS) on 0203 299 9000 Extn 33601.

Every care will be taken in the course of this study. However in the unlikely event that you are injured by taking part, compensation may be available.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King's College Hospital NHS Trust but you may have to pay your legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study the normal National Health Service complaints mechanisms are available to you. Please ask your research nurse, study physiotherapist or doctor if you would like more information on this.

15. Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the study will be kept strictly confidential and secure.

16. Involvement of the General Practitioner/Family Doctor (GP)

With your consent, your GP will be informed of your involvement in the trial. Any other medical Practitioners who treat you, e.g. should you be admitted to hospital for any reason, will also be informed.

17. Will you have access to my medical notes?

Relevant sections of your medical notes and data collected during the trial will be looked at, in confidence, by authorised individuals from the study team. This data will be kept strictly confidential by the research team. Data will be anonymised into participant trial number rather than name. Data will be stored securely and in locked filing cabinets. Computer spreadsheets will be password protected and accessible only by the direct research team.

18. What will happen to the results of the research study?

The results will be presented at scientific meetings and also published in the scientific literature.

19. Who is organising and funding the research?

This research trial is being sponsored by King's College Hospital. The Principal investigator of the study is Dr Sharlene Greenwood who will lead this trial.

20. Who has reviewed the study?

The study has been reviewed internally within the Renal Unit at King's College Hospital and has been reviewed by the Sponsor.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by London - Camden & Kings Cross Research Ethics Committee. It has also been approved by the Health Research Authority and each local hospital will also give confirmation that the study can go ahead.

21. Contacts for further information

Sharlene Greenwood
Consultant Renal Physiotherapist and Principal Investigator of this study
King's College Hospital, London, SE5 9RS
0203 299 6725
Email: Sharlene.greenwood@nhs.net

Dani Nebres
Study Coordinator
King's College Hospital, London, SE5 9RS
0203 299 6725
Email: d.nebres@nhs.net

Thank you

Thank you for considering taking part and taking the time to read this information sheet.
If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.