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Understanding Frailty, Falls and the Role of Exercise in Haemodialysis Patients: A Qualitative Study (FLEX-HD)

Patient Information Sheet

V3.0, dated 10th March 2017

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. 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. We'd suggest this should take about 45 minutes. Please feel free to talk to others about the study if you wish.

The first part of this Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about the conduct of the study. Do ask if anything is unclear or if you would like more information. Take time to decide whether or not you wish to take part.

Why is This Study Needed?

Long-term kidney disease that requires treatment with haemodialysis can often lead to health and wellbeing difficulties that increase the risk of trips, slips and falls. Falling is the second most common safety risk to people on haemodialysis within the UK and can lead to other issues such as broken bones, loss of mobility, independence and confidence, all negatively affecting quality of life. Despite this, falls have not received much research attention and at the moment we do not know a great deal about what causes them or what the impact of these is from the patients point of view. Other studies involving people with different diseases who fall, have found that exercise can be beneficial, but this hasn’t been tested with patients on haemodialysis. To help us to begin to design, develop and test such an exercise programme, we first need to understand patients’ experiences’ of living with kidney disease and regular haemodialysis, including their experiences of falling over, slips, trips, or unsteadiness. We also aim to find out what patients think about a specific intervention to address these problems and a bigger study in the future to test if this intervention is effective.

What Does Taking Part in the Study Involve?

In this study we are interested in the experiences and thoughts of haemodialysis patients who have experienced a fall. We aim to recruit 30 participants with the Leicester Dialysis Network. If you choose to take part, you will be involved in the study for a period of four months. During this time, we will invite you to take part in two interviews and to complete a diary about your daily activities and experiences. The interviews will be approximately three months apart. In the first interview will ask you about your experiences of dialysis and falling over. We will then ask you to keep a diary about your experiences of kidney dialysis and falls. After this we will ask you to take part in a second interview. This final interview will include a discussion about your diary, what you think about a specific intervention to address falls and a bigger study to test how effective this intervention is.

At the end of the study we will compare and contrast all of the things people have said and recorded in their diaries to give us an overall picture of:

- What it's like to live with kidney disease and haemodialysis
- How people experience falls and what they believe might help us to address this problem. This will help us to design an intervention to address falls. At the moment we don't know what this intervention will look like, but it may include things such as exercise and education, which are known to help other groups of patients who fall.
- What people think about being in a larger study designed to address falls

Why have I Been Chosen/ am I Eligible to Take Part?

You have been chosen because you are:

- Receiving regular haemodialysis for three months or more;
- Aged 18 or over;
- Able to read or speak English, and understand it;

and because

- You have had a fall in the past six months
- Your doctor considers you suitable to exercise (although we will not be asking you to exercising during this study).

These things mean that you have enough experience to tell us your views and thoughts.

Do I Have to Take Part?

No, it is completely up to you. If you decide to take part you will be asked to sign a consent form at your next haemodialysis appointment, once you have read this information sheet. You are free to withdraw at any time, without giving a reason and a decision to withdraw will not affect the standard of care you receive in any way.

What Should I do if I Want to Take Part?

If you would like to take part, please let the member of the research team know. They will come and speak to you about the study during a haemodialysis appointment. You will have the opportunity to ask any questions.

What Will Happen During my Next Haemodialysis Appointment?

At your next usual haemodialysis appointment one of the research team will ask if you have received and understood this information leaflet and whether you would like to take part in the study. You will also have the chance to ask any questions that you might have before deciding whether to join. If you are still happy to participate in the study you will be asked to sign a consent form and you will be given a copy of this form along with this information sheet to keep. With your permission, your GP will be informed that you are taking part.

What Will Happen After I Enrol in the Study?

During the study, we will ask you to continue your life in the usual way. You should follow your usual recommended diet, and take your usual medicines as prescribed.

After enrolling, the researcher will collect some basic details (for example, your age, gender, current medication, ethnicity, social situation, employment) and information about your condition, other illnesses and medications from yourself and your medical records. You will then be invited to attend two one-to-one interviews scheduled at your convenience. You will also be asked to keep a diary for a period of time between one and three months that suits you. More details about the interviews and the diary are provided below.

For first interview (the '**Pre-diary' interview**), you will be asked to take part in an individual interview, although you may bring along a relative or friend, if you wish. The interview will be led by a researcher who has no involvement with the clinical care team, and will only be heard by the research team. The interviews will be arranged at your convenience and can take place in a comfortable, private room at the hospital (away from the haemodialysis unit), in your own home, or during haemodialysis, whichever is preferable to you.

At the start of the interview the researcher will introduce the session, explaining the background and reasons for the study, how the interview will proceed, and details of audio-recording and note-taking. Ground rules for the interview will be set (e.g. keeping the interview anonymous and confidential) and you will be given the opportunity to ask questions.

Once you are ready, the interview will begin. At this point, the audio-recording will start and the researcher may make some notes on what is said. The interview will last for 60-90 minutes and we want to hear your views about living with kidney disease and your previous experiences of falls. You will not be asked to discuss anything you don't feel comfortable to, and you may stop the interview at any point.

At the end of the interview, we will ask you to keep a diary for a length of time that suits you between one and three months. We will also talk you through the diary keeping process and provide you with a 'diary keeping pack' which includes all the things you need to get started with your diary. You will be given another opportunity to ask questions. Your travel expenses will be reimbursed up to value of £25 per visit upon production of original receipts. Light refreshments will be provided during the interview.

Diary

We will ask you to keep a diary on your experiences of living with severe kidney disease, falls and any 'near misses', where you felt unsteady and nearly fell but were able to stop yourself. We are asking participants to keep a diary for several reasons. Firstly, you may overlook important and relevant things in an interview because they have become very ordinary to you. By asking you to document the 'ordinary' we can make sure we are not overlooking anything that might be important or relevant that might otherwise be missed. Diaries are also a good way of getting participants to document their true feelings and beliefs, which can sometimes be difficult when talking with a researcher face to face. Finally, in studies of falls in other patient groups, diaries are the best and most commonly used way to record falls. As haemodialysis patients haven't been asked to keep these sorts of diaries before, this study will also give us an idea of how willing they are to keep a diary and how we can support them to do this, as part of a bigger study in the future.

Detailed guidance on the sorts of things we would like you to record will be discussed in the pre-diary interview and written guidance will also be given. You will be in full control of all aspects of your diary including:

- What you decide to record and how you choose to do this. You may also choose to include photos, pictures and news clippings if you wish.
- When you complete your diary
- How much you record, and how much detail you decide to go into.

You will also have control over how long you decide to keep a diary for. We are asking participants to keep a diary for a minimum of one month, but if you wish you can keep it for up to three months, which will provide us with more detailed information over a longer period of time. You can change the length of time you decide to keep the diary for during the study if you wish.

You will also be able to choose how you decide to record your diary. We anticipate that most people will choose to keep a written diary, but some may prefer to use an audio (voice) recorder. If you would prefer to use an audio recorder, we can provide you with one as part of your dairy keeping pack, and give you some written details on how to use it. All of these options will be discussed with you as part of the pre-diary interview.

You will not need to make any extra visits to the hospital whilst you are keeping the diary, but we may contact you during the process to offer you support and help if you need it, particularly if you have chosen to voice record your diary. If you are happy for a researcher to contact you, you will be able to choose how often and how (by email, phone or at the haemodialysis unit) they will do this. Again you can alter these arrangements at any point. You may also contact the research team at any point if you have any questions or concerns. When you come to the end of the diary-keeping period, we will contact you to arrange to collect your diary and also to talk to you about a final interview (called a 'post-diary interview').

Finally, a **'post-diary' interview** will take place once you have completed your diary and we have collected it from you. You will be asked about your experiences of keeping your diary, and to talk through some of the things recorded in your diary in more detail. We will finish by asking you for your thoughts on an intervention to specifically address falls. Again, the interview will be one-to-one between you and a researcher, but you may bring along a relative or friend if you wish. The interviews will be arranged at your convenience and can take place in a comfortable, private room at the hospital (away from the haemodialysis unit), in your own home, or during haemodialysis, whichever is preferable to you. The interview will again last between 60-90 minutes and light refreshments will be available. Again, we will reimburse you for any travel expenses up to value of £25 per visit upon production of original receipts.

What Happens Next?

Your involvement in the study will be complete once you finish the 'Post-diary' interview, although the actual study will last for approximately two years. The interviews and audio diaries will be transcribed using a professional transcription service. We will analyse all these transcripts together with any written diary to build up a complete picture of participants experiences, beliefs and perceptions relating to the study aims.

What Happens When the Study Stops?

We expect the results of the research to become available from 2020.Once the study has finished we will be speaking at conferences about our research and writing articles for medical journals and other magazines. We will publicise the results in posters and leaflets in clinical areas so you can read them while you are there, we will write a report about them in our Kidney Research Newsletter and also aim to hold an event informing patients of the results. If you would like to receive our Kidney Research Newsletter, please ask the researcher or contact the Chief Investigator, Hannah Young (contact details at the end of this document). Individual participants will not be identified within these reports. Your usual clinical care will continue unchanged.

Are There any Benefits for me in Taking Part?

There are no direct benefits to you of taking part in this study, although some people find documenting and discussing their thoughts and experiences can be helpful. We hope that the results of the study will help improve existing care and services for haemodialysis patients as well as design and research improved treatments for patients in the future.

Are there any Risks or Disadvantages to Taking Part?

The main disadvantage of taking part is the time commitment involved in the visits for the interviews (2 visits if you decide to come into the hospital for them, each between 60-90 minutes) and completing the diary (approximately 5 hours in total, depending on how much you wish to write. No extra visits will be required for this part). If you come to the hospital for your interviews, we will reimburse your travel expenses and car parking up to value of £25 per visit upon production of original valid receipts.

Diaries and interviews may bring up areas where participants have experienced, or continue to experience difficulties. You don’t need to tell us about anything you don’t feel comfortable to and may stop the interview at any time. If you are experiencing a lot of difficulties, including having identified a fall in your diary, we may ask you if you wish to speak about it with your Nephrology team in more detail.

How will information about me be kept confidential?

We will follow ethical and legal practice in accordance with the Data Protection Act (1998). All information about you will be handled in confidence unless you disclose that you, or someone else, is in immediate danger of serious harm. Access to identifiable data (e.g. Names, addresses etc.) will be limited to selected members of the research team and to regulatory authorities, the NHS Trust, the sponsor and the host organisation for auditing and monitoring purposes. This information and other personal details will not be included in analysis, or in publications or reports. All information collected during the study will be identified by a unique code so that you cannot be identified from it. All data will be password protected and kept on secure computer servers and in a secure office environment within the University Hospitals of Leicester NHS Trust and the University of Leicester.

The data that we collect during the course of this study will be kept for 5 years. Our records of your personal information (e.g. names, addresses etc.) will be kept for up to 3 years following the end of the study, after which it will be destroyed.

Your identity will not be associated with any recordings made and everything you say will be entirely anonymous, including any direct quotations we may use in a report or publication about the study. If you decide to include photographs within your diary, if other patients, staff or family members (particularly children) can be identified, they will be excluded from the final analysis and any reports arising from the research.

How Can I Withdraw from the Study if I Want to do so?

The study will be most valuable if few people withdraw from it, so it is important to discuss any concerns you may have with a member of the study team before you agree to participate. However, you can withdraw from the study at any time and without giving a reason. You can withdraw by telephoning us on 0116 2584346 or by writing to the Chief Investigator (contact details at the end of this sheet).

If you decide to withdraw from the study whilst you are keeping your diary, you will be invited to return it, but this is optional.

You should be aware that if you lose capacity during the study, you will be withdrawn from any further study involvement. Any data collected up to that point will be kept for analysis and will be destroyed at the end of the study.

What if Something Goes Wrong?

In the unlikely event of you being harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

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 your questions [contact Hannah Young on 0116 2584346]. If you remain unhappy and wish to complain formally, you can contact the UHL Patient Information and Liaison Service by post to PILS, The Firs, Glenfield Hospital, Leicester LE3 9QP, telephone 08081 788337 (free phone number), or email pils@uhl-tr.nhs.uk

Who is Organising and Funding the Research?

The research is being organised by the University of Leicester and staff at the Leicester Kidney Exercise Team and the University Hospitals of Leicester, and funded by the National Institute of Health Research as part of a Doctoral Research Fellowship Award.

How Have Patients and the Public Been Involved in the Study?

Haemodialysis patients helped develop the research topic and what research questions should be asked. The input of haemodialysis patients has strongly influenced the research design and their views on the data collection methods have all be incorporated into the project. They have been actively involved in helping to prepare the study documents, the interview questions and diary instructions. Patients will continue to be involved throughout the study as part of a steering group.

Who Has Reviewed the Study?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be reviewed by an NHS Research Ethics Committee before it goes ahead.

This study has been reviewed by the South West – Central Bristol Research Committee. A favourable opinion means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

Contact for Further Information

If you would like any further information about this study, please contact the researcher in charge of this study (Hannah Young) by phone on: 0116 258 4346 or by post at:

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Thank you for reading this Information Sheet,
and for considering taking part in this study.