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Frailty, falls and the role of exercise in haemodialysis patients: a qualitative study

Submission date
10/04/2017

Recruitment status
No longer recruiting

Registration date
11/05/2017

Overall study status
Completed

Last Edited
25/07/2022

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Patients who are require haemodialysis (HD) (commonly known as kidney dialysis) need help to remove waste from their blood. This means that they often become frail earlier and quicker. Frailty describes a set of conditions which make patients vulnerable to sudden changes in health. This is due to both to a number of traditional factors (e.g. muscle wasting) which is very common in this population and to unique factors associated with end stage kidney disease (e.g. high levels of physical inactivity). Outcomes for frail HD patients are very poor. They are approximately five times more likely to fall than healthy older adults and more likely to break a bone as a result. Frailty and falls are also associated with reduced quality of life, loss of independence and increased use of health services. Programmes to address frailty and falls in HD patients have received little research attention. Other patients who are frail or might fall have exercise programmes designed to help them, but they haven't been tested in HD patients. Studies into exercise training for HD patients are urgently needed, as well as a detailed understanding of patients' experiences of frailty and falls from their own perspectives. The aim of this study is to explore the experiences of HD patients who fall and may be frail, their perceptions of a specific exercise intervention to address frailty and falls and whether patients would be prepared to take part in a bigger study.

Who can participate?

Adults aged 18 and older who have received haemodialysis for three months or longer and have fallen or are at risk of falling.

What does the study involve?

Participants are asked to take part in an interview to find out more about their experiences, thoughts and feelings of living with dialysis and falling. Afterwards they are asked to keep a diary for up to three months. They will use the diary to record their experiences of living with kidney disease and dialysis and, if they experience a fall, what happens and how they feel about it. Once participants have finished recording their diaries, they are asked to take part in a final interview to ask them more about what they have recorded in their diaries, their experiences about falling and frailty and what they think about a specific frailty and falls programme in the future.

What are the possible benefits and risks of participating?
There are no notable benefits to participants, however participants may find documenting and discussing their thoughts and experiences helpful. There are no notable risks with participants however this study may bring up areas where participants have experienced, or continue to experience difficulties. Participants are free not to tell the research team about anything they don't feel comfortable to and may stop the interview at any time. If the participant is experiencing a lot of difficulties the research team may ask them if they wish to speak about it with their Nephrology team.

Where is the study run from?
University of Leicester (UK)

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

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Hannah Young
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33933

Study information

Scientific Title
Understanding frailty, falls and the role of exercise in haemodialysis patients: A qualitative study (FLEX-HD)

Acronym
FLEX-HD

Study objectives
The primary aim of this study is to explore haemodialysis patients' experience of and beliefs about frailty and falls. The secondary aim of this study is to explore patients' perceptions of a frailty and falls specific intervention and the feasibility of a randomised clinical trial to evaluate such an intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Central Bristol Research Ethics Committee, 20/02/2017, ref: 17/SW/0048

Study design
Observational; Design type: Qualitative

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Renal disorders, Primary sub-specialty: Renal disorders; UKCRC code/ Disease: Renal and Urogenital/ Renal failure

Interventions

Following enrolment in the study participants take part in three phases of qualitative data collection.

Phase one: Pre-diary interview
Semi-structured pre- interviews are used to begin to explore participants past experiences of and beliefs about frailty, falls and to introduce and explain the diary-keeping process. Participants are provided with a 'diary-keeping pack' as part of this introduction. This pack includes an A5 notepad or audio recorder, pen, contact information, written guidance about what to record in their diary, and if appropriate, a simple step by step guide about how to use the voice recorder.

Phase two: Qualitative diaries
Participants complete a prospective diary tailored to elicit information on living with frailty and prospective quantitative and qualitative information regarding falls and 'near misses' over a period of one to three months, following the pre-diary interview. Diaries are primarily used in a written format, but provision for participants to audio-record their diaries are made to allow those with a wide range of abilities to participate. This stage does necessitate any visits on behalf of the patient. The researcher can contact the participant to support them to complete their diaries, if they wish. This contact can be done via email, phone or during a routine dialysis visit, whichever is preferable to the participant. The frequency of contact is negotiated with the participant after the initial interview in phase one. Following the completion of the diary keeping period the researcher contacts the participant to arrange collection of the diary and a follow-up diary interview.

Phase Three: Post diary interviews
Finally, a short, semi-structured 'post-diary interview' takes place. This interview reviews participants' diaries to ensure that no salient issues are missed and unclear accounts are clarified and to explore their feelings about keeping a diary and issues of non-completion. The participants' attitudes towards a frailty and falls specific intervention and their perceptions of being involved in a larger study is also explored.

Involvement in the study is finished once the post-diary (phase three) interview is complete. The interviews are led and facilitated by a researcher and last approximately 60-90 minutes. To allow the participant full freedom of expression, sessions typically take place in a comfortable, quiet room away from clinical areas, but can take place during haemodialysis, or in the participant's own home, if they request. The total maximum duration of the study period is five months.

Intervention Type
Other

Primary outcome measure
Experiences of patients will be explored using semi-structured qualitative interviews at baseline and around month four and solicited qualitative dairies kept between months one and three.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/09/2016

Completion date

01/03/2020

Eligibility

Key inclusion criteria
1. Be a prevalent haemodialysis patient (receiving HD for 3 months or greater)
2. Age 18 years or older
3. Clinically stable at the time of recruitment
4. Able and willing to give informed consent
5. History of falls in the last 6 months or high risk of falls

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Unable or unwilling to give informed consent
2. Patients who are unable to understand, read or speak English
3. Unable to participate in an exercise due to perceived physical or psychological barriers
4. Unfit to undertake exercise or exercise testing according to the American College of Sports Medicine guidelines and as determined by the patient's Consultant Nephrologist including:
4.1. Significant ischaemia, recent myocardial infarction (2 weeks) or other acute cardiac event
4.2. Unstable angina
4.3. Uncontrolled cardiac dysrhythmias causing symptoms or haemodynamic compromise
4.4. Symptomatic severe aortic stenosis
4.5. Uncontrolled symptomatic heart failure
4.6. Acute pulmonary embolus or pulmonary infarction
4.7. Acute myocarditis or pericarditis
4.8. Suspected or known dissecting aneurysm
4.9. Acute systemic infection, accompanied by fever, body aches or swollen lymph glands

Date of first enrolment
12/05/2017

Date of final enrolment
28/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leicester
Department of Infection, Immunity and Inflammation
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study results will be disseminated to clinical and scientific, renal and allied health professional communities, via abstract submission at national and international conferences and publication in a high-impact open-access peer reviewed journal. Patient partners will be informed of the results at national charitable events and newsletters. A 'celebration and dissemination event' will be hosted for all local patients to attend if they wish.

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	10/03/2017	11/05/2017	No	Yes
Interim results article	Participants' perceptions of frailty	22/07/2022	25/07/2022	Yes	No
HRA research summary			28/06/2023	No	No