

A quality improvement collaborative to scale up shared haemodialysis care for patients on centre based haemodialysis

Submission date 24/04/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/05/2017	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 08/07/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Kidney failure has a major impact on quality of life and survival. In a healthy person, the kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. When the kidneys fail, they stop cleaning the blood, leading to the build-up of harmful waste products. Haemodialysis (HD) is one of the most common treatments for kidney failure. It involves diverting the blood into an external machine so that it can be cleaned, before being returned to the body. In England approximately 20,000 people attend centres three times (totalling approximately 16 hours) per week to receive HD. Most are passive recipients of their care, engaging little with their own treatment.

Who can participate?

Adults who are being treated with haemodialysis in a participating centre

What does the study involve?

This is a study that only involves the completion of a number of questionnaires, and for those who agree, interviews. If the participant agrees, they are given a patient information sheet to keep and be asked to sign three copies of a consent form. Dialysis treatment will continue as normal. There are no extra hospital visits or medical tests and the study only examines the participant's usual care over 24 months. The participant is asked to complete a questionnaire every three months to document the number of tasks relating to the dialysis treatment that they participate in themselves. In addition the participant is asked to complete three short questionnaires every six months to explore the relationship between the patient and their involvement in their own care and the outcomes and experience they have as a result of this. It also asks about quality of life, the care received and the journey to the dialysis centre. This information is linked to other data sources that provide more detailed health information including information on hospital admissions and other significant events. Completing the questionnaires is completely optional, and the participant can still participate in this study without completing these questionnaires. As part of the study, a deeper investigation into

haemodialysis treatment is carried out using interviews and workshops with a small number of patients and carers. These individuals have the opportunity to indicate their interest complete additional consent for these interviews to be undertaken.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
12 dialysis centres (UK)

When is the study starting and how long is it expected to run for?
March 2016 to December 2018

Who is funding the study?
Health Foundation (UK)

Who is the main contact?
Professor Martin Wilkie
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Contact information

Type(s)
Scientific

Contact name
Prof Martin Wilkie

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Additional identifiers

Protocol serial number
31566

Study information

Scientific Title
A quality improvement collaborative to scale up Shared Haemodialysis Care for patients on centre based haemodialysis

Acronym

ShareHD

Study objectives

Primary research question:

To what extent does a programme of structured learning increase patient participation in haemodialysis activities or result in independent haemodialysis?

Secondary research questions:

1. What are the economic consequences of introducing a programme of structured learning to increase patient involvement in haemodialysis?
2. In terms of encouraging patient involvement in haemodialysis, what works, for whom, in what circumstances and why?

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - West London & GTAC Research Ethics Committee; 06/09/2016, ref: 16/LO/1558

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Specialty: Renal disorders, Primary sub-specialty: Renal disorders; UKCRC code/ Disease: Renal and Urogenital/ Renal failure

Interventions

In this cohort study approximately 600 dialysis patients are recruited from 12 dialysis centres. Once consent has been taken patients will be given questionnaires to complete that include demographics, a record of the number of dialysis related tasks that are being undertaken by the participant (3 monthly); a measure of patient activation, quality of life, renal symptom score, metacognition, confidence with self-needling and health literacy (6 monthly). In addition there is a 6 monthly health economic short questionnaire, as status change form to be completed if the treatment type or location changes and a patient appreciation card. There are also interviews for a smaller number of patients and carers who indicate that they are interested in this part of the study. At the end of the study there will be data linkage with Hospital Episode Statistics to obtain hospitalisation and co-morbidity at the time of recruitment. The whole study lasts 2 years.

Intervention Type

Other

Primary outcome(s)

Whether or not HD patients can learn and complete 5 or more out of 14 tasks, is collected on paper forms for the 12 participating renal units over three, six-month duration, time periods or steps (Step 1 (baseline): 0 to 6 months, Step 2: 6 to 12 months; Step 3: 12 to 18 months).

Key secondary outcome(s)

1. Number and proportion of HD patients who have Home HD or dialyse in centre independently will be measured by an event driven status change form that will identify when patients commence home haemodialysis and using information from the 3 monthly completed task summary sheets to determine whether patients are dialysing independently at dialysis centres
2. Economic evaluation will take an NHS and social care perspective and will compare Shared Haemodialysis Care with usual care in a cost-utility analysis using a cost-per quality adjusted life years (QALYs) approach at endline
3. Health related quality of life is assessed using the EQ-5D-5L at baseline, six and 12 months
4. Costs of the intervention will be collected throughout the study and will include set-up and running costs such as training, room hire, refreshments, materials, staff time, web site and staff

Completion date

31/12/2018

Eligibility

Key inclusion criteria

1. Established on centre based haemodialysis
2. Capacity to give written informed consent to participate in the study
3. Aged 18 years and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

596

Key exclusion criteria

1. People who are too unwell to engage in the study, as judged by the clinical team
2. People unable to understand written and verbal communication in English
3. Unable to give informed consent

Date of first enrolment

01/10/2016

Date of final enrolment

31/01/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**St James's University Hospital**

Beckett Street

Leeds

United Kingdom

LS9 7TF

Study participating centre**New Cross Hospital**

Wolverhampton Road

Wolverhampton

United Kingdom

WV10 0QP

Study participating centre**Manchester Royal Infirmary**

Oxford Road

Manchester

United Kingdom

M13 9WL

Study participating centre**Southmead Hospital**

Southmead Road

Westbury-on-Trym

Bristol

United Kingdom

BS10 5NB

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5ST

Study participating centre
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
York Hospital
Wiggington Road

York
United Kingdom
YO31 8HE

Study participating centre
Sunderland Royal Hospital
Kyall Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
<https://ror.org/018hjpz25>

Funder(s)

Funder type
Charity

Funder Name
Health Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The current 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?
Results article		20/07/2021	21/07/2021	Yes	No
Results article	change in the prevalence of how individuals undergoing in-centre haemodialysis for kidney failure are affected by symptoms	17/11/2023	08/07/2025	Yes	No
Protocol article	Protocol	24/11/2017		Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.3	27/07/2016	14/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes