

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

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

**Study website**  
<https://www.shreddialysis-care.org.uk>

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Martin Wilkie

**ORCID ID**  
<https://orcid.org/0000-0003-1059-6453>

**Contact details**  
Sheffield Teaching Hospitals NHS Foundation Trust  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU  
+44 1142 715148  
wilkieme@gmail.com

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Cohort study

## Study setting(s)

Hospital

## Study type(s)

Other

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

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).

## **Secondary outcome measures**

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

## **Overall study start date**

18/03/2016

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 586; UK Sample Size: 586

**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**

England

United Kingdom

**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**  
Wigginton Road  
York  
United Kingdom  
YO31 8HE

**Study participating centre**  
**Sunderland Royal Hospital**  
Kyll 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

## Sponsor details

Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
England  
United Kingdom  
S10 2JF  
+44 1142 714327  
Dipak.Patel@sth.nhs.uk

## Sponsor type

Hospital/treatment centre

## ROR

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

# Funder(s)

## Funder type

Charity

## Funder Name

Health Foundation

# Results and Publications

## Publication and dissemination plan

Planned publication of the results in peer reviewed scientific journals as well as other media such as patient magazines.

## Intention to publish date

31/12/2019

## 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

[Protocol article](#) Protocol

Date created	Date added	Peer reviewed?	Patient-facing?
24/11/2017		Yes	No



<a href="#">Results article</a>		20/07/2021	21/07/2021	Yes	No
<a href="#">Protocol file</a>	version 1.3	27/07/2016	14/06/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>	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