

Prepare for kidney care

Submission date 15/05/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 31/05/2017	Overall study status Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/02/2026	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. If the kidneys stop working properly, then the body is unable to get rid of the waste products building up in the blood. Eventually, the kidneys are no longer able to support the body's needs (kidney failure) and so a treatment to replace the work of the failed kidneys is needed. When kidney function drops to 15% of normal, patients experience tiredness, loss of appetite and sickness. At this stage, dialysis or kidney transplantation is considered. Dialysis is a treatment which involves diverting the blood into an external machine so that it can be cleaned, before being returned to the body. This treatment can take place in hospital or at home. There is evidence that some older people with many medical problems (co-morbidities) do just as well with conservative care as dialysis, but more evidence is needed to help patients and their families make the best decision. The aim of this study is to provide clear evidence to help patients and their families reach the best decision for them and influence NHS policy nationally on the best care for people living with kidney disease.

Who can participate?

People with kidney failure aged 80+ years and those aged 65+ years with multiple health problems.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive conservative care with additional home visits. This involves home visits with a nurse to assess the patient's care needs and their priorities during responsive management. The nurse calls the patient at home regularly to monitor symptoms and check that sufficient help is available. There are regular check-ups with the nurse at home and in-hospital visits. Hospital visits are less frequent than in people preparing for renal dialysis. Those in the second group come to hospital clinic visits regularly as per standard practice. Surgery to prepare for dialysis takes place. Dialysis is started when the doctor, nurse and patient agree it is needed. There are regular visits to hospital for treatment or check-ups. Participants are followed up every four months until the end of data collection or death.

What are the possible benefits and risks of participating?

There are no guaranteed benefits of taking part, however, the treatment given as part of the study may lead to an improvement in symptoms and general health. There are no notable risks involved with participating.

Where is the study run from?

Southmead Hospital and 29 other NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?

January 2017 to August 2026

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Jo Worthington

Prepare4KC@bristol.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Jo Worthington

ORCID ID

<https://orcid.org/0000-0002-2860-3511>

Contact details

Bristol Trials Centre

University of Bristol

1-5 Whiteladies Road

Bristol

United Kingdom

BS2 1NU

+44 (0)117 331 4586

Prepare4KC@bristol.ac.uk

Type(s)

Scientific

Contact name

Dr Fergus Caskey

ORCID ID

<https://orcid.org/0000-0002-5199-3925>

Contact details

UK Renal Registry

Learning and Research

Southmead Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB
+44 (0)117 414 8150
mdfjc@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 32254

Study information

Scientific Title

The prepare multi-morbid older people for end-stage kidney disease trial

Study objectives

The aim of this study is to establish the effectiveness and cost-effectiveness of preparing for responsive management compared with preparing for renal dialysis in relation to quality and length of life in frail, older people with multiple health problems and advanced chronic kidney disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Central - Berkshire Research Ethics Committee, 05/05/2017, ref: 17/SC/0070

Study design

Randomized; Interventional; Design type: Treatment, Process of Care, Complex Intervention, Management of Care, Active Monitoring

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Renal failure

Interventions

Participants will be randomly allocated 1:1 to the "prepare for responsive management" or "prepare for dialysis" treatment arms, stratified by site to ensure a balance in terms of local differences. Minimisation will be used to ensure balance in age (65-80 vs 80+) and rate of kidney function decline (less or equal to vs more than 5 ml/min/1.73m² in the last 12 months). Minimisation with probability weighting of 0.8 will be used in order to reduce predictability.

Prepare for responsive management (intervention): A nurse who specialises in looking after people having responsive management (conservative care plus) will arrange a date for a first home visit. The first home visit will take place within 3 weeks of the nurse telephoning patient. Over the next 8 weeks the specialist nurse will visit the patient up to three times to assess patient needs and plan future treatment. All assessments and decisions will be agreed with the local site specialist renal team. Following this, the frequency of specialist nurse visits will depend on how often the patient and the patient's specialist kidney team think the patient should be seen. Visits will be convenient for the patient and will alternate between hospital clinical visits and the nurse visiting the patient at home. In addition, the specialist nurse will contact the patient once a month to assess symptoms and review the treatment plan. If kidney function continues to fall and the patient develops symptoms which cannot be controlled by medication, the patient's specialist kidney team will discuss the option of moving on to the next stage of support, which may involve other professionals, such as palliative care specialists, who can help control symptoms.

Prepare for renal dialysis (comparator): Patients will attend the next scheduled kidney clinic appointment at the hospital, and will continue to attend kidney clinic appointments as often as the patient and specialist kidney team deem necessary. The specialist kidney team will discuss dialysis treatment options that are available and decided which one is most suitable. Depending on the dialysis treatment chosen, the patient may need scans and an operation to prepare for dialysis. If kidney function continues to decline and the patient develops symptoms of kidney failure, then the specialist team will recommend starting dialysis immediately. If the patient and the specialist kidney team consider it appropriate, other professionals, such as palliative care specialists, may become involved to help control symptoms.

Intervention Type

Other

Primary outcome(s)

Mean total of quality-adjusted life years (QALY) between the first patient recruited and the end of data collection is collected using the EQ-5D-5L at recruitment and every 4 months thereafter until 31 August 2025 (end of data collection).

Updated 01/08/2024 to change the end of data collection from 1 October 2021 to 31 August 2025.

Key secondary outcome(s)

Survival-related outcomes will be collected by research nurses from primary and secondary care clinical notes and during 4 monthly study visits/contacts. In addition, all participants will be asked on consenting to the RCT to consent to linkage to existing healthcare databases, such as Hospital Episode Statistics, the Office for National Statistics and the UK Renal Registry. This will provide data on the commencement of acute or chronic dialysis, hospital admissions for medical and surgical reasons and date and cause of death.

1. All-cause mortality
2. Cause-specific mortality

3. Place of death
4. Hospital-free days alive

Patient-reported outcome related:

1. Generic quality of life is measured using the EQ-5D-5L at recruitment (baseline) and every 4 months thereafter until 31 August 2025 or until withdrawal from the study or death
2. Disease-specific quality of life/symptom burden is measured using the POS-S renal at recruitment (baseline) thereafter until 31 August 2025 or until withdrawal from the study or death
3. Capability gain specific to older persons is measured using the ICECAP-O at recruitment (baseline) and every 4 months thereafter until 31 August 2025 or until withdrawal from the study or death
4. Capability during end-of-life care is measured using the ICECAP-SCM at recruitment (baseline) and every 4 months thereafter until 31 August 2025 or until withdrawal from the study or death
5. Patient treatment burden is measured using the MTBQ at recruitment (baseline) and every 4 months thereafter until 31 August 2025 or until withdrawal from the study or death

Physical functioning:

1. Is measured using the 'timed get up and go'- summary score at baseline and 12 monthly time points and assessed for changes over time. The physical assessment will be performed by the research nurse annually using standard operating procedures.
2. Grip strength is measured using a Jamar hand dynamometer at baseline and 12 monthly time points and assessed for changes over time. The physical assessment will be performed by the research nurse annually using standard operating procedures.

Relative/carer reported outcomes:

1. Impact on carers is measured using the PACKS impact on carers questionnaire (added 07/06 /2017: adapted from the iMTA valuation of informal care questionnaire) at participant recruitment (baseline) and every 4 months thereafter until 31 August 2025, or until participant withdraws from the study or dies
2. Impacts on carers is assessed using the QUALYCARE post-bereavement survey obtaining retrospective information covering the 1 week preceding death if the study participant dies. QUALYCARE data will be collected at 3-6 months after participant death

Health economic:

1. Incremental cost-per QALY gained from the health perspective is assessed by QALYs generated using EQ-5D-5L at recruitment (baseline) and every 4 months thereafter until 31 August 2025
2. Cost per equivalent year of full/sufficient capability gained, from health and societal perspectives is assessed using ICECAP (ICECAP-O the ICEpop capability measure for older people and ICECAP-SCM the ICEpop capability measure for supportive care management) at recruitment (baseline) and every 4 months thereafter until 31 August 2025

Updated 01/08/2024 to change the end of data collection from 1 October 2021 to 31 August 2025.

Completion date

28/08/2026

Eligibility

Key inclusion criteria

Patients known to renal services with new or existing stage 5 CKD (eGFR <15, with at least one result confirming this in the last 12 months) and:

1. Aged 65+ with a World Health Organisation (WHO) performance status 3+ (0 = Fully active, able to carry out all normal activity without restriction; 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; 2 = Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours; 3 = Symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden; 4 = Completely disabled; cannot carry out any self-care; totally confined to bed or chair), or
2. Aged 65+ with a Davies co-morbidity score 2+ (each of the following scores one point: Malignancy, ischaemic heart disease, peripheral vascular disease (including stroke), left ventricular dysfunction, diabetes mellitus, systemic collagen vascular disease, other significant pathology (including COPD, cirrhosis, psychiatric illness, HIV), or
3. Aged 80+

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 years

Upper age limit

120 years

Sex

All

Total final enrolment

448

Key exclusion criteria

1. Unable to consent, e.g. significant cognitive impairment or psychiatric disorder
2. Not medically fit for dialysis
3. Within 4 weeks of starting dialysis

Added 01/07/2019:

4. Patients that have had a previous kidney transplant
5. Patients that are 'active' on the kidney transplant waiting list or being worked up for the kidney transplant waiting list

Date of first enrolment

01/07/2017

Date of final enrolment

31/08/2024

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre

Southmead Hospital

Southmead Road
Westbury-on-Trym
Bristol
England
BS10 5NB

Study participating centre

Royal Free Hospital

Renal Unit
Pond Street
London
England
NW3 2QG

Study participating centre

Lister Hospital

Renal Unit
Corerys Mill Lane
Stevenage
England
SG1 4AB

Study participating centre

Birmingham Heartlands Hospital

Department of Renal Medicine
Bordesley Green East

Birmingham
England
B9 5SS

Study participating centre
Royal Stoke University Hospital
Trent Building
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
England
ST4 6QG

Study participating centre
Gloucester Royal Hospital
Great Western Road
Gloucester
England
GL1 3NN

Study participating centre
King's College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
England
SM5 1AA

Study participating centre
The Heath Hospital
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XW

Study participating centre
Kent and Canterbury Hospital
Ethelbert Road
Canterbury
England
CT1 3NG

Study participating centre
Royal Cornwall Hospital (treliste)
Treliske
Truro
England
TR1 3LJ

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
Scotland
EH16 4SA

Study participating centre
Leicester General Hospital
Gwendolen Road
Leicester
England
LE5 4PW

Study participating centre
Freeman Hospital
Freeman Road

Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
England
PO6 3LY

Study participating centre
The York Hospital
Wiggington Road
York
England
YO31 8HE

Study participating centre
Ipswich Hospital ESNEFT
Heath Road
Ipswich
England
IP4 5PD

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
England
PR2 9HT

Study participating centre
Royal Liverpool Hospital
Prescot Street
Liverpool
England
L7 8XP

Study participating centre

St Luke's Hospital

Little Horton Lane
Bradford
England
BD5 0NA

Study participating centre

Dumfries and Galloway Royal Infirmary

Cargenbridge
Dumfries
Scotland
DG2 8RX

Study participating centre

Guy's Hospital

Great Maze Road
London
England
SE1 9RT

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre

Altnagelvin Area Hospital

Glenshane Road
Londonderry
Northern Ireland
BT47 6SB

Study participating centre

Craigavon Area Hospital

Lurgan Rd
Craigavon

Northern Ireland
BT63 5QQ

Study participating centre

Antrim Area Hospital

45 Bush Rd
Antrim
Northern Ireland
BT41 2RL

Study participating centre

Salford Royal Hospital

544 Eccles New Road, Salford
Manchester
England
M5 5AP

Study participating centre

Ninewells Hospital & Medical School

Ninewells Avenue
Dundee
Scotland
DD1 9SY

Study participating centre

Queen Elizabeth Hospital

Queen Elizabeth Medical Centre
Edgbaston
Birmingham
England
B15 2TH

Sponsor information

Organisation

North Bristol NHS Trust

ROR

<https://ror.org/036x6gt55>

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

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.

Name of repository - Bristol Randomised Trial Collaboration

Data that will be shared - anonymised derived data

When the data will become available and for how long - following publication of the main trial papers until data have to be destroyed (currently 15 years following the end of the trial)

By what access criteria the data will be shared including with whom, for what types of analyses, and by what mechanism, whether consent from participants was obtained - The Trial

Management Group will consider all requests for access to the data on a case-by-case basis

Whether consent from participants was obtained - consent was/is obtained

Comments on data anonymisation - data will be anonymised before release

Any ethical or legal restrictions - data release will need to comply with all conditions of the data providers (e.g. NHS Digital and the UK Renal Registry) and the funder (NIHR HTA).

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/10/2024	29/10/2024	Yes	No

HRA research summary			26/07/2023	No	No
Other publications	Background and recruitment progress	27/05/2021	05/05/2023	Yes	No
Participant information sheet	version V3.0	05/05/2017	31/05/2017	No	Yes
Participant information sheet	version v5.0	12/11/2018	01/07/2019	No	Yes
Participant information sheet	version 8.0	20/11/2023	23/05/2024	No	Yes
Protocol file	version 4.0	09/09/2017	05/05/2023	No	No
Protocol file	version 9.0	20/11/2023	23/05/2024	No	No
Protocol file	version 10.0	26/06/2024	01/08/2024	No	No
Statistical Analysis Plan		30/08/2025	23/02/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes