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Prepare for kidney care

Submission date	Recruitment status	[X] Prospectively registered
15/05/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/05/2017	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/10/2024	Urological and Genital Diseases	[X] 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 2025

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

Who is the main contact?
Dr Jo Worthington
Prepare4KC@bristol.ac.uk

Study website
http://bristol.ac.uk/prepare-kc-trial

Contact information

Type(s)
Scientific

Contact name
Dr Jo Worthington

ORCID ID
http://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
http://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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

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 specialists 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 measure

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.

Secondary outcome measures

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.

Overall study start date
01/01/2017

Completion date
31/08/2025

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

Age group
Adult

Lower age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 512; UK Sample Size: 512

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
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Free Hospital
Renal Unit
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Lister Hospital
Renal Unit
Corerys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Birmingham Heartlands Hospital
Department of Renal Medicine
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

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

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

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

Study participating centre

St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

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

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

Study participating centre
Royal Cornwall Hospital
Truro
United Kingdom
TR1 3HD

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

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

Study participating centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
Freeman Hospital
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

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

Study participating centre
The York Hospital
Wiggington Road
York
United Kingdom
YO31 8HE

Study participating centre
Ipswich Hospital ESNEFT
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood

Preston
United Kingdom
PR2 9HT

Study participating centre
Royal Liverpool Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
St Luke's Hospital
Little Horton Lane
Bradford
United Kingdom
BD5 0NA

Study participating centre
Dumfries and Galloway Royal Infirmary
Cargenbridge
Dumfries
United Kingdom
DG2 8RX

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

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

Study participating centre

Altnagelvin Area Hospital
Glenshane Road
Londonderry
United Kingdom
BT47 6SB

Study participating centre
Craigavon Area Hospital
Lurgan Rd
Craigavon
United Kingdom
BT63 5QQ

Study participating centre
Antrim Area Hospital
45 Bush Rd
Antrim
United Kingdom
BT41 2RL

Study participating centre
Salford Royal Hospital
544 Eccles New Road, Salford
Manchester
United Kingdom
M5 5AP

Study participating centre
Ninewells Hospital & Medical School
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 414 9330
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan

Current publication and dissemination plan as of 13/01/2020:
1. Trial protocol: To be published in Trials, with an intention to publish by 31/06/2021
2. Trial Statistical Analysis Plan: To be published in Trials by 31/05/2021
3. Final study results: planned publication in a high impact peer reviewed journal with an intention to publish by 31/12/2024

Previous publication and dissemination plan as of 01/07/2019:
1. Trial protocol to be published in Trials with an intention to publish by 31/12/2019
2. Statistics Analysis Plan to be published by 31/12/2019
3. Final study results: planned publication in a high impact peer reviewed journal with an intention to publish by 31/12/2022

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Intention to publish date

30/11/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically 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?
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
Other publications	Background and recruitment progress	27/05/2021	05/05	Yes	No

			/2023		
Protocol file	version 4.0	09/09/2017	05/05 /2023	No	No
HRA research summary			26/07 /2023	No	No
Participant information sheet	version 8.0	20/11/2023	23/05 /2024	No	Yes
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
Protocol article		17/10/2024	29/10 /2024	Yes	No