Prepare for Kidney Care

A randomised controlled trial of preparing for renal dialysis versus preparing for responsive management in advanced kidney disease

A study for people who have low kidney function and are seeking further treatment, which may include preparing for responsive management or preparing for dialysis.

Patient Information Sheet

We would like to invite you to take part in our research study called 'Prepare for Kidney Care'. Before you decide, it is important to understand why the research is being done and what it will involve. A dedicated research nurse will go through this information sheet with you and answer any questions you have. Please ask them if there is anything that is not clear.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the study if you think you are interested in taking part. Please take time to read this information and discuss it with your family and friends if you wish. You are free to decide whether or not to take part in this study. If you choose not to take part the care you receive will not be affected in any way.

Part 1: If you are interested in finding out more

Background

Your kidney consultant has referred you because your kidney function has been below 15% of normal and you may be experiencing symptoms such as tiredness, loss of appetite and sickness. Symptoms arising from kidney disease can be unpredictable. Some people live with kidney disease without the need to make any adjustments to their lifestyle for the rest of their lives. Others experience different or more intense symptoms in the future, that may require a different approach to management. If people get to this point, they have the option to start renal dialysis, or have supportive treatment and care that does not involve dialysis.

Whether people are experiencing symptoms at present or not, it is important to start discussion and preparation for the possibility of future treatment, should symptoms arise or get worse. The care you receive now and into the future can be viewed as a 'pathway'.

For people over 65 with other health problems, we need more information about people's survival and quality of life for different pathways of managing kidney disease. More research evidence could help patients and their families to make more informed decisions about the right treatment pathway for them.

The Prepare for Kidney Care study aims to compare two pathways of care for managing symptoms of end stage kidney disease. These pathways are called:

- **Prepare for Renal Dialysis**
- **Prepare for Responsive Management**

Both pathways are similar, in that they initially focus on regular monitoring by your NHS clinical team and diet and lifestyle advice, with the aim of maintaining kidney function. There are some differences in the frequency

and location of kidney appointments in each pathway (as discussed below), but the main difference between the pathways is around what will happen if a person were to develop symptoms in the future that warrant further treatment. The 'prepare for Renal Dialysis' pathway will involve the possibility of starting dialysis (at home or in hospital), whereas the 'prepare for Responsive Management' pathway focuses on managing symptoms without dialysis.

There are likely to be pros and cons to both pathways. We do not have enough information about these pros and cons – particularly for patients who become symptomatic in the future. This is why we are running the Prepare for Kidney Care study. The ultimate aim of the study is to compare survival, quality of life, and patients' experiences of receiving care throughout the above two pathways.

Important things that you need to know

- People aged over 65 with multiple health problems and those aged 80 and over seem to do just as well when they choose to prepare for renal dialysis rather than preparing for responsive management, but this is based on the limited research evidence we have to date. There has never been a study that is big enough or reliable enough to fairly compare these two pathways of care.
- Kidney specialists therefore do not know whether preparing for renal dialysis or preparing for responsive management is better, in terms of people's survival and quality of life in people aged over 65 with multiple health problems and those aged 80 and over.
- We want to find out about people's experiences of preparing for renal dialysis and preparing for responsive management, so that in the future they can make an informed decision about the right treatment for them.
- If you agree to take part in the study, you will continue to be looked after by the same team of NHS doctors and nurses that you see at the moment.
- There will be no extra clinic visits or blood tests.

You can discontinue with the study at any time and for any reason. If you decide to discontinue with the study you will return to usual care at your renal unit, which could involve either preparation for dialysis or preparation to have all supportive treatment and care, but not plan to start renal dialysis even if things progress. You do not have to tell us why you want to discontinue with the study.

Why is the study needed?

When kidney function falls below 15% of normal, a number of symptoms can develop – tiredness, loss of appetite, sickness, restless legs, cramps, breathlessness and itching**.** Dialysis and responsive management can both be options at this stage, controlling symptoms and improving quality of life. We do not know which option is better for people like you.
Dialysis is a process that cleans the blood, either daily at home, or three times a week in hospital. The treatment removes waste products, extra salts, and extra fluid which build up in the body when the kidneys aren't working properly.

Some people receiving dialysis adapt to it well and are satisfied with their quality of life. Others report very poor quality of life on dialysis, with symptoms such as fatigue and little time spent at home.

For these reasons, some patients choose to have as much symptom management and control as possible without dialysis – this is known as responsive management. Responsive management is about carefully planning symptom control and support, mostly with medication and at home.

There is evidence that older people with other medical problems do just as well with responsive management as dialysis, but more research is needed to determine which aspects of the care help and in what circumstances. This research will ensure that patients and their families will be able to have clearer choices in future. The Prepare for Kidney Care study aims 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.

Why have I been invited to take part?

You are being invited to take part in the Prepare for Kidney Care study because you have kidney function below 15% and fall into one of these groups:

- Over 65 years with other health problems
- Over 80 years old

Do I have to take part?

Participating in this study is completely voluntary. You are free to change your mind and leave the study at any time without giving a reason. If you choose not to take part, or if you leave the study, your future medical treatment and normal standard of care will not be affected in any way.

What will happen if I take part?

If you agree to take part in the study, you will be asked to sign a Prepare for Kidney Care study consent form. Then one of our research nurses will ask you some questions about your health and do a simple physical assessment. You will be asked to complete a questionnaire designed to measure your health, quality of life and symptoms of kidney disease. We will then check whether you are willing to prepare either for (a) Responsive management or (b) Dialysis. This assessment should take no more than 60 minutes.

Once this has happened, the research nurse will contact the clinical trials unit and find out whether you have been allocated to prepare for (a) Responsive management or (b) Dialysis. Neither you nor the clinical team involved in your care will choose which treatment you receive. Instead, the treatment you receive will be allocated at random, through a process called 'randomisation'. This means that you will have an equal chance of receiving either treatment. The clinical team involved in your care are confident that both of these treatments are appropriate for you. We currently do not know if one treatment is better, or if they are both the same. By doing this clinical study, we hope to find out the advantages and disadvantages of the treatments and if one is better than the other.

The allocation process (randomisation) should take no more than 5 minutes and in most situations the result will be given to you straight away.

What happens with my NHS clinical visits and care?

If you are randomly allocated to ''prepare for responsive management''

- A specialist nurse/ healthcare professional who specialises in looking after people having responsive management will contact you within 2 weeks to arrange a date for your first home visit. This first home visit will take place within 3 weeks of the nurse telephoning you.

- Over the next twelve weeks the specialist nurse/ healthcare professional may contact you by telephone/ video communication or visit you up to three times to assess your needs and plan your future treatment. All assessments and decisions will be agreed with the rest of your specialist kidney team.
- Following this, the frequency of your visits will depend on how often you and your specialist kidney team think you should be seen. We will try to ensure that the visits are planned so that they are convenient for you. A home visit will take place annually after your final assessment visit in addition to your routine clinic appointments, though these visits can also be conducted in clinic or via telephone/ video communication if requested by you.
- In addition to the above, the specialist nurse/ healthcare professional will contact you by telephone once a month to assess if you have any symptoms and review your treatment plan.
- If your kidney function continues to fall and you develop symptoms which cannot be controlled by medication, then your specialist team will discuss with you the option of moving on to the next stage of support. This may involve other professionals, such as palliative care specialists, who can help control symptoms.

If you are randomly allocated to ''prepare for dialysis"

- You will attend your next scheduled kidney clinic appointment at the hospital. You will continue to attend kidney clinic appointments as often as you and your specialist kidney team agree is necessary.
- You and your specialist kidney team will discuss the dialysis treatment options that are available and decide which one is most suitable for you.
- Depending on the dialysis treatment you choose, you may need scans and an operation to prepare for dialysis.
- If your kidney function continues to decline and you develop symptoms of kidney failure, then your specialist team will recommend starting dialysis immediately or as soon as possible.
- If you and your specialist kidney team consider it appropriate then your care may involve other professionals, such as palliative care specialists, who can help control symptoms.

What happens at the research visits?

Because this is a clinical study, we would like to monitor the health and quality of life of all patients preparing for dialysis and all patients preparing for responsive management. This will allow us to compare the two groups. A dedicated research nurse will offer to visit you at home (once a year) and by telephone (twice a year). Your research visits will continue until the study completes, at the end of May 2025.

In person research visits (once per year)

The research nurse will arrange a convenient time to meet you at your home, in clinic or via telephone/ video communication, depending on what you prefer. This contact would take no longer than an hour. The research nurse will also ask questions about your health and any medication you are taking, and check your height, weight, blood pressure, and waist measurement. You will also be posted or emailed (depending on what you would prefer) a questionnaire to complete about your symptoms and quality of life around the same time as this visit. If you have a family member/ carer who has agreed to take part in the study with you, they will also

be sent a questionnaire to complete about any impact your kidney treatment has had on the people around you.

Telephone research appointments (twice per year)

The research nurse will arrange a convenient time to have a 20 minute telephone conversation with you about your health and any medication you are taking. You will also be posted or emailed (depending on what you would prefer) a questionnaire to complete about your symptoms and quality of life at around the same time. If you have a family member/ carer who has agreed to take part in the study with you, they will also be sent a questionnaire to complete about any impact your kidney treatment has had on the people around you.

If you become unable to take part in visits or questionnaires or unable to make treatment decisions

Visits can be rescheduled if necessary to fit in around your other health needs. If this is not possible, some of the information can be collected from your hospital and GP notes without you having to attend a visit.

If you are unable to fill in a patient questionnaire, perhaps because you feel unwell, it is important that this information is not missed. In these situations, close relatives and carers can ask you how you have been feeling and complete the questionnaires for you. We will therefore ask you to identify one or two individuals who would be able and willing to give us some of this information.

Any of us can lose the ability to make decisions about taking part in research at any time. In case that happens to you while you are taking part in this study, you will have to be withdrawn from the study and return to usual care at your renal unit. You will be sent no further questionnaires to complete, but the study team would keep the personal data already collected and continue to use it to obtain follow up information from your routine healthcare records (see Part 2 of this leaflet).

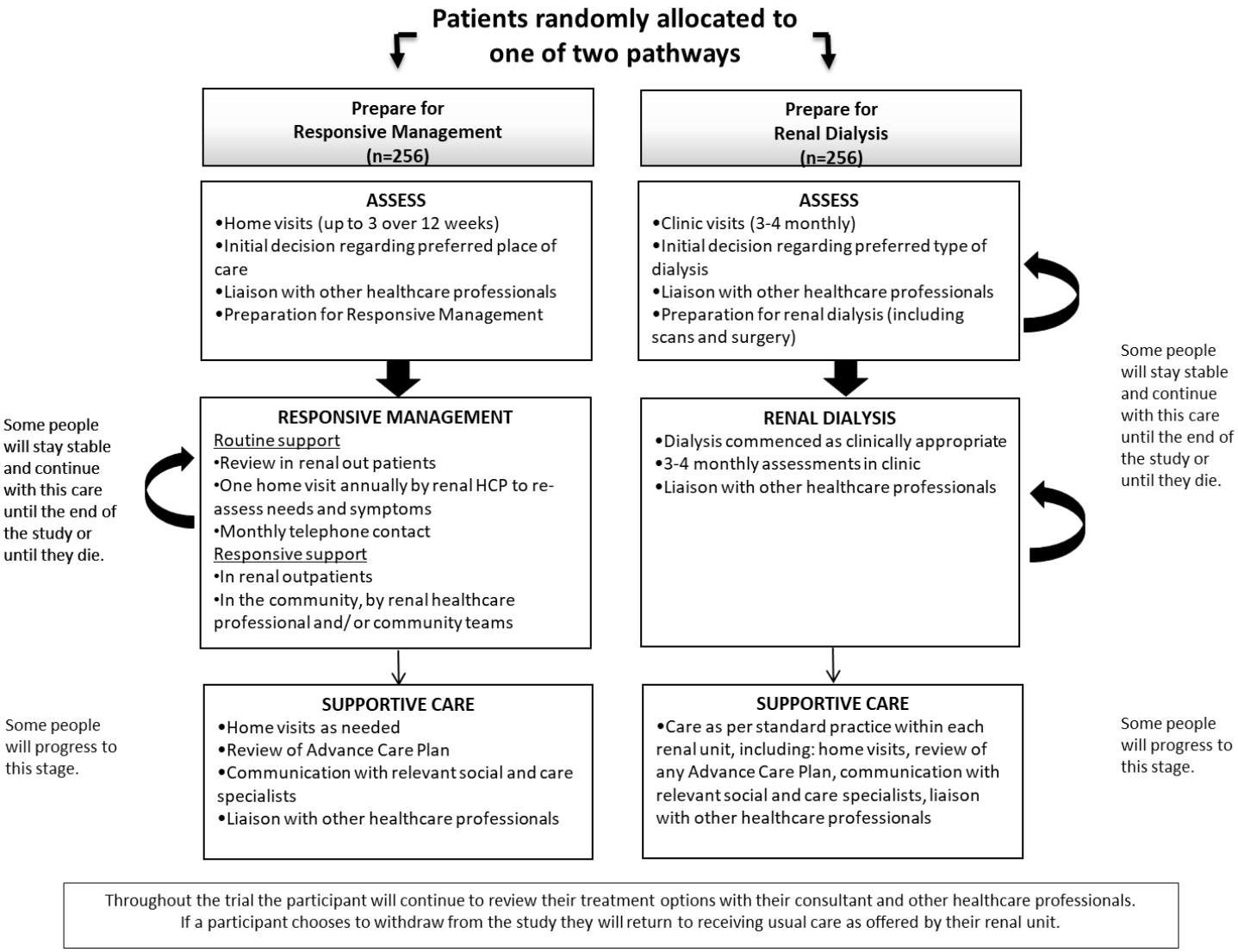
As low kidney function is often associated with other health problems, it is unfortunately likely that some people who agree to take part in the trial will die during the prolonged follow up period. Understanding the experiences these patients have in the last days and weeks of their lives is extremely important if we are to know which treatment option is best when advising people in the future. We will also therefore ask participants if we may contact one of their close relatives or carers in the event of their death. If we did so, we would wait a minimum of three months before contacting them.

What are the possible benefits of taking part?

There is no guarantee that you will benefit from taking part in this study. The treatment you receive as part of the study may lead to an improvement in your symptoms and general health, but we cannot predict whether this will be the case. However, information collected during this study may benefit patients like you with kidney disease in the future.

What are the possible disadvantages of taking part?

The study will take up some of your time, as explained above, but the study team don't foresee any risks involved with taking part in this study. Your specialist kidney team are happy for you to take part.



All face-to-face contact will follow strict social distancing protocols, in line with local Trust policies. If there is an over-riding infection control reason why any of the face-to-face visits above (clinic or home visits) cannot take place, then they can be undertaken remotely by telephone/ video communication, as deemed appropriate.

What happens after the study stops?

At the end of the study your NHS specialist kidney team will discuss with you the current treatment options in terms of preparation for responsive management and preparation for dialysis. It will be up to you and your NHS specialist kidney team to decide whether you should continue on your allocated treatment or change to something else.

What if I do not like my allocated treatment or want to withdraw from the study?

If you are not satisfied with the treatment you have been allocated to at any time then you can stop taking part in the trial and go back to the usual care someone with your level of kidney function would receive at your renal unit. This might not necessarily result in any change to your treatment if the treatment you are receiving as part of the research is the same as usual care. You can withdraw from the study at any time and without giving a reason. The study will be more valuable, however, if few people withdraw from it, so it is

important to discuss any concerns you may have with a member of the study team before you agree to take part or finally decide to withdraw.

You can withdraw by telephoning your local research nurse (for details see later in this leaflet) or by writing to the coordinating centre (for details see www.bris.ac.uk/prepare-kc-trial). This will allow us to discuss your concerns with you and determine what you want to happen next from the following options. You have the right to decide any and all of the options you want to withdraw from.

- **"No further treatment that you were allocated to":** This means that you wish to return to usual care but are happy to continue with completing questionnaires and research contacts with your local research team at the hospital every 4 months and that the coordinating team can access your health records.
- **"No further questionnaires to be sent from the coordinating research team":** This means you will no longer be sent questionnaires every 4-months by the coordinating research team at the University of Bristol. Any information you have provided previously will be retained and used for the study.
- "**No further research contacts from your local research team at the hospital**": This means that the Prepare for Kidney Care research team will no longer contact you to complete research visits (via telephone or a home visit). They will still have the permission you gave when you joined the study, to retain and use information provided previously.
- **"No further access to my health records":** This means that the Prepare for Kidney Care research team (coordinating or from the local hospital) will not be able to access your health records for further information about you.

Part 2: If you are thinking about taking part

How will the information I provide be used?

We hope that over 500 patients will take part in this study across the UK. Nephrologists will be informed of the recommendations from the study, so that in future all patients can receive the best information before deciding what treatment to have.

The results of this study will be published in scientific journals. No one will be able to identify you from any of the study reports.

Who is doing this study?

This study is being funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (HTA) (project number 15/57/39). The research is being carried out by a group of experienced doctors and researchers at each of the hospitals involved in this study. They are working in collaboration with researchers at the University of Bristol's Bristol Trials Centre (BTC), a fully registered Clinical Trials Unit. The study is sponsored by North Bristol NHS Trust.

Who has approved this study?

South Central, Berkshire, NHS Research Ethics Committee, your local hospital and your renal consultant have given approval for this study to be carried out. An independent Trial Steering Committee and a Data Monitoring Committee monitor safety and ensure that the study is carried out in accordance with good research practice.

Collecting data about you from other healthcare organisations

We will ask your permission to access your healthcare notes kept by the hospital and your GP so that we can find out about aspects of the care of your kidney disease, and other medical problems that may affect your health. We will also ask your permission to access data that have been collected about you during routine appointments and hospital visits by the organisations described at the end of the patient information sheet. This is important as it cuts down how much work you have to do telling us about your health and avoids extra blood tests. Also, it will make it possible to collect some information about you after the trial has finished. Lastly, if you do not continue with the trial or the questionnaires, we can still collect some information about your health.

In order to identify and obtain information about you, we will send information that identifies you (such as your name, address, gender, date of birth, and NHS number) to these organisations. The information they return to us may also contain some of the same information to identify you. An explanation about these organisations can be found at the end of this patient information sheet.

How will information about me be kept confidential?

All information collected about you as a result of your participation in the study will be kept strictly confidential, and will be used for the purposes of this research only. Your personal and medical information will be kept in a highly secure server within the University of Bristol or the UK Renal Registry and handled in the strictest confidence (in accordance with data protection law). Your information will be accessible only to the team of researchers directly involved with the study. No information about you will be shared with any third parties not directly involved with this research.

We will need to inform your GP that you are taking part in this study so that they take this into account when making any decisions about your care. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Once you have agreed to participate in this study you will be allocated a unique study number via the randomisation system which will be used on all your study documentation. This unique study number will be linked to your personal information, but you will only be identified by this unique number in the final study data. Your consent to the use of your study data or your personal data does not have a specific expiry date, but you may withdraw your consent at any time by notifying your study doctor. Unless otherwise instructed by you, we will retain your data for 5 years following the end of the study. This is made necessary by the current laws about clinical trials. The data will then be destroyed.

Sealed Envelope™ are the company who provide the randomisation software which helps to enable the process of allocation. We will provide Sealed Envelope with relevant information about you (age) to enable their system to allocate you to a group. The information provided to them will be kept securely and they will not be given patient contact details.

By signing the informed consent form, you consent to the study doctor and their staff collecting and using medical and personal data about you for the purposes of the study (study data). This includes: your name, address, date of birth, gender, your ethnic origin and personal data about your physical or mental health or condition. Authorised staff working for the sponsor of the study or the hospital Research and Development Department may require access to your personal information and/or medical records to check the data for this study and ensure that it is being conducted according to UK law. All information will be treated in the strictest confidence during the review process.

By participating in this study, you agree for the research team to follow your medical status on an on-going basis for the duration of the study and for five years beyond the end of the study. This involves collecting, processing, and transferring your personal data (name, address, gender, date of birth and NHS number) for medical research purposes only. This will be done by sending information to the health records organisations mentioned in Part 3 of this information sheet. For this process to work, some of your personal data will need to be stored on a secure, password-controlled database with access given to only a very small number of individuals delegated responsibility by the sponsor. The various organisations' systems will be asked for information which will then be stored in our highly secure database. In addition, in order to send out your follow-up questionnaires, your study doctor will need to provide the coordinating study centre (Bristol Trials Centre at the University of Bristol) with some of your contact details.

No information from which you can be identified will be shared with researchers other than the study team and the organisations listed in Part 3 of this leaflet. At the end of the study, anonymised study data may be shared with other researchers outside the University of Bristol, both in the United Kingdom and abroad.

Who do I contact if I want further information or have concerns?

If there is negligent harm during the trial when the NHS body owes a duty of care to the person harmed, NHS indemnity covers NHS staff, medical academic staff with honorary contracts and those conducting the study. NHS indemnity does not cover no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm.

If you have any questions about the study, or any aspect of your treatment or health whilst on the study, please ask to speak to your Prepare for Kidney Care research nurse or consultant [Sites to enter name, address, email address, telephone numbers including the 24 hour emergency contact number]. Alternatively you can contact the Prepare for Kidney Care Study Office (contact details on last page).

The Patient Advice and Liaison Service (PALS)/ Advice & Complaints Team (ACT) [delete as appropriate] should be contacted for any complaints. Your local PALS/ACT [delete as appropriate] is:

[Enter local details]

Independent advice may be sought from the

In the event of an emergency please contact:

List 24 hour emergency contact details here – this must match the information provided on the patient ID card and will be used to test the out of hours procedure for the study.

Part 3 Collecting data about you from other healthcare organisations

With your consent, data will be collected about you from these organisations:

a) **UK Renal Registry** – all kidney units in the UK send information about their patients to the UK Renal Registry. This is to make sure that patients at your kidney unit receive good quality care. As part of this, your blood test results and other information about you are routinely sent to the UK Renal Registry. This information is usually made anonymous (so that you cannot be identified as an individual). If you agree to take part in the study, you will be agreeing that we can use this information from the UK Renal Registry to find out what happens to your health during the study.

[Country specific information follows for each home nation– research sites to delete sections if not applicable plus delete highlighted line for their own country prior to use]

[For sites in England]

b**) NHS England** collects, stores and analyses information from healthcare organisations in England and Wales. If you take part in the study, we will send information that identifies you (study number, NHS number, Date of Birth and gender) to NHS England. They maintain two databases called **HES** (Hospital Episode Statistics) and **ONS** (Office for National Statistics). If they have records about you on either of these databases, they will send back identifiable information against your study number along with dates and details for hospital admission/ attendance and date and cause of death.

c) **Hospital Episode Statistics** – The NHS collects Hospital Episode Statistics information on all hospital admissions/ attendances, including when, why and for how long they happen. By collecting information from HES, we can tell what happens to your health during the study. For example, if someone is admitted to hospital this will recorded. By doing this, it means that we can use the information the NHS already collects rather than do regular extra study visits. This is particularly important for people with other health problems as treatment already takes up a lot of time.

d) **Office for National Statistics** – When someone dies in England, this is recorded in civil registration data. This includes date and cause of death. The Office for National Statistics can make these data available for research through NHS England. As well as providing information about date and cause of death, this reduces the chances of us sending post, emails, answer machine messages or calls to patients who are no longer alive, which might upset relatives or friends.

By consenting to this study, you agree that the study team will provide your details to NHS England for linkage to HES and ONS data.

[For sites in Scotland (delete if not applicable)]

b**) The Information Services Division (ISD) of NHS Scotland** collects, stores and analyses healthcare information about people living in Scotland. If you take part in the study, we will send information that identifies you (study number, Community Health Index number, Date of Birth and gender) to ISD. They will link this information to their databases to find information about you. If you have been admitted to hospital they will send back identifiable information against your study number along with the date and cause of hospital admission. The NHS collects information on all hospital admissions/ attendances, including when, why and for how long they happen. By using this information, we can tell what happens to your health during the study. For example, if someone is admitted to hospital this will recorded. By doing this, it means that we can use the information the NHS already collects rather than do regular extra study visits. This is particularly important for people with other health problems as treatment already takes up a lot of time.

c) **National Records for Scotland (NRS)** – When someone dies in Scotland, this is recorded in civil registration data. The National Records for Scotland can make these data available for research. As part of this study, we will send the National Records for Scotland enough information to be able to identify people in this study (study number, Community Health Index number, date of birth and gender) and if someone has died they will send back identifiable information (study number) along with the date and cause of death. This reduces the chance of us sending post, emails, answer machine messages or calls to patients who are no longer alive, which might upset relatives or friends.

By consenting to this study, you agree that the study team will provide your details to ISD and NRS for linkage to their databases.

[For sites in Wales (delete if not applicable)]

b) **Patient Episode Database for Wales (PEDW)** – The NHS in Wales collects information on all hospital admissions/ attendances, including when, why and for how long they happen. This is known as Patient Episode Database for Wales and is managed by an organisation called the **NHS Wales Informatics Service**. As part of

this study, we will send PEDW enough information to be able to identify people in this study (study number, NHS number, date of birth and gender) and if someone has been admitted to/ attended hospital they will send back identifiable information (study number) along with details of the hospital admission/ attendance. By collecting information from PEDW, we can tell what happens to a participant's health during the study. For example, if someone is admitted to hospital this will recorded. By doing this, it means that we can use the information the NHS already collects rather than do regular extra study visits. This is particularly important for people with other health problems as treatment already takes up a lot of time.

c**) Office for National Statistics –** When someone dies in Wales, this is recorded in civil registration data. The Office for National Statistics can make these data available for research through NHS England. As part of this study, we will send NHS England enough information to be able to identify people in this study (study number, NHS number, date of birth and gender) and if someone has died they will send back identifiable information (study number) along with the date and cause of death. This reduces the chances of us sending mail, messages or calls to patients who are no longer alive, which might upset relatives or friends.

By consenting to this study, you agree that the study team will provide your details to NHS England and NHS Wales Informatics Service for linkage to ONS and PEDW data.

[For sites in Northern Ireland (delete if not applicable)]

b**) Department of Health Hospital Information Branch (DoH HIB)** collects, stores and analyses information from healthcare organisations in Northern Ireland. As part of this study, we will send DoH enough information to be able to identify people in this study (study number, Health and Care Number, date of birth and gender) and if someone has been admitted to/ attended hospital they will send back identifiable information (study number) along with details of the hospital admission/ attendance. By accessing this information we can tell what happens to a participant's health during the study. For example, if someone is admitted to hospital this will be recorded. By doing this, it means that we can use the information the NHS already collects rather than do regular extra study visits. This is particularly important for people with other health problems as treatment already takes up a lot of time.

c) **Northern Ireland Statistics and Research Agency (NISRA)** – When someone dies in Northern Ireland, this is recorded in civil registration data. The NISRA can make these data available for research. As part of this study, we will send NISRA enough information to be able to identify people in this study (study number, Health and Care number, date of birth and gender) and if someone has died they will send back identifiable information (study number) along with the date and cause of death. This reduces the chances of us sending mail, messages or calls to patients who are no longer alive, which might upset relatives or friends.

By consenting to this study, you agree that the study team will provide your details to DoH and the NISRA for linkage to their databases.

Part 4 General Data Protection Regulation (GDPR)

North Bristol NHS Trust is the sponsor for this study based in United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Bristol Trials

Centre (University of Bristol), who manage the study on behalf of North Bristol NHS Trust will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at: https://www.nbt.nhs.uk/research-innovation/take-part-research/patient-data-research-privacy-policy and/or by contacting: prepare4kc@bristol.ac.uk. [NHS site name] will collect information from you and/or your medical records for this research study in accordance with our instructions.

[NHS site name] will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from North Bristol NHS Trust, Bristol Trials Centre and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

[NHS site name] will pass these details to Bristol Trials Centre along with the information collected from you and/or your medical records. The only people in North Bristol NHS Trust and Bristol Trials Centre who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

[NHS site name] will keep identifiable information about you from this study for 5 years after the study has finished.

Your own Prepare for Kidney Care Research Nurse details

(insert sticky label)

Or, you can contact the study team who are organising the research:

Prepare for Kidney Care Study Office

Population Health Sciences, Bristol Medical School,
1-5 Whiteladies Road, Bristol, BS8 1NU.

T: xx; Email: prepare4kc@bristol.ac.uk

or

Prof Fergus Caskey (Chief Investigator)

fergus.caskey@bristol.ac.uk

Thank you for reading this leaflet and considering taking part in Prepare for Kidney Care

Funding Acknowledgement: *This project is funded by the National Institute for Health Research (NIHR) HTA programme (project reference 15/57/39).*

Department of Health Disclaimer: *The views and opinions expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.*

BRTC Acknowledgement: *This study was designed and delivered in collaboration with the Bristol Trials Centre (BTC), a UKCRC registered clinical trials unit , is in receipt of National Institute for Health Research CTU support funding.*

Sponsor: *This study is sponsored by North Bristol NHS Trust.*