




BMJ Open Intervening to eliminate the centre-effect variation in home dialysis use: protocol for Inter-CEPt—a sequential mixed-methods study designing an intervention bundle

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ABSTRACT

Introduction Use of home dialysis by centres in the UK varies considerably and is decreasing despite attempts to encourage greater use. Knowing what drives this unwarranted variation requires in-depth understanding of centre cultural and organisational factors and how these relate to quantifiable centre performance, accounting for competing treatment options. This knowledge will be used to identify components of a practical and feasible intervention bundle ensuring this is realistic and cost-effective.

Methods and analysis Underpinned by the non-adoption, abandonment, scale-up, spread and sustainability framework, our research will use an exploratory sequential mixed-methods approach. Insights from multisited focused team ethnographic and qualitative research at four case study sites will inform development of a national survey of 52 centres. Survey results, linked to patient-level data from the UK Renal Registry, will populate a causal graph describing patient and centre-level factors, leading to uptake of home dialysis and multistate models incorporating patient-level treatment modality history and mortality. This will inform a contemporary economic evaluation of modality cost-effectiveness that will quantify how modification of factors facilitating home dialysis, identified from the ethnography and survey, might yield the greatest improvements in costs, quality of life and numbers on home therapies. Selected from these factors, using the capability, opportunity and motivation for behaviour change framework (COM-B) for intervention design, the optimal intervention bundle will be developed through workshops with patients and healthcare professionals to ensure acceptability and feasibility. Patient and public engagement and involvement is embedded throughout the project.

Ethics and dissemination Ethics approval has been granted by the Health Research Authority reference 20-WA-0249. The intervention bundle will comprise components for all stakeholder groups: commissioners, provider units, recipients of dialysis, their caregivers and families. To reach all these groups, a variety of knowledge

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The complementary use of mixed research methods (ethnography, qualitative research, national survey, statistical modelling and health economics) to synthesise the intervention bundle.
- ⇒ National survey data linked to actual patient outcomes are analysed cross-sectionally to develop a causal graph describing the drivers and barriers of home dialysis uptake, and longitudinally to model patient's treatment modality history and mortality.
- ⇒ Patient and public involvement and engagement is embedded throughout from inception to dissemination ensuring the perspective of people with kidney failure inform the proposed interventions that will be tested for acceptability by all stakeholders.
- ⇒ The COVID-19 pandemic has already changed how dialysis centres organise their services, which will impact the research but offers the opportunity to observe how these changes affect the uptake of home therapies.
- ⇒ An individual patient-level health economic model based on contemporary UK Renal Registry data with a model structure informed by exemplar renal replacement therapy models identified by National Institute for Health and Care Excellence fully considers the individual characteristics of the patients and candidate interventions.

exchange methods will be used: short guides, infographics, case studies, National Institute for Health and Care Excellence guidelines, patient conferences, 'Getting it Right First Time' initiative, Clinical Reference Group (dialysis).

INTRODUCTION

The 23rd UK Renal Registry (UKRR) report, using data from 2019, found the prevalence of kidney replacement therapy (KRT) for kidney failure in adults to be 1293 pmp,

with a continued annual rate of increase of 2%–3%.¹ This significant health burden was estimated in 2009 to represent 1%–2% of the National Health Service (NHS) budget,² a proportion that has potentially increased as KRT increases.³ In the UK, KRT takes the form of dialysis (43.2%, haemodialysis or peritoneal dialysis, PD) or kidney transplantation (56.8%).¹ Dialysis therapy occurs in two main settings: in-centre haemodialysis (ICHD) delivered at a hospital or satellite unit (35.8%), or in the home (7.4%), as either home haemodialysis (HHD, 2%) or PD, 5.4%. Home dialysis provides benefits including increased control and freedoms for some with kidney failure, especially those in employment or wishing to travel, and greater treatment satisfaction,^{4–7} with observational data showing better survival outcomes^{8–11} and more controversially, some suggestion of potential cost savings.^{10 12–14}

While strongly supporting individuals' preferences when choosing their dialysis modality, the National Institute for Health and Care Excellence (NICE) has, for several years, recommended an increase in the use of home dialysis.^{15–17} Despite this and the *National Kidney Federation Home Dialysis Manifesto* published in 2013¹⁸ rates of home dialysis uptake remain low with a recent detailed analysis of UKRR data (2011–2015), showing a decrease in its use.¹⁹ Importantly, uptake rates in black, Asian, mixed race and minority ethnic groups (BAME) were significantly lower, accounting for 28% of patients using ICHD but just 22% on PD and 13% on HHD.¹⁹ Furthermore, patients from more deprived backgrounds have lower rates of home dialysis uptake: in 2015, only 9.8% of patients using PD were from the most socially deprived backgrounds compared with 16.3% from the least deprived backgrounds.¹⁹ These disparities, which persist, as emphasised in the recent *Renal Getting it Right First Time* national report,²⁰ are also seen in other countries.^{21 22} Important as these disparities are, they are less than the difference between dialysis centres in the overall uptake of home therapies (termed here 'centre variation'). The probability of being initiated on PD at the start of KRT ranged between 6.3% and 47.9% across centres in the UK.¹⁹ Ethnicity and socioeconomic status had a far greater impact on home therapy use in some centres than others. It is this unwarranted variation in access to home therapies, a recognised contributor to kidney health inequalities in the UK,²³ that is the primary focus of the '*Intervening to eliminate the centre-effect variation in home dialysis use*' (Inter-CEPT) study.

Several factors have been reported as barriers and facilitators to home dialysis uptake, and it is important to distinguish between those operating at the patient level versus the institutional level. For patients, these factors, apart from those already alluded to, include inadequate and poorly timed predialysis education, preparation and inadequate psychosocial support.^{4–7 24–28} People approaching KRT experience psychosocial difficulties such as anxiety over potential complications and a feeling of being ill-equipped to self-manage, emphasising the

need for programmes that provide both educational and emotional support.^{5 7 24 25 28 29} Perceived care giver burden has also been linked to low uptake of home therapy.^{29–31} In Canada, Australia, New Zealand and the USA, home dialysis may come at an increased cost to individuals, referred to as 'out of pocket costs'.^{26 30 32–34} These costs, unknown in the UK, might also act as barriers to home dialysis.^{3 23}

At the centre level, barriers include lack of trained staff and limited funding for increasing home therapy usage.^{25 32 35} However, it is likely that institutional culture also plays an important part, with opinions and biases that staff might have regarding home dialysis impacting how effectively (or not) the unit promotes home therapy.^{11 14 18 27 28 29 36–38} World wide, several studies and systematic reviews have explored the influence of policy on home dialysis,^{28 37 39} showing that a combination of educational programmes for patients and staff,^{36 40} targets, performance indicators and financial incentives can increase home therapy uptake.^{25 34 41 42} It is not clear whether these approaches are sustained over time, but increased use of PD in the USA was not associated with a detrimental effect on survival.⁴³ Of these initiatives, the Ontario Home Dialysis Initiative, focussing on PD, has been the most successful, showing that multiple components for the intervention are necessary, including home dialysis coordinators, assisted PD and support for dialysis access pathways that incorporate urgent start of treatment.⁴² Also, when considering centre variation, it is important to consider the relative rates of: patient survival, transfer from home to centre-based dialysis and kidney transplantation when making comparisons. Data from the international Peritoneal Dialysis Outcomes and Practice Patterns Study indicate that differences in transplantation rates have the greatest effect on time spent on PD (*accepted for publication, Clinical Journal of the American Society of Nephrology*), so it is clearly important to establish to what extent this accounts for different uptake rates of home dialysis.

For financial incentives to be effective in the long-term it is crucial to understand the true cost of different dialysis modalities. The recent NICE systematic review concluded that the cost of home dialysis may be lower, but that there is still significant uncertainty in the UK.¹⁶ This is mainly due to the lack of clarity around the current costs of dialysis and transport, which would likely be less for home dialysis but are not currently included within the dialysis payment tariff. Another factor which remains uncertain is the impact of assisted PD, which some studies have shown to be essential in making home dialysis more available to older or more comorbid people.^{42 44 45} Assisted PD in the UK does attract a higher level of reimbursement and it is quite likely that its more extensive use in people who are more marginal candidates for home dialysis will largely erode any cost-benefit associated with this modality. This would likely apply to assisted home HD, which has been adopted successfully but in a limited way in other countries.⁴⁶

Table 1 Objectives of the Inter-CEPt study

Objectives	Work package	Outcomes
Gain in-depth insights into cultural and organisational factors contributing to centre uptake of home therapies	WP1	Insights derived from ethnographic case studies
Understand and quantify the interplay of patient- and centre-level factors, including geography and satellite facilities, affecting uptake, taking into consideration transplantation as a competing treatment and other patient outcomes such as death	WP1,2,3	Quantitative survey, informed by case studies that is linked to patient-level UK Renal Registry data to establish the key factors responsible for home therapy uptake which also informs the economic evaluation
Identify factors most likely to be modifiable, effective and easily adopted	WP4	A detailed synthesis of centre-level and patient-level factors that explain home therapies uptake
Develop an optimal intervention incorporating these factors that is acceptable to patients and healthcare professionals, taking account of limited financial resources	WP5	Develop candidate components into an intervention bundle derived from the detailed synthesis
Use economic evaluation to develop a contemporary economic model comparing the modalities and establish the cost-effectiveness and return on investment for implementing the intervention bundle	WP3, WP5	Optimised intervention bundle to ensure acceptability, feasibility and cost-effectiveness

Given the complexity of the problem, Inter-CEPt aims to identify and explore patient and centre factors driving uptake of home dialysis and use these findings to design an intervention bundle to overcome this. To achieve this, a number of objectives have been set (table 1).

To ensure the research is of value, the Inter-CEPt team will work closely with the leadership team of the national Renal Services Transformation Project, currently underway, with their representation on the study oversight committee. It is anticipated that the COVID-19 epidemic has impacted the use of home therapies. Patients treated with home dialysis were less likely to develop COVID-19 and being on dialysis is associated with a high mortality from the illness.⁴⁷ This presents both opportunities for the research (eg, which centres were most able to expand their home dialysis programmes) and difficulties (eg, conducting conventional ethnographic fieldwork). These are elaborated on in the methods below.

METHODS AND ANALYSIS

Research design and study flow

Inter-CEPt is a sequential, mixed-methods study with the purpose of designing an intervention bundle (see figure 1). Work packages (WP) 1–3, which start in parallel, will combine the insights into qualitative ethnographic and qualitative (WP1) with a survey linked to patient-level UKRR data (WP2) to synthesise factors that explain home dialysis usage. These findings will be integrated with the economic evaluation (WP3/4) forming the design of an appropriate and cost-effective intervention bundle to promote home dialysis utilisation (WP3/5).

Patient and public involvement and engagement

There will be active patient and public involvement and engagement (PPIE) in all aspects of the research. Our patient coapplicants will contribute to the regular investigator meetings held throughout the project, ensuring that the patient perspective is always to the fore, David

Coyle (Patient Partnership Lead, National Institute for Health Research (NIHR) 7 and the ethnography research team). There will be two PPIE advisory groups working with us over the duration of the project, an expert group based at Keele University, advising on research design,

STUDY FLOW CHART

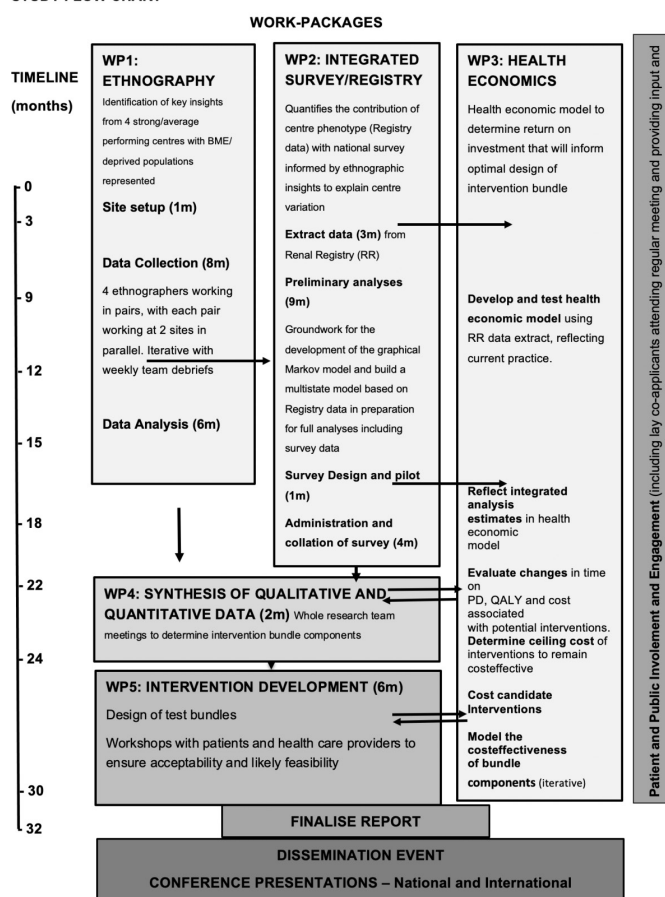


Figure 1 Study flow and inter-relatedness of work packages. PD, peritoneal dialysis; QALY, Quality-Adjusted Life Years.

conduct and dissemination and a Patient Advisory Group (PAG) of current or previous users of dialysis. The PAG will advise on interpretation of ethnographic findings, survey development and will contribute to the workshops (WP5) and dissemination of findings. There will also be independent patient representation on the Inter-CEPT Advisory Group drawn from Kidney Care UK. This group will ensure that the project as it develops remains relevant and will provide guidance and networks as needed for dissemination of the projects' outputs.

Theoretical frameworks

The non-adoption, abandonment, scale-up, spread and sustainability (NASSS) framework, which can be used to examine and explain the overall acceptance of innovations in healthcare, will be used to inform each strand of the study.⁴⁸ NASSS identifies seven groupings of explanatory factors related to: the condition/illness (end-stage renal disease); the technology (home therapies); the value proposition (to both the patient and the provider); adopters (staff, patients and carers); organisation (including capacity, capability and readiness to change); the broader system (including policy context, legal dimensions, sociocultural context) and the embedding and adapting of change over time. Application of NASSS will help to explore and explain why, for example, some units have obtained above national average uptake rates.

When developing the intervention, we will draw on the capability, opportunity and motivation to change behaviour (COM-B) framework, which is internationally recognised as one of the most robust evidence-based frameworks for designing behaviour change interventions.^{49 50} It is highly relevant as the move towards more home dialysis usage requires changes in behaviours and attitudes by staff, patients and their carers.

Work package 1: qualitative research: a focused ethnography

WP1 explores factors that contribute to a 'centre effect'. It will increase our understanding of the perceptions, behaviours and understandings of staff, patients and their family members and how these interact with organisational and institutional cultures. We will use a comparative ethnographic methodological approach, including observational, interview and reflective data from four case study sites.⁵¹

Selection of case study sites

Using two-stage purposive sampling to select case study sites from the 52 dialysis units in England, stage 1 assigns each renal unit in England (n=52) to one of four categories, using a taxonomy developed from UKRR data.¹ Four categories in the taxonomy are: (1) high uptake of home therapies (top 15% nationally based on the proportion of patients using home therapies), (2) high uptake of home therapies among ethnic minorities (top 15%), (3) centres with home therapy uptake for all patients at rates around the national median (10 above or below the median) and

(4) centres with home therapy uptake for ethnic minorities at rates around the national median (10 above or below). Renal units with fewer than 50 total renal patients and/or fewer than 20 BAME patients are excluded to ensure large enough cohorts for the ethnographic work.

From the list generated, a second sampling stage is used to select single case study sites from each group, ensuring a balanced selection based on: maximum geographical variation (North, Midlands, South, London); population density (urban/rural); sociodemographic characteristics (less affluent/affluent/mixed) and ethnic diversity (low/high), and transplant versus non-transplant centres.

Data collection

Due to the COVID-19 pandemic, a proportion of the data collection will be conducted remotely, still adhering to consent and data protection principles. The following procedures will be used⁵²:

Non-participant observation of relevant meetings in each renal unit

The focus will be on how dialysis modality decisions are discussed and the details of the decision process, including education information given and assumptions made by both patients and staff on dialysis choice and patient characteristics (eg, BAME, socioeconomic deprivation, low health literacy).

Non-participant observation of dialysis choice consultation

The focus will be the content of healthcare professional-patient interaction; the information provided to patients on treatment options and how this is relayed; assumptions made by both patients and health professionals and the nature of these encounters, including the tone of conversations, language used, verbal and non-verbal reactions.

Short reflection interviews after individual dialysis choice consultation (6–8 encounters per site)

Immediately after the consultation observations staff, patients and willing family members/carers will be invited to participate in short reflection interviews (~15 min). These will be cognitive interviews, incorporating think-aloud techniques to discuss immediate reactions, thoughts and feelings.⁵³ The aim is to generate rich data about whether patients understand home therapy in a consistent way and in the manner intended.⁵⁴

Semistructured interviews (staff) 12–14 per site

For staff interviews, we will explore how patients are supported in their treatment decisions and their reflections on the barriers and facilitators for such treatment decisions, especially in regards to ethnic minority and less affluent patients and how these are supported/encouraged to choose home dialysis.

Semistructured interviews (patients and carers/family members): 10–12 patients, 5 carers/family per site

Interviews will explore in depth how patients have made their treatment choices and their reflections on factors that have helped or hindered treatment choices. Home

residence postcodes will be converted to a deprivation quartile on the Index of Multiple Deprivation using the online tool Geoconvert (<http://geoconvert.mimas.ac.uk>) to assess socioeconomic status.

All interviews will be audio-recorded using an encrypted digital recorder and kept on a secure network drive at the University of Birmingham premises. The data will then be transcribed verbatim by a professional transcription company and checked against recordings for accuracy.

Secondary data collection

We will also collect written documentary data such as unit policies, strategies, meeting notes and materials developed for patient counselling and education.

Eligibility criteria for interviews

Inclusion criteria (patients and carers/family members)

- ▶ Expected to start KRT with dialysis within the next 3–6 months.
- ▶ Unplanned dialysis initiation, even if dialysis has already commenced in whom a decision regarding preferred dialysis modality has not been made.
- ▶ Commencing dialysis following a failed kidney transplant.
- ▶ Aged 18 and above.
- ▶ Carers, family members or individuals supporting eligible patients.

Exclusion criteria (patients)

- ▶ Unable to consent to take part, including those with significant cognitive impairment (although mild cognitive impairment will not preclude participation).
- ▶ People with acute kidney injury or anticipated recovery of kidney function.

Inclusion criteria (staff)

- ▶ Renal unit staff members who have regular contact with renal patients and who engage in treatment discussions or who have oversight of decision-making processes within the renal unit (consultants, registrars, specialist home therapy nurses, pre-dialysis nurses, dialysis unit ward staff, dietitians, psychologists/counsellors, clinical lead, business manager).

Exclusion criteria (staff)

- ▶ Renal unit staff who do not have regular contact with renal patients, who do not engage in treatment discussions or who do not have oversight of decision-making processes within the renal unit.

Qualitative data analysis and synthesis

Data from each site will be analysed using conventional content analysis. This will happen contemporaneously with ethnographic data allowing emerging themes from the analysis to be further investigated in interviews. Field notes from observations will be shared securely with the team and discussed weekly to enable an iterative data analysis process. Field data from ethnographers' field notes and interview transcripts will be imported into the qualitative data analysis software QSR NVivo V.12 to support inductive thematic analysis.⁵⁵ The data from each

site will be analysed separately to capture unique centre effects. Using a representative sample of 10% of each data category, two researchers will create an initial coding framework, which may be adjusted following review and discussion with the rest of the team. The analytical approach will be inductive, based on iterative data coding and comparison. Identified themes will be mapped to the NASSS framework to determine the primary factors that drive the acceptance of home therapies and how these factors interact. The second stage of analysis will look across the four sites' ethnographies to characterise the centre effect and highlight specific practices that can be explored further in the subsequent national survey (WP2).

Work package 2 (WP2): graphical Markov and multistate modelling using a centre survey linked to UKRR data

Rationale

Using findings from WP1 and an updated literature review, we will design a national predominantly quantitative survey to reach all 52 dialysis units in England. Its purpose is to identify patterns of practice, explore reasons for poor home therapy uptake and evaluate the effects of commissioning strategies. In addition, linking the survey findings to actual patient outcome data obtained from the UKRR will enable quantification of how different factors influence home therapy uptake in the context of alternative treatment and related clinical outcomes.

Survey design and content

The survey will be online, requiring approximately 20 min to complete. Clinical leads will be requested to disseminate the survey link among key members of their unit; we aim to have a minimum of eight responses per unit to obtain a diverse range of expertise, so increasing the quality and completeness of the responses. Commissioners of renal services will also be invited to complete relevant parts of the survey. To maximise response rates and assure comparability, it will feature brief questions with a tick box or Likert scale response and space for free text. Key lines of enquiry are shown in [table 2](#).

The survey will be created and administered using the Online Surveys tool. It will be piloted for relevance and readability by renal unit staff and PPIE representatives in the West Midlands. The survey will be made available to potential participants electronically via a web link embedded in a brief invitation email. Completing the survey will be taken as consent to participate in the study. Respondent's data will be handled confidentially.

Statistical analysis

Survey data will be analysed descriptively, mapping home therapy provision patterns across England and highlighting similarities and disparities in renal unit practices. Respondents' views on service provision, possible improvements and commissioning will be analysed looking for differences and commonalities across stakeholder group (eg, clinical leads, commissioners), thereby providing a

Table 2 Likely key components of the survey

Thematic area	Potential areas for questioning	Alignment to NASSS framework
Pathway for patient education	<ul style="list-style-type: none"> ► Use of shared decision-making tools ► Renal unit approach to patient education (how offered, flexibility, iterative provision) ► Involvement of family members ► Information provided (mode/timing), individual tailoring ► Peer support ► Regularity of review of patient education organisation and delivery to optimise home dialysis support 	Domain 3: Value proposition
Clinical leadership and attitudes	<ul style="list-style-type: none"> ► Quality Improvement projects within the renal unit to improve home dialysis use; methodological support ► Home dialysis-related metrics used as key performance indicators ► Supportiveness of clinical leadership, hierarchy ► Pathways to management and education for urgent start patients ► Strength of home dialysis leadership (all modalities) ► Positive/negative views of home dialysis among consultants, renal nurses 	Domain 5: Organisation
Home dialysis service	<ul style="list-style-type: none"> ► Principles underpinning service provision ► Whether/how patients from specific groups are prioritised when offering home treatment options ► Eligibility/criteria for accessing treatment options ► Renal unit response to diverse/unmet population needs ► Examples of innovative practice, use of new technologies ► Staffing levels, service stresses limiting access ► Waiting lists for home dialysis training, infrastructure supporting training ► Out of hours support ► Assisted PD service and models for delivery 	Domain 2: Technology Domain 3: Value proposition Domain 5: Organisation
Access service	<ul style="list-style-type: none"> ► Pathways for urgent catheter insertion, obstacles ► Medical pathway 	Domain 5: Organisation
Finance and commissioning	<ul style="list-style-type: none"> ► Impact of innovations for example, home dialysis incentivisation ► Influence of tariff structures and funding model on home dialysis provision and uptake ► Renal unit level of budgetary control, responsibility ► Commissioner access to home dialysis use data 	Domain 6: Wider systems
Network, GIRFT, RSTP response ^b	<ul style="list-style-type: none"> ► Identification of home dialysis as a regional issue ► Awareness of regional projects to increase home dialysis access ► Regional network prioritisation of access to home dialysis 	Domain 6: Wider systems
COVID-19	<ul style="list-style-type: none"> ► Changes to service organisation/delivery with COVID-19 ► Incorporation of COVID-19 risk into patient education 	Domain 7: Adoption and Embedding

This is not exhaustive and will be adjusted or extended to incorporate the findings of WP 1. GIRFT, Getting it Right First Time; NASSS, non-adoption, abandonment, scale-up, spread and sustainability ; RSTP, Renal Services Transformation Plan.

preliminary understanding of the relative contribution of different factors to the home dialysis centre effect. This analysis will also identify key issues for further exploration in the health economic analysis (WP3).

Once survey data have been linked to the UKRR patient-level data (size estimate 27 000), the following analyses will be undertaken:

1. *Summary of baseline data and flow of patients* (demographics, use of KRT modalities).
2. *Graphical Markov modelling of factors that explain home dialysis uptake.* We will employ sequences of regressions coupled with a causal graph defining a graphical Markov model that extends path analysis to formulate an explanatory model for home dialysis uptake.^{56–59}

Figure 2 illustrates a postulated causal graph, which will be based on the findings from WP1.

This approach provides a framework to identify potential causal relationships among many patient-related and

practice-related factors and their impact on home dialysis uptake, thereby offering a powerful tool to deal with the complexity likely to be identified by the ethnographic

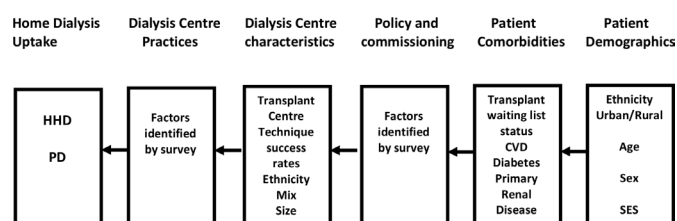


Figure 2 Example of postulated order of sequences of regressions model variable. Variables located on the right are regarded as explanatory to those located on their left. The associations between two variables in different boxes can be direct or indirect through intermediary variables. CVD, cardiovascular disease; HHD, home haemodialysis; PD, peritoneal dialysis; SES, socio-economic status.

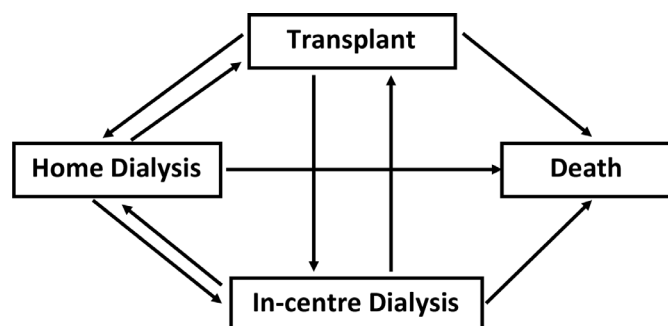


Figure 3 Multistate model to estimate the rates of home dialysis usage. Combined, similar models will be built replacing home dialysis by two states for PD and HHD separately, allowing for transitions between these two treatment modalities. The rates of transitions from one state to another will be modelled in terms of important centre-level and patient-level explanatory variables identified by the graphical Markov model, on rates of home dialysis use. HHD, home haemodialysis; PD, peritoneal dialysis.

study. Importantly, it is possible to assess interactions or whether any association holds in the same direction and magnitude for different patient demographics, for example, ethnicity or socioeconomic status. The primary outcomes of this approach include (1) *a causal graph that displays pathways of associations starting from demographic factors through intermediary factors leading to home uptake*, including a measure of relative importance, which will greatly simplify the synthesis of findings (WP4); (2) *an interpretation based on graph theory and probabilistic theory* to explore the relationship between selected subsets of variables, thereby enabling assessment of competing hypotheses. Specifically, it will examine the association between any two or more variables, partitioning out the contribution of different groups of variables as relevant, led by group discussions (WP4). This will provide a robust mechanism for the choice of the most important modifiable and cost-effective factors when developing the intervention (WP5) and (3) *multistate modelling of patient-level treatment modality history and mortality*: Results from the graphical Markov model will inform the development of a multistate model,⁵⁹ for patients requiring renal replacement therapy. This will estimate the rates of transition from and to: home and in-centre dialysis, transplantation and in-centre dialysis, and death (figure 3). The transition rates will include random intercepts at the centre level to account for heterogeneity among dialysis units if there are enough transitions. The estimated parameters of this model will inform the health economic analysis (WP3).

The renal registry is characterised by high levels of data completeness, except for comorbidity data as the returns to the Registry from different units are variable. Maximum likelihood estimation will be used to fit all the models, as this method of estimation yields parameter estimates that are not affected by the exclusion of missing outcome data if a missing-at-random assumption is plausible. Depending on the amount of missing data, expectation-maximisation imputation will be considered

because it preserves the covariance structure of the data, combined with multiple imputation to adjust the estimated SEs, and, thus obtain estimates that make effective use of all the available data.

Work package 3 (WP3): health economics

This WP will create a health economics model that will inform the design of appropriate interventions to promote home dialysis uptake, using UKRR data. To decide on a model structure, we will review existing models and get feedback on our proposed approach from relevant stakeholders.

Analysis plan

To inform the conceptualisation of the model, the health economics team will review the previous economic models describing renal replacement therapy identified by the recent NICE systematic review,¹⁶ any subsequent publications and examine the UKRR data to understand the data available to support possible events and model structures. The proposed model will be discussed with stakeholders for feedback. The model will be informed by the most relevant sources available, capitalise on existing data sets describing health-related quality of life (EQ5D), event rates and costs the group has access to,^{60 61} and align with consensus value-based outcomes in kidney disease.⁶² Acknowledging the issue with existing reference cost data, the costs of renal replacement therapy modalities will capitalise on a multicentre dialysis costing exercise occurring in parallel.

Once all parameter values have been retrieved, we will build the economic model (a patient-level simulation model) in the statistical software R alongside the multistate model from WP2. The economic outcomes will be average Quality-Adjusted Life Years (QALY) and costs, from an NHS and personal social services perspective, over the lifetime of patients. The validity will be checked by comparing the proposed model's outputs to existing registries and modelling studies, validated by stakeholders and in response to these iterated as required to improve accuracy. To test the sensitivity of the parameter inputs, we will examine which assumptions and parameter values impact the economic outcomes the most.

Work package 4 (WP4): synthesis of qualitative and quantitative data

This WP combines data from previous WP, synthesising and interpreting it to develop potential intervention bundles. The synthesis will be guided by the NASSS and COM-B framework (table 3), which provide a clear structure and allow for integrating results derived from multiple resources in the following steps:

1. Data from WP1-3 will be used to map the factors affecting home therapy onto the domains of the NASSS framework.
2. Each factor will be discussed during a team workshop, looking at the evidence behind its complexity and significance within each of the seven framework domains.

Table 3 COM-B framework domains, potential intervention components relating to home therapy uptake

Intervention categories	Typical definitions	Examples for this intervention
<i>Education</i>	Increasing knowledge or understanding	<i>Raising awareness</i> of reduced access to home therapies by some groups among clinicians, patients, caregivers and their families
<i>Persuasion</i>	Using communication to induce positive or negative feelings or stimulate action	Comparative publication of key performance indicators
<i>Incentivisation</i>	Appropriate commissioning of home dialysis services	Specific guide for commissioners on home dialysis, which might include incentives
<i>Coercion</i>	Creating expectation of punishment or cost	Financial penalties for failing to reach agreed performance indicators
<i>Training</i>	Imparting skills	Unconscious bias training
<i>Restriction</i>	Using rules to increase the target behaviour by reducing the opportunity to engage in competing behaviours	It is likely that specific behaviours that disincentivise home therapies will be identified by the ethnographic study
<i>Environmental restructuring</i>	Changing the physical or social context	<i>Specific guidance for dialysis providers</i> how their units are structured to ensure they support home therapy use how finances are managed by service finance departments and unit managers clinic structures, staffing, delivery of assisted dialysis in the home
<i>Modelling</i>	Providing an example for people to aspire to or imitate	<i>Guidance on Best Clinical Practice</i>
<i>Enablement</i>	Increasing means/reducing barriers to increase capability or opportunity	Changes to organisational practices that favour culture within a dialysis centre (attitudes, behaviours), for example increasing the time and support for patients, approaches to creating innovative solutions for perceived or actual barriers to home
Policy categories	Typical definitions	Examples for this intervention
<i>Communication/marketing</i>	Using print, electronic, telephonic or broadcast media	Educational materials, reports, infographics
<i>Guidelines</i>	Creating documents that recommend or mandate practice. This includes all changes to service provision	Next iteration of NICE guidance for the treatment of advanced kidney disease
<i>Fiscal</i>	Using the tax system to reduce or increase the financial cost	In this example, tax=dialysis tariff system. Previous research conducted by this team has shown that financial incentives can influence home dialysis use.
<i>Regulation</i>	Establishing rules or principles of behaviour or practice	<i>Performance Indicators</i> Indicators for UK Renal Registry Reporting Indicators for the Getting it Right First Time (GiRFT) initiative
<i>Legislation</i>	Making or changing laws	Unlikely to be necessary
<i>Environmental/social planning</i>	Designing and/or controlling the physical or social environment	Provision of adequate facilities to support home dialysis
<i>Service provision</i>	Delivering a service	Review of service specifications for home dialysis (especially in the context of the planned review of renal services by NHS England)

COM-B, Capability, opportunity and motivation framework for changing behaviour; NHS, National Health Service; NICE, National Institute for Health and Care Excellence.

The team will also discuss the scope for change in practice looking at these factors, factoring in patterns and themes from literature sources.

3. An iterative synthesis will be performed using material from the first team workshop, plus further exploration and reanalysis of WP1–3 data. Additional data from ethnographic work, survey data and the health economic model will be used to contribute to the synthesis.
4. A second team workshop will review the additional analysis and finalise the list of factors affecting home dialysis uptake and identify codependent factors. We will use the effect estimates from WP3 to assess the relative

impact of each factor on home dialysis uptake, time on home therapy, QALY gains and costs. This process will be supported by the review of existing literature which explores the underlying mechanisms. Alongside the NASSS framework, the synthesis will be guided further by the eight-stage process of intervention development outlined by the authors of the COM-B framework. This process will link WP4 and WP5, so that the intervention development work in WP5 draws on the synthesis undertaken in WP4 and is directly informed by it.

Work package 5 (WP5): intervention development

An independent reference group (RG) consisting of clinicians and patients will be convened to discuss the findings of the WP1–3 and, in interactive workshops, to design the intervention bundles. The RG will consist of 19 participants, including patients on different dialysis methods, doctors, specialist nurses, allied health professionals and policy leads. They will not have had an input in the first three WP and will be recruited by the advisory group from the extensive networks of the project team members.

The first workshop will introduce the study to the RG and discuss the results of WP1–3 and shortlisting modifiable factors as well as potential interventions using the COM-B model categories of; education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement. These modifiable factors are likely to be related to (a) patient–clinician interaction, (b) renal unit organisation and (c) the wider policy/system context. This discussion is expected to generate 3–5 potential interventions to help increase home dialysis uptake across centres. The proposed interventions and their components will then be reviewed, looking at the available literature providing evidence for their feasibility and effectiveness in renal patients. The first intervention development workshop in WP5 provides an opportunity for the synthesised results to be discussed and challenged by a wider group of staff and patient stakeholders using the Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side-effects and safety, Equity criteria.⁴⁹

The second workshop will review the evidence and refine the bundles of interventions, focusing on how individual interventions could be packaged together into bundles for maximum impact. This will identify 2–3 potential intervention bundles which can be modelled to determine the numbers transitioning onto home therapies, time on treatment and cost-effectiveness using the health economic model from WP3. Net cost differences that result from these bundles will inform maximum cost to ensure cost-neutrality to the healthcare system using a value implementation framework.⁶³ The RG will also discuss essential components of each suggested intervention package and how they are projected to affect behaviour and policy change. Potential components of the intervention are described in [table 3](#).

ETHICS AND DISSEMINATION

Ethics approval has been granted by the Health Research Authority (reference 20-WA-0249, Wales Research Ethics Committee 6, Integrated Research Application System reference 281908).

Dissemination of results

To ensure a robust dissemination process, the study oversight committee has representation from the following organisations and stakeholders: Renal Services

Transformation Project (NHS England), KidneyCare UK, Kidney Research UK, Getting it right first time, National Kidney Federation (including BAME representation). A project report will be produced for the NIHR, with summaries tailored to commissioners, healthcare providers, patients and carers. These will be shared through the networks that make up our Advisory Group.

The ethnography findings, graphical Markov modelling, multistate model, health economic modelling and description of how the final intervention bundle was produced will be submitted to peer-reviewed journals. We will also collaborate with the Renal Association Clinical Guidelines Group and ensure that our proposals for an intervention bundle are incorporated into the recommendations of future NICE guidelines.

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Contributors MT updated the literature review that informs the background to the project. KA, DC, SD, LP-D, ML, IS-T, IPW and SJD (corresponding author and CI) are all co-applicants on the original funding application, IW replacing Gill Combes (see acknowledgements) in the later stages. DC is lead for PPIE, KA and LD for work-package (WP) 1, ML and IS-T for WP 2 data analyses and SD for survey, JF and HH for WP3 and IW for WP4 and WP5. All the co-applicants and HH contributed to the finalisation of the protocol, contributing equally to the development of the manuscript and ongoing execution of the research. LP-D is responsible for overall coordination of the project and research governance.

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Competing interests SJD (CI) receives research funding and is on an Advisory Board for Baxter Healthcare and research funding from Fresenius Medical Care (both companies deliver dialysis treatments, including home dialysis). ML receives research funding from Baxter Healthcare. JF has speaker honoraria from Fresenius medical care, consultancy fees from Novartis, travel support from Amgen, and conducts research funded by the National Institute of Health Research and the Health Foundation into in-centre haemodialysis, Kidney Research UK into peritoneal dialysis, and Vifor Pharma into pharmacotherapies for uraemic pruritus.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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