

## The Prepare for Kidney Care Randomised Controlled Trial: Recruitment Progress and Challenges

Dr Helen Winton<sup>1</sup>, Dr Alba Realpe<sup>1</sup>, Dr Leila Rooshenas<sup>1</sup>, Dr Fergus Caskey<sup>1,2</sup>

<sup>1</sup>Population Health Sciences, University of Bristol, Bristol, United Kingdom, <sup>2</sup>Southmead Hospital, North Bristol NHS Trust, Bristol, United Kingdom

### Background

Differences in how kidney failure is treated within the NHS reflects uncertainty about the best approach to manage symptoms in elderly, frail patients with chronic kidney disease (CKD). Whether to undertake dialysis is a difficult decision for older people with co-morbidities, and starting dialysis is associated with a deterioration in functional status and treatment burden. The best quality observational evidence to date does not tell us whether patients would be better off having dialysis or conservative care. Comparison of dialysis patients with matched conservative care cohorts suggests an equivalent survival in patients aged over 80, or over 70 with multiple health problems, and quality of life has a similar trajectory in both groups until initiation of dialysis.

Many people thought it would not be possible to carry out a RCT of preparing for dialysis vs conservative care in this group of patients, but 'Prepare for Kidney Care' is changing attitudes. Recruitment to RCTs, however, is challenging. Lessons learned from the embedded QuinteT Recruitment Intervention (QRI) work over the first 3 years, has aided a steady increase in recruitment.

### Interventions and Outcome Measures

Eligible patients (eGFR <15, aged 80+, or 65-79 with multiple health problems/ poor functional status) are approached. Patients providing informed consent are randomised to either prepare for dialysis as per local care, or to responsive management, delivered through a combination of outpatient/ home visits to provide routine support, and support that responds to the patient's needs (from renal unit staff, palliative care teams and community staff). The primary outcome is quality adjusted life years (QALYs). QRI has been integrated throughout the RCT and qualitative research will investigate patients' experiences of the trial treatments. Eligible patients declining the RCT are invited to participate in an observational cohort, the Registry follow-up (RFU) study. Integration with the UK Renal Registry will allow further comprehensive data capture and assessment of external validity of the RCT.

### Progress

The study opened to recruitment July 2017 and as of January 2020 223/512 (44%) patients have been randomised. There are 24 sites open, with further sites opening. Additional funding has been secured from NIHR to extend recruitment to June 2021. Follow up will continue until September 2023. 101 patients have consented to the RFU.

Site screening log review alongside QRI audio-recordings of recruitment consultations and in-depth interviews with site staff have provided insight into recruitment barriers. The biggest challenge to date is that some clinicians are not willing to support the trial because they feel their service is already excellent. Another big challenge has been that not all eligible patients screened are being approached due to a pre-existing treatment plan. Of 223 patients randomised and accepting allocation, however, most, if not all, had already started to consider one of the two treatment pathways in routine care, demonstrating patient acceptability.

### Conclusion

This is the first RCT to compare preparation for dialysis versus conservative care in older, multi-morbid patients. Its findings will provide patients, families and professionals with much-needed evidence to enable informed decision-making about treatment options.