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P087 -The Prepare for Kidney Care Randomised Controlled Trial: Background, Intervention, Outcome Measures and Progress

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Background:

Whether to undertake dialysis is a difficult decision for older people with multiple health problems and chronic kidney disease (CKD). Starting dialysis is associated with a deterioration in functional status and treatment burden. 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. Quality of life has a similar trajectory in both groups until initiation of dialysis. Differences in how kidney failure is treated within the NHS reflects uncertainty about the best approach to manage symptoms in this group of patients. Reflecting this, whether someone chooses to prepare for dialysis or conservative care seems to depend on the renal unit they attend.

The Prepare for Kidney Care randomised controlled trial (RCT) seeks to establish the effectiveness and cost-effectiveness of preparing for dialysis compared with preparing for responsive management (a protocolised form of conservative care) in relation to quality and length of life in multi-morbid, frail, older people with advanced kidney disease.

Interventions and Outcome Measures:

Eligible patients (CKD5, eGFR <15, aged 80+, or 65-79 with multiple health problems or poor functional status) are approached. After providing written informed consent, patients are randomised to either prepare for renal dialysis, as delivered locally, or 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). The RCT will also collect data on secondary outcomes (e.g., patient reported outcomes and time spent in hospital) and include a health-economic analysis. The QuinteT Recruitment Intervention (QRI) has been integrated throughout the RCT to optimise recruitment and informed consent, and integrated qualitative research will investigate patients' experiences of the trial treatments. Eligible patients that decline 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 in July 2017 with a recruitment target of 512. By end Jan 2019 there are 16 sites open to recruitment and 83 patients randomised. A further 9 sites are in set-up.

Recruitment and intervention development are supported by the QRI. Audio-recordings of 33 recruitment consultations and 32 in-depth interviews with site staff has provided insight into recruitment barriers which have been fed back to the trial team in 'real time', enabling accelerated learning and iterative changes to recruitment processes and trial intervention. Follow up is currently planned to continue until December 2021, an anticipated average three years per participant.

Conclusion:

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

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