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P098 -Making the impossible possible: overcoming challenges to delivering a randomised controlled trial comparing 'Preparation for Renal Dialysis' with 'Preparation for Responsive Management' in older, co-morbid patients

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There is uncertainty around how best to treat older, multi-morbid patients with chronic kidney disease. The Prepare for Kidney Care ('Prepare') randomised controlled trial (RCT) seeks to establish the effectiveness and cost-effectiveness of 'preparing for renal dialysis' compared with 'preparing for Responsive Management': a protocolised form of conservative care. The RCT will compare survival and quality of life in patients with CKD5, eGFR <15, aged 80+, or 65-79 with co-morbidities.
There was concern that recruiting to Prepare would be challenging, due to anticipation that subjecting treatment-decisions to randomisation might be controversial. The 'Quintet Recruitment Intervention' (QRI) was applied to understand recruitment issues, and implement strategies to address these in 'real-time'. Here, we report the QRI findings and changes implemented during the first 18-months of Prepare, with the aim of exposing challenges that may be transferable to other ambitious renal trials.
Methods
Recruitment was investigated by: scrutinising screening/randomisation figures across centres/over time; interviewing professionals involved in trial delivery (n=32); and audio-recording recruitment consultations between recruiters and eligible patients (n=33). Quantitative data were analysed descriptively, and qualitative data were analysed using thematic and conversation analyses. Data were triangulated to build credible explanations for recruitment issues, which were fed-back to the trial team iteratively.
Results
To date, 83 patients have been randomised from 11 UK sites. Patients and families/carers have engaged with the trial, with an encouraging proportion consenting to randomisation (mean=44%). Nonetheless, several recruitment challenges were addressed since the trial's opening.
Recruitment was initially restricted by difficulties implementing the protocol across renal units, which varied in their infrastructures, current care pathways, and mix/numbers of professionals. Recruitment was originally a research nurse (RN)-activity, but not all RNs had sufficient renal knowledge to explain the trial. Gate-keepers also varied across units, necessitating different approaches to screening/identifying/approaching patients. Home-visits were initially fundamental to recruitment-processes and the trial intervention, but resource issues and institutional blocks made this problematic in some centres. These issues collectively hampered momentum, leading to protocol changes that introduced greater flexibility around recruitment and the trial intervention, enabling sites to operationalise these in a way that suited their units and patients' needs.
Recruitment data and recorded consultations revealed high acceptance rates (>50%) and clear information-provision in several sites, but missed opportunities in others. Recruiters often suspended discussion about the trial on hearing a preference for/against treatment, despite patients revealing subtle misconceptions. Some believed they could be randomised to immediate dialysis, which was deemed unacceptable given that they did not (yet) require symptom-management. Difficulties also arose whilst conveying equipoise, as disclosing uncertainty around the benefits of dialysis appeared to eradicate any rationale for considering this as a viable treatment. Feedback/training is focusing on highlighting the balance between

benefits/disadvantages of each arm, and emphasising that the trial compares pathways for potential future treatment, if needed.

Discussion

Recruitment to the Prepare study is feasible and progressing well, with continued efforts to understand and address difficulties. Future RCTs involving complex interventions should consider renal units' unique clinical/research arrangements and iteratively examine and adapt trial processes as needed.