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P292 - 'I just don't want to rock the boat': uncovering barriers and facilitators to recruitment in the H4RT trial with an integrated QuinteT Recruitment Intervention.

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Introduction

The High-volume Haemodiafiltration (HDF) vs High-flux Haemodialysis (HD) Registry (H4RT) Trial compares the clinical and cost-effectiveness of high-volume HDF and high-flux HD for end-stage kidney disease patients receiving in-centre haemo-dialysis/-diafiltration. Variation in current practice for delivery of HD and HDF means that clinicians, nurses or patients might have strong preferences for one modality that could impede recruitment; logistical challenges might emerge delivering HDF in centres where not previously available. Given such challenges, a QuinteT Recruitment Intervention (QRI) was integrated into the internal pilot to optimise recruitment and informed consent.

Methods

The QRI combined primarily qualitative data with descriptive analyses of quantitative recruitment data:

- 1) In-depth interviews with members of the Trial Management Group (TMG), recruiters (research nurses and nephrologists) and patients (accepting, declining and withdrawing from H4RT) investigated perspectives on trial design, equipoise and barriers and facilitators to recruitment (professionals); and views on presentation of study information and reasons for accepting, declining or withdrawing (patients).
- 2) With consent, audio-recordings of study discussions with patients were analysed to explore information provision and reasons underlying participation decisions.
- 3) Eligibility and recruitment pathways were mapped for clinical centres, noting when and from whom patients received information about the trial. Screening logs documenting numbers screened, eligible, approached and agreeing to participate identified points where large numbers of patients were 'lost'. Data were compared across centres and with insights into practice gained from interviews and audio-recordings, to identify most efficient practices.
- 4) TMG meetings were observed for insight into trial conduct and overarching challenges.

Results

Patients were 'lost' to recruitment at various points: a) exclusion of units from recruitment to H4RT to avoid research fatigue given competing studies or for logistical reasons (travel, machine availability); b) exclusion of patients by clinicians due to beliefs regarding suitability of HD/HDF; c) patients identified ineligible due to being judged unlikely to achieve high-volume HDF, with some centres suspending recruitment whilst practice was reviewed in order to enable compliance in meeting criteria for high-volume HDF. However, 40% of patients invited to join the study accepted. Decliners most commonly feared 'feeling worse' following change to what they perceived to be a relatively fragile 'status quo' with their current regime. The active involvement of clinicians in recruitment was the single most effective factor in optimising recruitment across several centres. This increased conversion rates (numbers of patients invited who consented to H4RT) with very brief interactions with clinicians reassuring patients sufficiently to accept participation. Prompt-cards were disseminated to remind clinicians to discuss H4RT. Findings also informed the provision of training to research nurses (group and individual, including 'Tips and Guidance'

documents) to encourage clinician involvement, guide discussions with patients and address compliance issues.

Discussion

Recruitment to H4RT was possible and the study was acceptable to patients. There is potential to improve recruitment further by addressing logistical barriers and increasing clinician involvement in recruitment processes. Barriers identified will be relevant to other nephrology trials and may assist in providing more accurate calculations of the number of centres and time required for recruitment.