

Adapting the QuinteT Recruitment Intervention (QRI) to optimise recruitment in an ongoing randomised controlled trial

Introduction

Randomised Controlled Trials (RCTs) are the most rigorous study design to evaluate healthcare interventions. However, their success relies on patient recruitment. The QuinteT Recruitment Intervention (QRI) aims to address recruitment difficulties and enhance information delivery in RCTs, using qualitative methods. It has been implemented in 26 current and completed RCTs, either as part of the initial study design, or brought in part-way through when recruitment is particularly challenging. The QRI comprises two-phases: Phase I - investigation of recruitment processes, using interviews, screening logs and recordings of trial consultations; Phase II - developing an action plan in agreement with the RCT's Chief Investigator. A QRI typically takes 12-18 months. Where trials are experiencing recruitment difficulties, and have to respond swiftly to funders it may not be possible to complete a full QRI. We report and reflect on a developmental abridged version of the QRI as applied to a UK-based RCT comparing urological surgical procedures.

Methods

An abridged QRI was applied at two time points, 20 and 30 months into the recruitment phase of the RCT, each culminating in a collaborators' workshop. Semi-structured interviews were undertaken with the CI, 16 recruiting urologists, and 2 research nurses (time point 1) and 5 urologists (time point 2). Interviews, screening and recruitment data were analysed to explore reasons for patient non-participation. Workshops were attended by the majority of recruiting centres and involved facilitation of an interactive discussion session based on emergent findings from the QRI. Attendees discussed the implications of these findings, and considered whether they would be able to amend their subsequent recruitment practices.

Results

Issues that may have hindered recruitment emerged from the analysis: different interpretations of eligibility criteria reduced the potential sample population in some centres, and different positions of equipoise emerged in relation to one very familiar and established procedure, and a newer, less well-established technique. Additionally, there was inconsistency between the reasons for patient preferences as documented in screening data and described in interviews. Prior to the first meeting, 113 patients had been randomised (average 4.7 per month). In the subsequent 10 months, 135 patients were randomised (average 13.5 per month). The second collaborators' meeting was held in November 2016. If current rates are maintained, the study is now expected to successfully achieve its recruitment target.

Conclusions

An abridged QRI in the form of interview data and good quality screening information, combined with the accumulated knowledge of the commonly-cited barriers to trial recruitment, appeared to lead to an increase in the average number of monthly randomisations in this RCT. If RCTs require a short-term fix to recruitment challenges, an abridged version of the QRI may be useful. However, without the benefit of a full Phase I of the QRI, there is a limited understanding of recruitment barriers and processes, reducing opportunities to offer tailored suggestions for improving communication which may be necessary in some RCTs.