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Understanding and Improving Recruitment to Randomised Controlled Trials: Qualitative Research Approaches

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Abstract

Context: The importance of evidence from randomised trials is now widely recognised, although recruitment is often difficult. Qualitative research has shown promise in identifying the key barriers to recruitment, and interventions have been developed to reduce organisational difficulties and support clinicians undertaking recruitment.
Objective: This article provides an introduction to qualitative research techniques and explains how this approach can be used to understand—and subsequently improve—recruitment and informed consent within a range of clinical trials.
Evidence acquisition: A literature search was performed using Medline, Embase, and CINAHL. All studies with qualitative research methods that focused on the recruitment activity of clinicians were included in the review.
Evidence synthesis: The majority of studies reported that organisational difficulties and lack of time for clinical staff were key barriers to recruitment. However, a synthesis of qualitative studies highlighted the intellectual and emotional challenges that arise when combining research with clinical roles, particularly in relation to equipoise and patient eligibility. To support recruiters to become more comfortable with the design and principles of randomised controlled trials, interventions have been developed, including the QuinteT Recruitment Intervention, which comprises in-depth investigation of recruitment obstacles in real time, followed by implementation of tailored strategies to address these challenges as the trial proceeds.
Conclusions: Qualitative research can provide important insights into the complexities of recruitment to trials and inform the development of interventions, and provide support and training initiatives as required. Investigators should consider implementing such methods in trials expected to be challenging or recruiting below target.
Patient summary: Qualitative research is a term used to describe a range of methods that can be implemented to understand participants' perspectives and behaviours. Data are gathered from interviews, focus groups, or observations. In this review, we demonstrate how this approach can be used to understand—and improve—recruitment to clinical trials. Taken together, our review suggests that healthcare professionals can find recruiting to trials challenging and require support with this process.

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1. Introduction

Clinical policy and practice recommend the use of current best evidence to guide decisions about patient care, which is essential for providing high-quality healthcare [1]. Randomised controlled trials (RCTs) are recognised as the most effective methodology for the evaluation of the effectiveness and safety of healthcare interventions [2], especially when brought together in systematic reviews [3]. However, the lack of high-quality evidence to support clinical decision making means that many fundamental questions in medicine—including in the management of urological patients—remain unanswered. Guidelines are often based on expert opinion or weak evidence [4], and new trials are therefore required to tackle many major questions in urology. Studies such as the Prostate Cancer Intervention Versus Observation Trial [5] and the Prostate Testing for Cancer and Treatment trial (ProtecT) study [6,7] demonstrate that urological RCTs can be undertaken successfully. However, less than a third of trials achieve their original recruitment target [8].

Reviews have reported that successful RCT recruitment is associated with a number of factors, including addressing clinically important questions at a timely point, employing dedicated research staff, ensuring that staff are trained about trial processes and interventions, and having straightforward data collection [9,10]. In addition, effective strategies to improve recruitment include telephone reminders, financial incentives, open-trial designs where participants know which treatment they are receiving in the trial, and use of opt-out rather than opt-in procedures [3]. However, Bower and colleagues [11] highlighted that there was also a need to develop effective interventions aimed at those recruiting to trials. Although patient information leaflets are strictly regulated by ethics committees, the communication style of the recruiter (usually a clinician or nurse) plays an important role in patients' understanding of the information and their willingness to join the study [12]. Research has shown that information conveyed during recruitment appointments varies considerably in content and quality [13], and patients often have a poor understanding of RCT concepts [14–17]. A systematic review of interventions to improve the recruitment activity of clinicians reported that the most promising interventions were studies that used qualitative research to identify key issues and develop interventions to improve recruitment [18]. This focused review provides an introduction to qualitative research techniques and summarises how this approach can be used to understand—and subsequently improve—recruitment to RCTs.

1.1. Qualitative research

Qualitative research is an umbrella term used for a range of methodologies used to generate rich accounts of how people make sense of the world and how they experience events [19]. Whereas quantitative research focuses on "how many" and "how much", qualitative research seeks to answer "how" and "why" questions [20]. Data are primarily gathered from interviews, focus groups, and observations intensively in small numbers to facilitate understanding. Data collection and analysis are iterative processes that continue until saturation is reached (ie, the point at which no new themes emerge) [21].

2. Evidence acquisition

This article does not intend to provide a systematic review of the current literature, but instead highlights ways in which qualitative methods can be used to understand recruitment to RCTs**.** A search of Medline, Embase, and CINAHL was undertaken in October 2016 using a combination of the following keywords *qualitative*, *recruit**, *consent*, *RCT*, *trial**, and *random**. Titles and abstracts were reviewed to assess relevance. Studies with a qualitative methodology that focused on recruitment or informed consent in any RCT were included. As this article focuses on the recruitment activity of healthcare professionals, studies focusing solely on patient experiences of RCTs were not included (studies that included perspectives of both patients and recruiters were included, with only the latter reported in the synthesis). All types of healthcare professionals (ie, clinicians and nurses) were included. Only articles in English were reviewed. Studies in paediatric trials were excluded. No studies were excluded by quality. Reference lists of the retrieved articles were also examined for additional relevant articles, and newly published studies that were identified as relevant whilst the review was being prepared were included.

The first and senior author discussed which papers should be included in the review until agreement was achieved and, in total, 35 articles were selected. Quality was assessed using the Critical Appraisal Skills Programme checklist [22] by two reviewers (D.E. and S.H.). Individual assessments were compared and any areas of discrepancy were resolved by discussion. Figure 1 presents each step of the literature search and selection process of articles, and the full search strategy is available (see Supplementary material).

3. Evidence synthesis

3.1. Summary of included papers

Thirty-five qualitative studies [13,23–56] were included in the review. Many studies (23/35) explored recruitment issues within the context of a single RCT [13,23–25,30–33,36–40,42,44,46–48,51–54,56], whilst eight provided a synthesis of results from multiple RCTs [26–28,41,45,49,50,55]. Four studies sampled healthcare professionals who recruited to RCTs generally, rather than a specific trial [29,34,35,43]. Overall, the quality of these studies was good (see Supplementary material), although common methodological issues revolved around whether data analysis was sufficiently rigorous (it was sometimes not clear if saturation was achieved or if multiple researchers had analysed data to enhance reliability of the findings).

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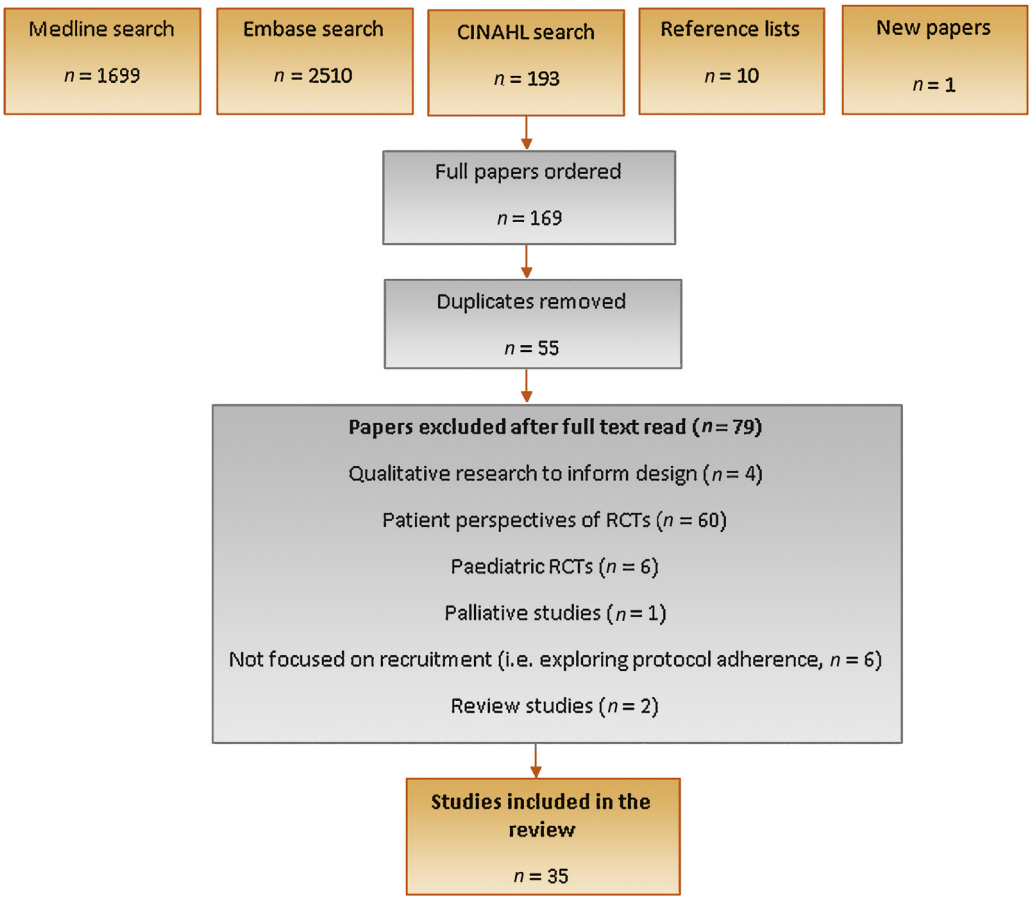

Fig. 1 – Steps of the literature search and selection process of articles. RCT = randomised controlled trial.

Recruiters were from urological cancer trials [13,23,25,27,28,40,41,44,55], other cancer trials [24,27,28,32,35,40,44,49,50,52,54,55], mental health [27, 28, 39,46,50,55], orthopaedics [31,33,38,49,56], diabetes [36,47], vascular surgery [40,49], peripartum trials [37,53], HIV [30], smoking cessation [42], and pressure area care [51]. The majority of studies (32/35) focused on RCTs that were conducted in the UK [13,24–29,31–41,43–56].

Studies consisted mostly of interviews or focus groups with those involved in recruitment to RCTs [13,23–37,39,42–44,46–56], sometimes alongside interviews with patients who had been offered the opportunity to join the trial [23–26,33,37]. Several studies audio recorded consultations where recruiters discussed the RCT with eligible patients [13,24–26,31,32,38,40,41,44,45,49,50,52,55]. A summary of the included studies is shown in Table 2.

Table 1 – Commonly reported barriers to recruitment

Recruitment issue	References
Lack of eligible patients	[24,27,36,44,52,53]
Patients dislike concept of randomisation	[24,25,27,35,50,52]
Patients express strong preferences for a particular treatment	[23–25,32,35,44,52,53]
Lack of clinician time for research activities	[23,29,33,34,36,39,42,43,46,47,51,53]

3.2. *Part 1: why is recruitment so challenging?*

3.2.1. *Exploring facilitators and barriers to recruitment*

Overall, interviews with healthcare professionals highlighted a number of positive aspects of being involved in research. For instance, recruiters described how intellectual challenges and professional kudos were incentives to participate in RCTs [30,43]. Many felt that participation in trials was beneficial in that it provided patients with access to novel treatments [29,30,34,39,43,51], gave patients hope [29,30], and monitored participants closely [30,39,43].

The majority of studies used interviews to understand recruiters' perceptions of factors that impacted upon recruitment to RCTs. Many described how collaboration within the clinical team was vital [29,34,35,51,54]. Awareness and understanding of the particular RCT was also deemed to be important [29,33,39,42,43,54], particularly in terms of the eligibility criteria [34,35,39] and study processes [35,36,39]. Many recruiters felt that receiving regular updates and feedback from the trial team was beneficial [34,35,47], although some found this overwhelming [36].

Recruiters highlighted a range of logistical and practical issues that had made recruitment challenging (Table 1). Many commented on a lack of eligible patients

Table 2 – Summary of the included studies

Study	Research setting	Qualitative methods
Bill-Axelson et al (2009) [23]	Main study comparing radical prostatectomy with active monitoring for prostate cancer in Sweden	Interviews with patients (n = 9) and clinicians (n = 5)
Blazeby et al (2009) [24]	Feasibility study comparing chemoradiation versus chemotherapy and surgery for oesophageal cancer in the UK	Interviews with patients (n = 14) RCT consultations recorded (n = 26)
Donovan et al (2009) [25]	Feasibility/main study comparing prostatectomy, radiotherapy, and active monitoring for prostate cancer in UK	Interviews with recruiters and patients RCT consultations recorded
Donovan et al (2014) [27]	Six UK RCTs in a range of clinical contexts, with different types of RCT interventions, with a range of primary recruiters, and at different stages of the implementation of the RCT	Interviews with clinicians and nurses (n = 72)
Donovan et al (2014) [28]	Six UK RCTs in a range of clinical contexts, with different types of RCT interventions, with a range of primary recruiters, and at different stages of the implementation of the RCT	Interviews with clinicians (n = 32)
French et al (2016) [29]	Specialist nurses from a variety of research studies (including RCTs) in general adult acute care or community settings in the UK	Interviews with specialist nurses (n = 12)
Hales et al (2001) [30]	RCT for an HIV drug in Australia	Interviews with clinicians (n = 10)
Griffin et al (2016) [31]	Feasibility study comparing surgery and nonoperative care for hip impingement in the UK	Interviews with TMG (n = 10) and clinicians (n = 21) RCT consultations recorded (n = 87)
Hamilton et al (2013) [32]	Feasibility study comparing surgery or radiotherapy for laryngeal cancer in the UK	Interviews with clinicians and research nurses RCT consultations recorded
Horwood et al (2016) [33]	Main study comparing intraoperative local anaesthetic wound infiltration or usual care for joint pain in the UK	Interviews with patients (n = 24) and clinicians/nurses (n = 15)
Lamb et al (2016) [34]	Community nurses involved in wound care trials in the UK	Interviews with research nurses (n = 8)
Langley et al (2000) [35]	Clinicians recruiting to cancer trials in the UK	Interviews with clinicians (n = 20)
Lawton et al (2015) [36]	Type 1 diabetes main RCT comparing multiple daily injections or pump therapy in the UK	Interviews with clinicians and nurses (n = 18)
Lawton et al (2016) [37]	Peripartum pilot RCT comparing drug with placebo in the UK	Interviews with clinicians/nurses (n = 27) and patients (n = 22)
Mann et al (2014) [38]	Pilot study comparing intraoperative local anaesthetic wound infiltration or usual care for joint pain in the UK	RCT consultations recorded (n = 53)
Mason et al (2007) [39]	Main study comparing types of antidepressants for depression RCT in the UK	Interviews with recruiting GPs (n = 41)
Mills et al (2014) [40]	Feasibility/main study comparing prostatectomy, radiotherapy, and active monitoring for prostate cancer in the UK and two anonymised RCTs	RCT consultations recorded (n = 103)
Mills et al (2011) [41]	Feasibility/main study comparing prostatectomy, radiotherapy, and active monitoring for prostate cancer in the UK	RCT consultations recorded (n = 93)
McIntosh et al (2005) [42]	Smoking cessation trial in the USA	Focus groups with clinicians (n = 30)
Newington et al (2014) [43]	Clinicians and nurses involved in research (including RCTs) in the UK	Interviews with clinicians and nurses (n = 11)
Paramasivan et al (2011) [44]	Feasibility study comparing surgery with radiotherapy for bladder cancer in the UK	Interviews with clinicians/nurses (n = 9) and TMG (n = 2) RCT consultations recorded (n = 4)
Paramasivan et al (2015) [45]	Two anonymised UK RCTs differed in clinical contexts and complexity of the recruitment process	Interviews with clinicians/nurses (n = 20) and patients (n = 23) RCT consultations recorded (n = 35)
Patterson et al (2010) [46]	Main RCT comparing art therapy with usual care for schizophrenia in the UK	Interviews and focus groups with clinicians (n = 17)
Potter et al (2009) [47]	Main RCT comparing telephone support with usual care for type 2 diabetes in the UK	Interviews with nurses (n = 10)
Potter et al (2014) [48]	Hypothetical feasibility RCT in breast reconstruction after mastectomy for breast cancer in the UK	Interviews with clinicians (n = 31)
Rooshenas et al (2016) [49]	Six UK RCTs in a range of clinical contexts, with different types of RCT interventions, with a range of primary recruiters, and at different stages of the implementation of the RCT	Interviews with clinicians (n = 23) RCT consultations recorded (n = 105)
de Salis et al (2008) [50]	Five UK RCTs in a range of clinical contexts, with different types of RCT interventions, with a range of primary recruiters, and at different stages of the implementation of the RCT	Interviews with clinicians and nurses RCT consultations recorded
Spilsbury et al (2008) [51]	Main RCT comparing alternating pressure mattress overlays and replacements	Focus group with nurses (n = 9)
Stein et al (2016) [52]	Feasibility RCT comparing test direct chemotherapy versus usual care in the UK	Interviews with clinicians and nurses (n = 14) RCT consultations recorded (n = 36)
Stuart et al (2015) [53]	Main RCT comparing home-based support with usual care for pregnant women in the UK	Interviews with community midwives (n = 13)
Strong et al (2016) [54]	Feasibility study comparing chemoradiation versus chemotherapy and surgery for oesophageal cancer in the UK	Interviews with clinicians (n = 21)
Tomlin et al (2014) [55]	Five UK RCTs in a range of clinical contexts, with different types of RCT interventions, with a range of primary recruiters, and at different stages of the implementation of the RCT	Interviews and focus groups with nurses (n = 43) RCT consultations recorded (n = 23)
Wade et al (2009) [13]	Feasibility/main study comparing prostatectomy, radiotherapy, and active monitoring for prostate cancer in the UK	RCT consultations recorded (n = 23)
Zeibland et al (2007) [56]	Main study comparing spinal rehabilitation with surgery for treatment of chronic back pain in the UK	Interviews with clinicians (n = 11)

GP = general practitioner; RCT = randomised controlled trial; TMG = trial management group.

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[24,27,36,44,52,53], and that eligible patients often disliked the concept of randomisation [24,25,27,35,50,52] or had strong treatment preferences for particular interventions [23–25,32,35,44,52,53]. Recruiters also described lack of time as a key barrier to recruiting to RCTs [23,29,33,34,36,39,42,43,46,47,51,53].

However, some studies suggested that even when logistical and organisational issues were addressed, recruitment continued to be challenging [27,28,46]. Indeed, several recent studies have highlighted that there may be more deep-rooted reasons as to why recruitment can be difficult. These relate to complex emotional and intellectual issues, which may—albeit unintentionally—affect recruitment, and are described below.

3.2.2. Misunderstanding RCT concepts and design

Whilst recruiters acknowledge the importance of evidence-based practice [23,29,34,35,39,43,56], most have not had formal training [27,38,55] and can show poor understanding of RCT methods and concepts [27,29,35,46,48,51,56]. For instance, interviews with surgeons who had recently completed recruitment to a multicentre, pragmatic RCT comparing a rehabilitation programme with surgery for treatment of chronic low back pain showed that they had misunderstandings about the trial design. Many did not understand the concept of equipoise, were unclear about the trial's aims, and were not aware of the rationale for the pragmatic inclusion criteria [56].

Given this, it is perhaps not surprising that recruiters can find it challenging to communicate with patients about trials [23–25,30,31,35,38,44,52], can find it difficult to articulate the trial design in simple terms [24,31,44,52], and struggle to explain randomisation [24,25]. Furthermore, studies have showed that recruitment consultations tend to be led by the recruiter and predominately cover the topics that they deem important to discuss [13,38,55]. This means that there is often insufficient evidence for the recruiter to judge the participant's level of understanding or willingness to join the trial. It has instead been suggested that information provision should be tailored to the patient's concerns and questions, and that specific communication techniques—such as using open questions and pauses, and enabling the patient to interrupt—provide opportunities for the patient to discuss what is important to them [13].

3.2.3. Emotional challenges of dual roles

Several studies alluded to the complexities of combining research with clinical roles [23,26–30,36,39,42,43,48,50–52,55]. Findings from interviews with recruiting staff from six RCTs showed that whilst they expressed strong commitment to the RCT and research in general, clinicians and nurses experienced emotional and intellectual challenges related to their roles as scientists and clinicians [27,28]. Clinicians described themselves as scientists or practicing clinicians, with some combining both. Nurses identified themselves as having three major roles: caring clinical nurse, patient advocate, and recruiter/scientist. As both groups discussed their roles and the challenges and conflicts within them, they expressed emotion and discomfort. Lawton and colleagues [36] have also highlighted the emotional challenges that could arise from the conflicting priorities of their research roles and clinical responsibilities. In these studies, most recruiters had not raised these issues with chief investigators (CIs) and colleagues, and were unaware how their views contributed to recruitment difficulties.

3.2.4. Discomfort with RCT eligibility criteria

The synthesis by Donovan and colleagues [27] found that within their research roles, clinicians were typically responsible for eligibility assessments of patients and nurses had considerable influence over which eligible patients to approach. Clinicians often described reluctance to recruit particular patients or groups of patients who fitted the eligibility criteria for the RCT but were perceived to be "unsuitable" for other reasons. Most nurses expressed their right to use clinical judgement to decide whom to approach about the RCT. In some trials, when they approached patients, they had a tendency to become awkward and apologise for "bothering" potential patients about the trial. These findings were also identified in part in several single RCT studies reporting that recruiters may not approach all eligible patients [23,30,32,34,35,39,43,44,46–48,52,53,56]. Taken together, this means that many eligible patients will not have had the opportunity to consider RCT participation.

3.2.5. Lack of equipoise between RCT treatment options

"Community equipoise" refers to the principle that there is uncertainty or disagreement in the clinical community about which treatment is best [57], whilst "individual equipoise" exists when an individual is uncertain about treatment superiority [58]. Interviews have suggested that recruiters can find it difficult to be in individual equipoise and instead favour a particular treatment arm in an RCT [23–25,27,28,31,32,38,44,45,47,49,52,54]. Donovan and colleagues [28] found that clinicians, particularly surgeons, had "hunches" that particular treatments were superior in general or for specific patients or groups. The conflict between the wish to gain robust evidence and personal preferences created considerable discomfort in some cases.

Using data from six RCTs, Rooshenas et al [49] interviewed 23 clinicians to understand their intentions for communicating equipoise, and audio recorded 105 of their consultations where they presented the RCT to eligible patients. Interviews revealed that clinicians expressed different levels of uncertainty, ranging from complete ambivalence to clear beliefs that one treatment was superior. Irrespective of their personal views, all clinicians intended to set their personal biases aside to convey trial treatments neutrally to patients. However, analysis of the consultations demonstrated that equipoise was omitted or compromised in 46% of the recorded appointments, by clinicians offering treatment recommendations, presenting imbalanced descriptions of trial treatments, or disclosing their personal opinions or predictions about trial outcomes [49].

3.2.6. Difficulty exploring patient preferences

Across many studies, recruiters reported that patients declined RCT participation because they held strong

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treatment preferences for particular interventions [23–25,27,32,35,44,52,53]. Aside from recruiter influences, patient preferences can be informed by a number of factors, including information and advice from family and friends [25] and the media [25]. Mills and colleagues [41] conducted an analysis of audio recordings of recruitment appointments with 93 participants in a trial of localised prostate cancer treatments. Patient preferences ranged from hesitant opinions to well-formed intentions to receive a particular treatment. These preferences frequently changed after detailed discussion of treatments and trial rationale with recruitment staff. However, several studies have highlighted that recruiters can feel uncomfortable exploring these further [24,32,40,44,52] and are more likely to accept patient preferences if they align with the recruiter's own views [27,28].

3.2.7. *Identifying specific recruitment issues in RCTs*

Whilst the challenges identified are commonly reported across a range of RCTs, it is important to note that the degree that these issues are present and the extent that they affect recruitment will inevitably vary between RCTs. For instance, whilst recruiters often struggle to feel comfortable with the concept of uncertainty between trial arms, training and support strategies can sometimes help overcome this so that recruitment targets are met [25]. In other instances, the lack of recruiter equipoise has been so fundamental that the RCT had to be closed [32].

In addition to these common themes, each RCT will have a set of unique issues that need to be resolved [50]. Urological RCTs often involve complicated pathways that can be particularly lengthy, and include many different healthcare professionals or multiple centres [44]. The availability and evidence base for treatment options outside of each RCT will vary (particularly within fields such as urology, where there are rapidly changing treatment options [23]), which may have implications for clinician equipoise. Some RCTs may also have complex designs, making them even more difficult to discuss with patients. For instance, recruiters from one urological trial had to explain the need for neoadjuvant chemotherapy, the timing of randomisation in relation to the cycles of chemotherapy, and two extremely different treatment arms (surgery to remove the cancer and bladder, or a selective bladder preservation technique that involved radiotherapy to destroy the cancer and preserve the bladder except where the tumour persisted when surgery was recommended) [44].

3.3. *Part 2: what solutions are there to recruitment difficulties?*

3.3.1. *Developing training programmes for those recruiting to trials*

Taken together, the previous section has highlighted the need for training and support for recruiters (both for generic and RCT-specific issues). Only a relatively small number of studies have used qualitative research to develop training for those recruiting patients into RCTs [24,26,31,32,38,44,50,52]. One study developed a peer-review training programme, whereby four research nurses from an orthopaedic pilot study provided regular feedback on each other's recorded RCT consultations. All the nurses felt that communication and recruitment abilities were improved, and stated that they would want to repeat this process in subsequent trials [38].

The other interventions identified had originated from the ProtecT study, whereby a complex intervention was developed to improve rates of randomisation and informed consent [25]. Table 3 summarises the key issues identified and strategies implemented to overcome these. This intervention has since been refined in a number of RCTs [24,26,31,32,44,50,52], and the final version of the QuinteT Recruitment Intervention (QRI) is conducted in two phases. Phase 1 aims to understand the trial recruitment process by

Table 3 – Issues identified in the ProtecT study and strategies to improve recruitment [25]

1. Organisation and presentation of study information Treatments tended to be presented in a standard order: surgery, radiotherapy, and then active monitoring. Analysis showed that these options were not presented equally. Recruiters were asked to present the treatments in a different order [(1) active monitoring, (2) surgery, and (3) radiotherapy] and to describe their advantages and disadvantages.
2. Terminology used in study information The term "trial" was sometimes interpreted as monitoring ("try and see"), so recruiters were asked to use "study" instead. Recruiters had tried to reassure patients that there was a good 10-yr survival ("the majority of men with prostate cancer will be alive 10 yr later"). However, patients interpreted this to suggest that they might die in 10 yr. It was recommended that recruiters present survival in terms of "most men with prostate cancer live long lives".
3. Specification and presentation of the nonradical arm Recruiters often called the non-radical arm "watchful waiting," but patients had interpreted this as "no treatment", where the disease would be watched and the patient waited for death ("watch while I die"). This was renamed "active monitoring" and redefined to involve three monthly or six monthly prostate specific antigen tests, with intervention if required or requested.
4. Presentation of randomisation and equipoise Both recruiters and patients had difficulty with randomisation and equipoise. Recruiters were supported to feel comfortable discussing uncertainty and explaining that patients were suitable for all three treatments. They were also advised to explain the rationale for randomisation and explain that if the patient were uncertain, randomisation represented a way of resolving the dilemma of treatment choice.
5. Exploring patient preferences Recruiters initially felt uncomfortable discussing patient preferences. Training emphasised that it was important to elicit and explore preferences, particularly if these were not well founded in evidence (eg, rejecting radiotherapy because of a mistaken belief that it would lead to hair loss).

ProtecT = Prostate Testing for Cancer and Treatment trial.

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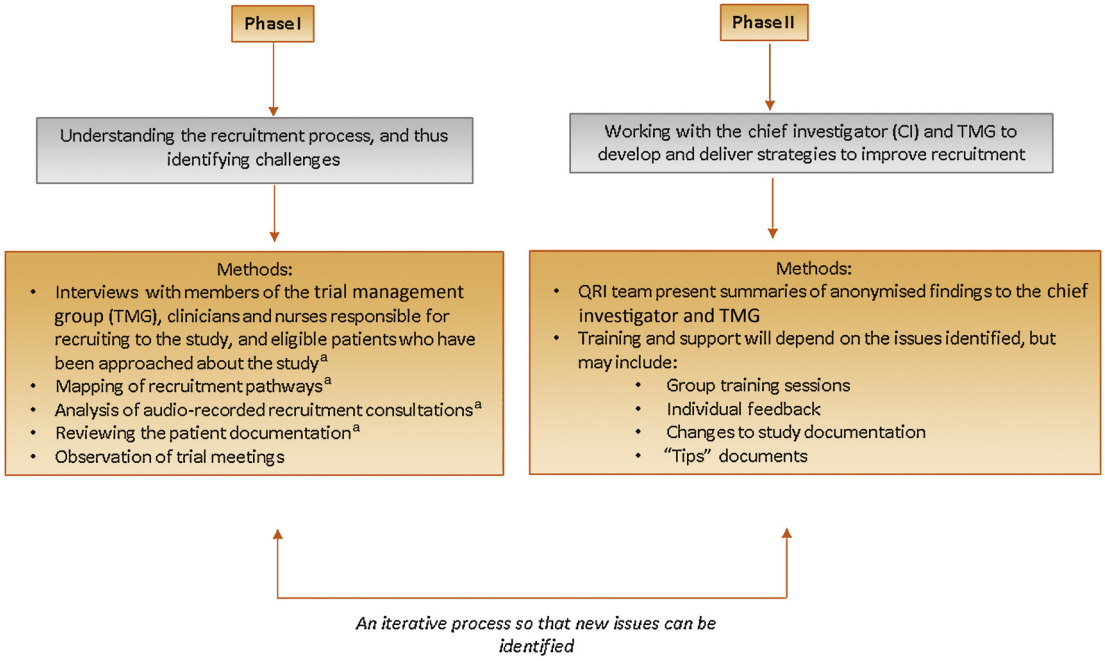

Fig. 2 – Overview of the QuinteT Recruitment Intervention. [a] Actions are mandatory.

conducting in-depth interviews with healthcare professionals involved in recruitment and patients approached about the study, audio recording recruitment discussions, analysing screening log data to understand patient pathways, observing study meetings, and reviewing study documentation, with rapid analysis of findings and reporting to the CI and trial management group (TMG). In phase 2, the QRI team works collaboratively with the CI and TMG to implement strategies to improve recruitment (see Fig. 2) [26]. To date, these methods have been implemented in 25 RCTs. The QRI has optimised methods that enable recruitment to be completed in feasibility/pilot or main RCTs [25,26,31,52]. In other instances, the QRI has provided detailed evidence to support a decision to cease recruitment [32].

3.3.2. *Challenges of integrating qualitative research in RCTs*

Whilst these methods produce important insights about recruitment practices, the challenges of integrating qualitative research with RCTs has been well documented. For instance, recruiters are often reluctant to provide audio recordings of consultations [24,26,38,44,50,52]. If the qualitative research is integrated into an RCT where recruitment is already ongoing, the process of obtaining additional ethical approval can be lengthy [26]. It has therefore been suggested that qualitative work should be integrated structurally and culturally into the RCT, ideally before recruitment begins and at the feasibility stage, in order to produce the greatest results [50].

3.3.3. *Future directions for research*

It is important to note that current interventions are limited by the availability of only observational evidence of their effectiveness, therefore limiting the ability to determine causality between interventions and recruitment rates [26]. A recent review has identified the need to develop more robust designs to develop an evidence base on how best to support recruiters [59]. More robust studies are needed to assess the effectiveness of training programmes, although these will need to give careful consideration to how "successful" interventions should be defined (ie, completion of study or evidence to support closure) and what the outcomes should be (ie, screening and eligibility counts, recruitment rates, or changes in informed consent). Furthermore, given that research has demonstrated that patients can find RCT concepts confusing [14–17], it is important not to neglect the patient's perspective of the recruitment process, and to further develop methods to facilitate joint decision making and ensure fully informed consent.

4. Conclusions

Many fundamental questions in the management of patients in most specialities remain unanswered, and RCTs are required to provide high-quality evidence to support clinical decision making. Recruitment difficulties were often attributed to logistical issues (such as a lack of time for research activities) or patient-related factors (including strong treatment preferences or disliking randomisation). In 2012, Fletcher and colleagues [18] highlighted the potential of using qualitative research to understand recruitment, and since this, qualitative studies have shed further light on the challenges of recruiting patients [24,26–29,31–34,36–38,40,43,45,48,49,52–54]. Taken together, these highlight how recruitment is a complex and fragile process in which recruiters can experience emotional and

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intellectual challenges related to their dual roles of researchers and clinicians. This role conflict may (unintentionally) affect recruitment in a number ways, for example, by creating difficulty conveying equipoise, discomfort with the eligibility criteria, and exploring patient preferences. Therefore, there is a need to develop training and support programmes to enable recruiters to become more comfortable with the design and principles of RCTs. Donovan and colleagues [28] state that this should include ensuring that recruiters understand and can communicate key aspects of the RCT design, and how to gently explore patients' preferences. It has also been suggested that nurses and doctors who recruit to RCTs require different training and support. Doctors may benefit from support in relation to assessments of eligibility and equipoise [28], whereas nurses require support for perceived conflicts in their roles as a recruiter, patient advocate, and clinician, and for helping them to be comfortable with approaching all patients [27].

Whilst common themes haven been identified in this review, each RCT will have a set of unique issues that need to be resolved. In urology RCTs, this may include lengthy patient pathways, complex designs, and rapidly changing treatment options. Only a small number of training programmes have been developed from issues identified by qualitative methods [24,26,31,32,38,44,50,52]. Most of these have been QRIs [24,26,31,32,44,50,52], which consist of in-depth investigation of recruitment obstacles in real time, followed by implementation of tailored strategies to address these challenges as the trial proceeds. These interventions have optimised practices that enable recruitment to be completed in feasibility/pilot or main RCTs, or have provided detailed evidence to support a decision to cease recruitment. The multifaceted and flexible nature of qualitative research can provide important insights into the complexities of recruiting to trials so that subsequent interventions can be developed, although quantitative research would be more suited to rigorously evaluating such programmes to determine the components that can lead to improved recruitment and informed consent in RCTs.

In summary, this article demonstrates that qualitative research can provide important insights into the complexities of recruitment to trials, which can inform support and training initiatives as required. Investigators should consider implementing such methods in urological RCTs that are expected to be challenging or are recruiting below target to tackle the most challenging clinical questions facing patients and clinicians.

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Study concept and design: Elliott, Donovan.
Acquisition of data: Elliott.
Analysis and interpretation of data: Elliott, Husbands, Donovan.
Drafting of the manuscript: Elliott.
Critical revision of the manuscript for important intellectual content: Elliott, Husbands, Hamdy, Holmberg, Donovan.
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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.eururo.2017.04.036.

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