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

Daisy Elliott [a,*], *Samantha Husbands* [a], *Freddie C. Hamdy* [b], *Lars Holmberg* [c,d], *Jenny L. Donovan* [a,e]

[a] *School of Social and Community Medicine, University of Bristol, Bristol, UK;* [b] *Nuffield Department of Surgical Sciences, Headington, Oxford, UK;* [c] *Cancer Epidemiology & Population Health, Faculty of Life Sciences and Medicine, King's College London, Guy's Hospital, London, UK;* [d] *Department of Surgical Sciences, Uppsala University, Uppsala, Sweden;* [e] *NIHR Collaboration for Leadership in Applied Health Research and Care West at University Hospitals Bristol NHS Trust, Bristol, UK*

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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.

* Corresponding author. School of Social and Community Medicine, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol BS8 2PS, UK. Tel. +44 (0) 117 3313921.
E-mail address: daisy.elliott@bristol.ac.uk (D. Elliott).

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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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