University of BRISTOL

Recruitment to RCTs: Clear obstacles and hidden challenges

Jenny Donovan

MRC | Hubs for Trials Methodology Research

ConDuCT-II Hub

NHS
National Institute for Health Research

NIHR CLAHRC West
Collaboration for Leadership in Applied Health Research and Care West

Outline

- Importance of recruitment to RCTs
- Why is recruitment so difficult?
    - What are the key challenges for recruiters?
- Is there a solution to recruitment difficulties?
    - Quintet Recruitment Intervention (QRI)

Quintet
Qualitative research **Integrated** within **Trials**

Importance of recruitment

- Need rapid recruitment of a high proportion of eligible patients to ensure
  - Tackle the most important clinical questions
  - Sufficient power to answer the question
  - Generalisable findings
  - Efficient use of resources
- But recruitment difficulties remain the main cause of RCTs failing…

Why is RCT recruitment so difficult?

Clear obstacles

- Consistently reported barriers
  - Organisational issues
  - Fewer eligible patients than expected
  - Patients’ preferences are clear and strong

“All those who’ve said ‘no’ have had very good reasons – nothing we could do anything about. One didn’t want a computer deciding, another wanted to keep control, others just want [int 1] full stop”

Improving logistics

- CIs and PIs work hard with CTUs to tackle organisational barriers

- But…

  "I'm a strong supporter of this trial, but it's been a nightmare, quite frankly… I've never had so many problems with recruitment in all my born days"

Why is RCT recruitment really so difficult?

- Disrupts usual clinical practice
  - Eligibility assessment
  - Alters the doctor-patient relationship
  - Requires additional
    - Information provision
    - Data collection and processes
- Recruitment is a complex and fragile process

What about the hidden challenges to RCT recruitment?

Hidden challenges

- Intellectual and emotional issues, related to
  - Patient eligibility
  - Clinical and research roles
  - Equipoise
  - Commitment
  - Preferences
  - ‘Control’ arm
  - RCT processes and terminology
- Not shared with colleagues and CIs
- Not always perceived to affect recruitment

Equipoise

“I don’t know, and I believe that that’s why I’ve got equipoise. I don’t know, you don’t know, nobody knows ... That’s why it has to be randomised ...

But…

Good quality surgery’s the best option but I accept that it needs to be shown and if you’re asking me how do I persuade a patient if I don’t believe it myself?... Well, the answer is it’s not been shown so it’s only a hunch and that’s what bias is so I put my biases aside.

But if they pin me down and they say, ‘do you think the earlier you get it the more likely you are to cure it?’ Well I’ve got to say, ‘yes’ because I think that, you know.”

Commitment to RCT

Surgeon Z: If you go into the study, it would involve say treatment (a) or treatment (b). We then do the treatment and follow you up afterwards for five years to make sure.

Patient 11: Yeah, that's interesting.

Surgeon Z: So the most important thing is that if you decide you'd rather have treatment (a) or you'd rather have treatment (b)…

Patient 11: I'm pretty ambivalent really.

Surgeon Z: Yes, well just don't make that decision today. If you can't make your mind up, consider the study, but if you don't want to do the study because you're thinking it might be too much bother, you don't have to give us a reason, it will not alter the way we feel about you in anyway. It's simple, you can walk away at any time.

Patient 11: Excellent.

Role - doctor

"I see my role as a researcher and as a clinician as engaging my patients and the community not just for this illness but a long-term relationship for us together to improve clinical practice and reduce uncertainty"

But…

"There's always a slight conflict between the patient sitting in front of you and their wishes, and wanting to take part in the trial and wanting to support it, to increase recruitment…"

"Are you helping or hindering them when you counsel them? You know yourself there are so many uncertainties… So it's inevitable at times that you feel uncomfortable."

Role – nurse

- Most employed as researchers (nurses)
  - Some could see complementarity
  - Most felt conflicting roles on the boundary between clinical and research

“How will I know when I should be a nurse and when should I be a researcher?”

“I always have the patient’s best interests at heart at the expense of the research… I’d never talk them into a trial, that’s not what I’m about, I’m a nurse, first and foremost.”

“We’re nurses carrying out research – not researchers.”

Impact on recruitment?

Doctor: There's a proportion of patients who will say to me, ''What do you think doctor?'' And in that situation, I think my gut feeling is important. I always tell them. I wouldn't have become a surgeon if I thought another form of therapy was the best form of therapy, would I?

Impact on recruitment?

- Nurses

"I feel a bit uncomfortable... The fact that I want them to get the intervention group, I'm sure that's coming through. I tried to downplay it, but I'm sure my voice changes, there's a lilt."

Is there a solution?

Quintet Recruitment Intervention (QRI)

- QRI integrated into feasibility, pilot or main RCTs
- QRI applied to ongoing RCTs with recruitment difficulties

Quintet Recruitment Intervention (QRI)

- Phase I: Identify recruitment issues
  - In-depth interviews with recruiters, patients, RCT staff
  - Audio-recording of recruitment appointments
  - Scrutiny of study documentation
  - Map eligibility and recruitment processes
- Phase II: Plan and implement strategies to overcome obstacles and challenges
  - Recruiter feedback/training (group and individual)
  - Tips documents
  - Changes to trial documentation

For information about QRI collaboration

jenny.donovan@bristol.ac.uk

RCT recruiter training workshops

1-day interactive workshops to enhance skills in recruiting

7th March – NIHR CRN: WE

21nd March – NIHR CRN: WE

3rd May – Surgeons only - MRC ConDuCT-II Hub

For further information: Nicola.Mills@bristol.ac.uk

Quintet

Qualitative research Integrated within Trials

Donovan et al. Trials 2014, 15:5
http://www.trialsjournal.com/content/15/1/5

TRIALS

RESEARCH Open Access

Clear obstacles and hidden challenges: understanding recruiter perspectives in six pragmatic randomised controlled trials

Jenny L Donovan[1*], Sangeetha Paramasivan[1], Isabel de Salis[1] and Merran Toerien[2]

Abstract

Background: Recruitment of sufficient participants in an efficient manner is still widely acknowledgec major challenge to the mounting and completion of randomised controlled trials (RCTs). Few recruitm interventions have involved staff undertaking recruitment. This study aimed i) to understand the recru process from the perspective of recruiters actively recruiting RCT participants in six pragmatic RCTs, ar identify opportunities for interventions to improve recruitment.

Methods: Interviews were undertaken with 72 individuals (32 doctors or RCT Chief investigators (CIs); other health professionals) who were actively recruiting participants in six RCTs to explore their experi recruitment. The RCTs varied in scale, duration, and clinical contexts. Interviews were fully transcribed using qualitative content and thematic analytic methods derived from grounded theory. For this anal systematically extracted from each RCT and synthesised across all six RCTs to produce a detailed and understanding of the recruitment process from the perspectives of the recruiters.

Results: Recruiters readily identified organisational difficulties, fewer than expected eligible patients, a treatment preferences as the key barriers to recruitment. As they described their experiences of recrui previously hidden issues related to their roles as researchers and clinicians emerged, imbued with disc emotion. The s ... ts of pa and the effecti ... tial RCT and conflicts b ... re that contributed to ... pport n identified for b

Conclusions: T ... proces obstacles were ... ment, u RCT CIs. Qualita ... t are th recruiters to be ... an enga openly with pa

Keywords: Equ

* Correspondence: jen
[1]School of Social and
Hall, Bristol BS8 2PS, U
Full list of author infor

Mills et al. Trials 2014, 15:323
http://www.trialsjournal.com/content/15/1/323

TRIALS

RESEARCH Open Access

Training recruiters to randomized trials to facilitate recruitment and informed consent by exploring patients' treatment preferences

Nicola Mills[1*], Jane M Blazeby[1], Freddie C Hamdy[2], David E Neal[3], Bruce Campbell[4], Caroline Wilson[1], Sangeetha Paramasivan[1] and Jenny L Donovan[1]

Abstract

Background: Patients' treatment preferences are often cited as barriers to recruitment in randomized controlled trials (RCTs). We investigated how RCT recruiters reacted to patients' treatment preferences and identified key strategies to improve informed decision-making and trial recruitment.

Methods: Audio-recordings of 103 RCT recruitment appointments with 96 participants in three UK multicenter pragmatic RCTs were analyzed using content and thematic analysis. Recruiters' responses to expressed treatment preferences were assessed in one RCT (ProtecT - Prostate testing for cancer and Treatment) in which training on exploring preferences had been given, and compared with two other RCTs where this specific training had not been given.

Results: Recruiters elicited treatment preferences similarly in all RCTs but responses to expressed preferences differed substantially. In the ProtecT RCT, patients' preferences were not accepted at face value but were explored and discussed at length in three key ways: eliciting and acknowledging the preference rationale, balancing treatment views, and emphasizing the need to keep an open mind and consider all treatments. By

ELSEVIER

CrossMark

Journal of Clinical Epidemiology 67 (2014) 912–920

Journal of Clinical Epidemiology

The intellectual challenges and emotional consequences of equipoise contributed to the fragility of recruitment in six randomized controlled trials☆

Jenny L. Donovan[a,*], Isabel de Salis[a], Merran Toerien[b], Sangeetha Paramasivan[a], Freddie C. Hamdy[c], Jane M. Blazeby[a]

[a]School of Social and Community Medicine, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol BS8 2PS, UK
[b]Department of Sociology, Wentworth College, University of York, Heslington, York YO10 5DD, UK
[c]Nuffield Department of Surgical Sciences, University of Oxford, Old Road Campus Research Building, Oxford OX3 7DQ, UK

Accepted 17 March 2014; Published online 5 May 2014

Abstract

Objective: The aim of the study was to investigate how doctors considered and experienced the concept of equipoise while recruiting patients to randomized controlled trials (RCTs).

Study Design and Setting: In-depth interviews with 32 doctors in six publicly funded pragmatic RCTs explored their perceptions of equipoise as they undertook RCT recruitment. The RCTs varied in size, duration, type of complex intervention, and clinical specialties. Interview data were analyzed using qualitative content and thematic analytical methods derived from grounded theory and synthesized across six RCTs.

Results: All six RCTs suffered from poor recruitment. Doctors wanted to gather robust evidence but experienced considerable discomfort and emotion in relation to their clinical instincts and concerns about patient eligibility and safety. Although they relied on a sense of community equipoise to justify participation, most acknowledged having "hunches" about particular treatments and patients, some of which undermined recruitment. Surgeons experienced these issues most intensely. Training and support promoted greater confidence in equipoise and improved engagement and recruitment.

Conclusion: Recruitment to RCTs is a fragile process and difficult for doctors intellectually and emotionally. Training and support can enable most doctors to become comfortable with key RCT concepts including equipoise, uncertainty, patient eligibility, and randomization, promoting a more resilient recruitment process in partnership with patients.

Keywords: Randomized controlled trials; Recruitment; Equipoise; Uncertainty; Qualitative research; Uncertainty; Training

1. Introduction

Recruitment to randomized controlled trials (RCTs) is difficult. Approximately 50% of initiated RCTs reach their original recruitment target [1], and poor recruitment undermines the power of RCTs to answer key questions and their external validity and leads to considerable waste of research resources. Most research on RCT recruitment has focused on ways of increasing patient participation, for example, by providing additional or favorable information [2] or comparing lengths of information sheets [3]. However, systematic reviews have identified only a small number of successful interventions directed at patients [4] and pointed to the lack of prospective research in ongoing RCTs and studies involving recruiters [5]. The research that has been done with recruiters includes a survey of pediatricians that suggested that their views could influence levels of participation [6] and two studies that have indicated that difficulties with equipoise can act as a barrier to recruitment to RCTs [7,8].

There has been considerable debate about the concept of "equipoise" in relation to RCTs since the study design was first formally recognized in the 1940s. At the heart of the debate is the need to justify the recruitment of patients to studies incorporating an experiment rather than ensuring they receive the best medical care under a physician's

Funding: The research was supported by the UK Medical Research Council (Quartet study and ConDuCT Hub) and sponsored by the University of Bristol. The RCTs were funded by UK national funding bodies including National Institute of Health Research (NIHR), Wellcome Trust, and Cancer Research UK.

Conflict of interest: None.

* Corresponding author. Tel.: (0)117-9287214; fax: (0) 117-9287325.
E-mail address: jenny.donovan@bristol.ac.uk (J.L. Donovan).