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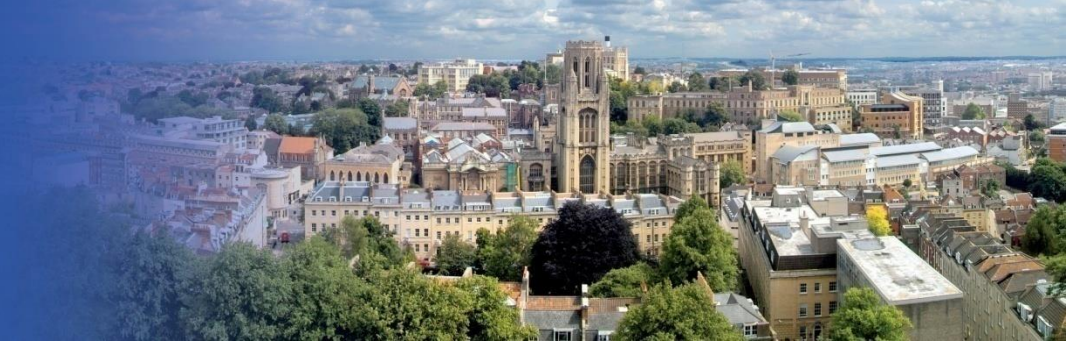

Understanding recruitment to RCTs: Clear obstacles and hidden challenges for recruiters

MRC Hubs for Trials Methodology Research

ConDuCT-II Hub

Jenny Donovan

Quintet group

Outline

- Why is RCT recruitment so difficult?
  - Clear obstacles
  - Hidden challenges
- A solution to recruitment difficulties…
  - Quintet Recruitment Intervention (QRI)

Research to understand recruitment

- Research with recruiters in six RCTs
  - 32 doctors or RCT CIs
  - 40 nurses/other health professionals
- RCT areas
  - Cancer and general surgery, oncology, paediatrics, primary care and psychiatry
- Intervention types
  - Surgery, radiotherapy, drugs, and social support
- *Now working with 20 RCTs*

Key findings

- Recruitment to RCTs is difficult because of
  - Clear obstacles
  - Hidden challenges

Clear obstacles

- Consistently reported barriers
  - Organisational issues

    "…the logistics - the nurse can't attend the clinic, or MDT didn't go through the patients that could have been eligible…"
  - 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, others just want [int 1] full stop"
- 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"

Hidden challenges to recruitment

- Intellectual and emotional issues, related to
  - Usual clinical practice
  - Patient eligibility
  - Equipoise
  - RCT processes and terminology
  - Roles
  - Commitment
  - Treatment preferences
  - ‘Control’ arm
- Not shared with colleagues and CIs
- Not perceived to affect recruitment

Hidden challenges to recruitment

- Intellectual and emotional issues, related to
  - **Usual clinical practice**
  - Patient eligibility
  - **Equipoise**
  - **RCT processes and terminology**
  - Roles
  - Commitment
  - Treatment preferences
  - ‘Control’ arm

Usual practice compared with an RCT

"In clinical practice I have to steer patients to a choice. I can't steer them to equipoise because equipoise is the worst possible outcome for them isn't it? In clinical practice, I give them arguments that build up their feeling about that particular option."

In RCT…

- Express your uncertainty
- Build up the patient's confidence in uncertainty
- Prepare patient for the concept of randomisation…

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 randomized ...

Good quality surgery is 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.

Impact on recruitment?

Recruiter T5: 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?

Terminology – loaded with meaning

- RCTs contain a lot of terms that may be perceived differently by patients and recruiters
  - Random
  - Trial
  - Early
- Misunderstandings can be crucial…

‘Loaded’ terminology

Patient: I mean, what is the trial? That’s what I’m trying to get at.

Recruiter: The trial is, we would enter you into this trial and the trial would choose the option for you.

Patient: Does the trial, is it something else that’s going to start before we actually get the treatment?

Recruiter: You would have that treatment, whichever one the trial chose for you.

Patient: No, I don’t think I’m getting this. This word trial to me seems to be a completely wrong word. It’s not a trial, it’s actually what you’re going to get. It’s the actual treatment, isn’t it?

Randomisation – some real examples

“RN will phone up the trials office and say, can you please randomise this patient – in other words someone will roll the dice and there’s then a fifty-fifty chance you’ll get chemotherapy or not.”

“Essentially what we do, is we flip a coin – it’s not quite as crude as that - but we take each patient who agrees to take part and we randomly assign them to either receive [intervention] or not.”

Hidden challenges to recruitment

- Intellectual and emotional issues, related to
  - **Usual clinical practice**
  - Patient eligibility
  - **Equipoise**
  - **RCT processes and terminology**
  - Roles
  - Commitment
  - Treatment preferences
  - ‘Control’ arm
- We need to address the clear obstacles and hidden challenges with training and support for recruiters

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

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 acknowledged to be a major challenge to the mounting and completion of randomised controlled trials (RCTs). Few recruitment interventions have involved staff undertaking recruitment. This study aimed i) to understand the recruitment process from the perspective of recruiters actively recruiting RCT participants in six pragmatic RCTs, and ii) to identify opportunities for interventions to improve recruitment.

Methods: Interviews were undertaken with 72 individuals (32 doctors or RCT Chief investigators (CIs); 40 nurses/ other health professionals) who were actively recruiting participants in six RCTs to explore their experiences of recruitment. The RCTs varied in scale, duration, and clinical contexts. Interviews were fully transcribed and analysed using qualitative content and thematic analytic methods derived from grounded theory. For this analysis, data were systematically extracted from each RCT and synthesised across all six RCTs to produce a detailed and nuanced

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 exploring preferences, recruiters enabled participants to become clearer about whether their views were robust enough to be sustained or were sufficiently weak that participation in the RCT became possible. Conversely, in the other RCTs, treatment preferences were often readily accepted without further discussion or understanding the reasoning behind them, suggesting that patients were not given the opportunity to fully consider all treatments and trial participation.

Conclusions: Recruiters can be trained to elicit and address patients' treatment preferences, enabling those who may not have considered trial participation to do so. Without specific guidance, some RCT recruiters are likely to accept initial preferences at face value, missing opportunities to promote more informed decision-making. Training interventions for recruiters that incorporate key strategies to manage treatment preferences, as in the ProtecT study, are required to facilitate recruitment and informed consent.

Trial registration: ProtecT RCT: Current Controlled Trials ISRCTN20141297. The other two trials are registered but have

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ORIGINAL ARTICLE

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

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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

Paramasivan et al. Trials (2015) 16:88
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TRIALS

RESEARCH Open Access

A simple technique to identify key recruitment issues in randomised controlled trials: Q-QAT - quanti-qualitative appointment timing

Sangeetha Paramasivan[1], Sean Strong[1], Caroline Wilson[1], Bruce Campbell[2], Jane M Blazeby[1] and Jenny L Donovan[1*]

Abstract

Background: Recruitment to pragmatic randomised controlled trials (RCTs) is acknowledged to be difficult, and few interventions have proved to be effective. Previous qualitative research has consistently revealed that recruiters provide imbalanced information about RCT treatments. However, qualitative research can be time-consuming to apply. Within a programme of research to optimise recruitment and informed consent in challenging RCTs, we developed a simple technique, Q-QAT (Quanti-Qualitative Appointment Timing), to systematically investigate and quantify the imbalance to help identify and address recruitment difficulties.

Methods: The Q-QAT technique comprised: 1) quantification of time spent discussing the RCT and its treatments using transcripts of audio-recorded recruitment appointments, 2) targeted qualitative research to understand the obstacles to recruitment and 3) feedback to recruiters on opportunities for improvement. This was applied to two RCTs with different clinical contexts and recruitment processes. Comparisons were made across clinical centres, recruiters and specialties.

Results: In both RCTs, the Q-QAT technique first identified considerable variations in the time spent by recruiters discussing the RCT and its treatments. The patterns emerging from this initial quantification of recruitment appointments