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Exploring treatment preferences facilitated recruitment to randomized controlled trials

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Abstract

Objective: To explore how patients' treatment preferences were expressed and justified during recruitment to a randomized controlled trial (RCT) and how they influenced participation and treatment decisions.

Study Design and Setting: Qualitative analysis of audio recordings of recruitment appointments with 93 participants aged 51−70 years in a UK multicenter RCT of localized prostate cancer treatments.

Results: Treatment preferences at recruitment were more complex and dynamic than previously assumed. Most participants expressed views about treatments early in appointments, ranging on a continuum from hesitant to well-formed opinions. As recruiters elicited men's views and provided detailed evidence-based treatment and study information, some opted for their preference, but many became uncertain and open to RCT recruitment, often accepting a different treatment from their original ''preference.'' Discussion of treatment preferences did not act as the expected barrier to recruitment but actively enabled many to express their concerns and reach an informed decision that often included RCT participation.

Conclusion: Exploring treatment preferences and providing evidence-based information can improve levels of informed decision making and facilitate RCT participation. Treatment preferences should be reconceptualized from a barrier to recruitment to an integral part of the information exchange necessary for informed decision making about treatments and RCT participation. © 2011 Elsevier Inc. All rights reserved.

Keywords: Treatment preferences; Prostate cancer; ProtecT study; Qualitative research methods; Randomized controlled trial; Recruitment to RCTs

1. Introduction

Randomized controlled trials (RCTs) are increasing in number and complexity to tackle key evaluative health care questions, but overcoming recruitment difficulties and increasing participation rates are still a challenge [1]. Low rates of recruitment may threaten the external validity of RCTs [2], lead to the need for considerable further resources, or cause trials to end prematurely, leaving important research questions unanswered. Recruitment to RCTs should only occur when there is ''equipoise''—uncertainty over the most effective treatment [3]—and when potential recruits have been given sufficient information to make an informed choice about participation [4]. Patients' treatment preferences have been identified as a barrier to trial recruitment and one of the major reasons for low participation levels [5−7]. A recent systematic review showed that substantial numbers of potential recruits refused randomization because of treatment preferences, particularly those who were employed and well educated [7].

Although the impact of patients' treatment preferences on RCT recruitment is thought to be considerable, research to understand these preferences is meager and lacks theoretical insight [8]. The vast majority of studies that assessed the impact of treatment preferences on randomized trials identified through recent systematic reviews have assumed that preferences were easily defined and measured [7,9]. ''Simple preferences'' have been elicited ''whereby the participants indicated which treatment they preferred'' [9,p. 5] using ''very simple measures'' [10,p. iii] such as single-item scales, with little consideration of validity, reliability, or sensitivity [11], or what was being measured. However, a small but significant body of literature emphasized the complexity of treatment preferences, revealing them as multifaceted psychological phenomena that could change

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What is new?

- Patients' treatment preferences expressed during randomized controlled trial (RCT) recruitment were found to be more complex and dynamic than previously assumed in the literature, ranging on a continuum from hesitant views to strong intentions to receive a particular treatment.
- Exploration of treatment preferences by recruitment staff facilitated recruitment by helping potential trial participants to express their concerns, focus views, and reach an informed decision about RCT participation or choice of treatment.
- Patients' treatment preferences should be reconceptualized from a ''barrier'' to trial recruitment to an integral part of the information exchange necessary for informed decision making about treatments and trial participation.
- Future research should focus on developing strategies to support trial recruiters in carefully eliciting and exploring treatment preferences so that they can provide targeted information to those who need it most.

over time and required rigorous assessment in trials [11−13]. Moreover, studies have shown that the way in which information about different treatments in both clinical practice and trials is presented to patients, for example, positively or negatively framed survival probabilities and verbal or numerical risks of disease recurrence, shapes their attitude toward the treatments offered [14−18]. A recent conceptual framework to understand patients' treatment preferences and their effects on decision making in RCTs further highlighted the complex nature of preferences [19]. The framework proposed the development of preferences within trials as a four-stage process relating to information, reasoning, judgment, and decision making, each stage with implications for recruitment procedures, but the authors conceded that more theoretical and empirical research were required to test its usefulness [19]. Little is known empirically about how preferences are expressed by patients during RCT appointments and whether these can be addressed to improve the levels of recruitment.

We investigated how treatment preferences were expressed and discussed with recruitment staff during routinely audiotape-recorded recruitment appointments in a multicenter RCT of treatments for localized prostate cancer (the ProtecT [Prostate cancer testing and Treatment] study). These appointments were ''real-life'' interactions between recruiters and potential RCT participants and enabled a detailed prospective investigation using qualitative research methods of how preferences were initially expressed and justified, how they changed during recruitment discussions, and how they impacted on participation and treatment decisions. Insights from these dynamic interactions provided a framework for investigating the role of treatment preferences in informed consent and RCT recruitment.

2. Patients and methods

2.1. Study group

In the ProtecT study, overall 2,698 men aged 50−69 years and diagnosed with localized prostate cancer after community-based prostate-specific antigen (PSA) testing attended an appointment with a study nurse to consider recruitment to an RCT comparing radical prostatectomy, radical conformal radiotherapy, and active monitoring of PSA levels ($<1\%$ of eligible men did not attend) (for further details, see Ref. [20]). Before the appointment, men were provided with a detailed written patient information sheet containing details about treatments and the need for an RCT. Recruiters were research nurses, predominantly female, with many holding senior positions and having previous experience of research. Nurses were given training and feedback to ensure that they provided accurate and detailed information about the study and treatments and to enable recruitment to be as uniform as possible across the different centers. A checklist was provided to remind them of the essential study information concerning diagnosis, advantages and disadvantages of treatments (including those outside the trial), the need for an RCT, the purpose of randomization, and the right to refuse participation or take time to consider. They were encouraged to elicit and explore potential participants' preferences before assisting them in reaching an informed decision about participation or treatment [14,20]. If men expressed a clear preference for one of the treatments or were not willing to be randomized, nurses enabled them to select a treatment; if they were sufficiently uncertain and willing to consider all three treatments, they were invited to have their treatment randomly allocated. The ProtecT study was designed as a comprehensive cohort RCT [21]—all those diagnosed with prostate cancer (randomized or not) were followed up in the same way.

2.2. Data collection and analysis

Recruitment appointments in the ProtecT study were routinely audiotape recorded for training and monitoring purposes [22]. This enabled a systematic assessment of interactions between participants and recruiters and, in this analysis, particular focus on treatment preferences. All recruitment appointments across all nine clinical centers over a 3-month period (October to December 2005) were included in this qualitative study. Men attended one appointment (with the exception of two men who attended two appointments), lasting between 30 minutes and 2.5 hours,

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