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It's not just what you say, it's also how you say it: Opening the 'black box' of informed consent appointments in randomised controlled trials

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ABSTRACT

Randomised controlled trials (RCTs) represent the gold standard methodology for determining effectiveness of healthcare interventions. Poor recruitment to RCTs can threaten external validity and waste resources. An inherent tension exists between safeguarding informed decision-making by participants and maximising numbers enrolled. This study investigated what occurs during informed consent appointments in an ongoing multi-centre RCT in the UK. Objectives were to investigate: 1] how study staff presented study information to participants; 2] what evidence emerged as to how well-informed participants were when proceeding to randomisation or treatment selection; and 3] what aspects of the communication process may facilitate improvements in providing evidence of informed consent. Qualitative analysis of a purposive sample of 23 recruitment appointments from three study centres and involving several recruitment staff applied techniques of thematic, content and conversation analysis (CA). Thematic analysis and CA revealed variation in appointment content and structure. Appointments were mostly recruiter-led or participant-led, and this structure was associated with what evidence emerged as to how participants understood information provided and whether they were in equipoise. Participant-led appointments provided this evidence more consistently. Detailed CA identified communication techniques which, when employed by recruiters, provided evidence as to how participants understood the choices before them. Strategic use of open questions, pauses and ceding the floor in the interaction facilitated detailed and systematic exploration of each participant's concerns and position regarding equipoise. We conclude that the current focus on content to be provided to achieve informed consent should be broadened to encompass consideration of how information is best conveyed to potential participants. A model of tailored information provision using the communication techniques identified and centred on eliciting and addressing participants' concerns is proposed. Use of these techniques is necessary to make potential participants' understanding of key issues and their position regarding equipoise explicit in order to facilitate truly informed consent.

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Introduction

The randomised controlled trial (RCT) is accepted as the gold standard methodology for evaluating effectiveness of healthcare interventions. However, low accrual threatens the power of RCTs, external validity of findings, and may necessitate additional investment of research resources (Britton et al., 1998). Maximising recruitment is therefore crucial. Barriers to recruitment may be clinician-related (perceived lack of resources, time constraints, loss of professional autonomy and concern about impact on doctor–patient relationships) or patient-related (difficulties with informed consent, uncertainty, or preferences for particular treatments, Mills et al., 2006; Ross et al., 1999).

RCTs can only be undertaken where there is 'equipoise': that is, there is no evidence to show that a person would be advantaged or disadvantaged by being allocated to a particular treatment (Chard & Lilford, 1998; Freedman, 1987). Ethically potential recruits must be given sufficient information to make an informed decision about participation (ICH, 1996; World Medical Association, 2004). In practice, they should be fully informed, in equipoise and accept randomisation to determine treatment (Bower, King, Nazareth, Lampe, & Sibbald, 2005; Mills et al., 2003). This raises questions as to what level of detail of information is required for a person to give informed consent, and when and how it should be provided (Boulton & Parker, 2007). Current practices leave room for improvement: in one RCT 51% of participants believed the doctor

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had chosen their treatment and only 23% knew they had been randomised (Hietanen, Aro, Holli, & Absetz, 2000). Participants frequently fail to understand the rationale for RCTs (Featherstone & Donovan, 1998, 2002; Robinson et al., 2004). A systematic review, attempting to identify optimal methods of obtaining informed consent showed that providing more information led to greater understanding of the nature of RCTs and rights to withdraw or choose treatment but lower consent rates (Edwards, Lilford, are Thornton, & Hewison, 1998).

While content and presentation of written participant information sheets (PIS) are highly standardised (Grossman, Piantadosi, & Cohavey, 1994; NRES, 2005), the content and quantity of spoken information provided in informed consent appointments are not monitored and their effects on participant understanding are unknown (Brown, Butow, Butt, Moore, & Tattersall, 2004). Providing an accurate PIS is not enough to ensure comprehension of key issues (Dixon-Woods et al., 2007). Potential participants need time to discuss and understand concepts of randomisation and equipoise (Featherstone & Donovan, 1998; Jenkins, Fallowfield, Shouhami, & Sawtell, 1999; Mills et al., 2003).

A small number of studies have audio- or video-taped informed consent appointments. These found recruiters were poor at initiating discussions of the participant's perspective (Brown, Butow, Ellis, Boyle, & Tattersall, 2004; Tomamichel et al., 1995), checking participant comprehension of information (Brown, Butow, Ellis, et al., 2004; Jenkins et al., 1999; Tomamichel et al., 1995) and explaining key concepts such as randomisation and equipoise (Albrecht, Blanchard, Ruckdeschel, Coovert, & Strongbow, 1999; Brown, Butow, Ellis, et al., 2004; Donovan et al., 2002; Jenkins et al., 1999).

Brown, Butow, Butt, et al. (2004) proposed a typology to evaluate the content and quality of information given by oncologists seeking informed consent for clinical trials. They proposed a) strategies to promote collaborative decision-making, b) a specific sequence of topics for discussion, c) wording to convey key trial concepts and d) communication techniques to avoid subtle coercion and render conflicts of interest explicit. Applying this typology in evaluating informed consent consultations in clinical trials for cancer treatment, Brown, Butow, Ellis, et al. (2004) found considerable variation in practice. Many oncologists paid lip service to shared decision-making, by merely offering the option of delaying treatment decision. Key content was often omitted: the rationale for randomisation was covered in less than half of consultations. Moreover, as the authors acknowledge, while this methodology identifies whether the recruiter has raised an issue, it does not capture how participants interpret the information or whether the invitation to express views is taken up.

A growing body of literature demonstrates an association between communication behaviour and patient outcomes in treatment decision-making (Arora, 2003; Ong, de Haes, Hoos, & Lammes, 1995). Shared decision-making (Charles, Gafni, & Whelan, 1999) is advocated in life-threatening diseases such as cancer (Gatellari, Butow, & Tattersall, 2001; Ong et al., 1995). Yet current approaches to informed consent conform more closely to the informed model of decision-making than the shared model (Charles et al., 1999). The emphasis is on what information must be provided in one direction, from health professional to patient, with the patient deliberating on treatment options and reaching a decision. Shared decision-making (two-way exchange of information between professional and patient, joint deliberation and joint decision-making, Charles et al., 1999) has been advocated for informed consent discussions (Brown, Butow, Butt, et al., 2004), but there is little evidence of it taking place in practice (Brown, Butow, Ellis, et al., 2004).

This study aimed to open the "black box" of what goes on during informed consent appointments in a large ongoing multi-centre RCT, the ProtecT study (Prostate testing for cancer and Treatment, investigating effectiveness and cost effectiveness of three treatments for Prostate cancer, Donovan et al., 2003). The objectives were to investigate: 1] how study staff presented study information to participants; 2] evidence that emerged as to how well-informed participants were when proceeding to randomisation or treatment selection; 3] aspects of the communication process that may facilitate improvements in evidence of informed consent. It was intended that findings would be used to develop advice to improve informed consent appointments to RCTs more generally.

Methods

Main study design

The ProtecT (Prostate testing for cancer and Treatment) study involved a programme of prostate specific antigen (PSA) testing amongst men in the community, inviting those with localised prostate cancer to be randomised to one of three treatments (Donovan et al., 2003). Multi-centre research ethics committee approval was obtained. Men aged 50–69 years in GP practices in nine UK centres were invited to an appointment and given detailed written and spoken information about the implications of having a PSA test, uncertainties about treatments and the need for a randomised trial of treatment. Those consenting to testing who had abnormal results were offered further diagnostic tests including biopsy.

Those diagnosed with localised prostate cancer attended an appointment with a urologist to discuss the diagnosis and be given a detailed written PIS and introductory spoken information about the treatment trial comparing radical surgery (RS), radical conformal radiotherapy (RT) and active monitoring (AM, regular PSA tests and treatment as required). Participants attended a longer informed consent appointment ('information appointment') scheduled a week later, to allow an opportunity to absorb the information given. The information appointment was with a trained research nurse whose aim was to assist the man to reach an informed decision about whether to participate in the RCT and consent to randomisation, or choose treatment outside the RCT.

Design of present study

The study reported here is a qualitative study embedded within the main RCT. Qualitative research was integrated into both feasibility (Donovan et al., 2002) and main studies: information appointments were routinely tape-recorded to investigate differences in recruitment rates between centres and help train new staff (Donovan et al., 2008). This qualitative study used audio-recordings of information appointments to investigate interaction between recruiters and potential participants and was primarily conducted by JW (appointed to the ProtecT team in 2005 so not previously involved in ProtecT research).

Participants

Purposive sampling ensured the selection of a wide range of audio-recordings of appointments: from three study centres, over an extended time-period, including appointments conducted by several recruitment staff with different approaches to obtaining informed consent, and among participants with a range of socio-demographic characteristics. Variations in randomisation rates (the percentage of those eligible consenting to participate in the RCT) occurred between centres and over time (Donovan et al., 2008) and facilitated sampling of appointments for this study. Examples of each of three outcomes defined *a priori* to reflect potentially varying levels of informed consent were included:

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