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ORIGINAL ARTICLE

An observational study showed that explaining randomization using gambling-related metaphors and computer-agency descriptions impeded randomized clinical trial recruitment

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Abstract

Objectives: To explore how the concept of randomization is described by clinicians and understood by patients in randomized controlled trials (RCTs) and how it contributes to patient understanding and recruitment.

Study Design and Setting: Qualitative analysis of 73 audio recordings of recruitment consultations from five, multicenter, UK-based RCTs with identified or anticipated recruitment difficulties.

Results: One in 10 appointments did not include any mention of randomization. Most included a description of the method or process of allocation. Descriptions often made reference to gambling-related metaphors or similes, or referred to allocation by a computer. Where reference was made to a computer, some patients assumed that they would receive the treatment that was "best for them". Descriptions of the rationale for randomization were rarely present and often only came about as a consequence of patients questioning the reason for a random allocation.

Conclusions: The methods and processes of randomization were usually described by recruiters, but often without clarity, which could lead to patient misunderstanding. The rationale for randomization was rarely mentioned. Recruiters should avoid problematic gambling metaphors and illusions of agency in their explanations and instead focus on clearer descriptions of the rationale and method of randomization to ensure patients are better informed about randomization and RCT participation.

Keywords: Randomized controlled trials; Recruitment; Randomization; Qualitative research; Recruitment to RCTs; Patient information

Conflicts of interest statement: The authors have no competing interests to declare.

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1. Introduction

Randomized controlled trials (RCTs) are the most rigorous study design to evaluate health-care interventions [1]. However, their success relies on patient recruitment, and this can be challenging [2]. Randomization or random allocation has been defined as: the process of assigning trial participants to treatment or control groups using an element of chance to determine the assignments to reduce bias (p.7) [3]. Research has indicated that the concept of randomization is difficult to communicate [4] and that patients can find it challenging to understand [5,6]. Linked to this, it has been suggested that failure to accept randomization is a major reason for patients declining to participate in RCTs [7].

Guidelines for good clinical practice state that patients must be informed about the purpose of the trial, the treatment options, randomization, and the right to withdraw [8]. Guidance from the UK Health Research Authority (HRA) is available on how to describe randomization in patient information leaflets and recommends that the following points should be explained to patients: the reason for randomizing, that treatment will not be allocated in line with usual clinical decision-making, that treatment will be randomly allocated, and that neither the patient nor the doctor will decide the allocated treatment. In the guidance, it suggests that this process is ''akin to drawing lots, tossing a coin, or rolling a die'', although specific details about the patient may be used to ensure groups in the trial are as similar as possible and that the patient is just as likely to receive either/any of the study arms [9].

Much of the research to date has reported on patients' difficulties with understanding randomization via self-reported questionnaires [10], or interview data completed post hoc, based on their responses to hypothetical scenarios [11,12]. Relatively, little research has examined what recruiters actually say about randomization during recruitment appointments with some exceptions [13,14], and patients' responses are even less commonly reported. The QuinteT Recruitment Intervention (QRI) [15] has demonstrated the benefit of investigating what is actually said during recruitment appointments [16,17]. The QRI is an established recruitment intervention that includes a review and analysis of screening and recruitment data, interviews with recruiting clinicians, and audio recordings of consultations with patients where trial information is discussed. Thereafter, an action plan, typically in the form of support and specific training to help improve recruitment, is discussed and agreed with the Chief Investigator of the RCT. The aim of the QRI is to improve information delivery and increase participant recruitment and informed consent. This article is derived from the QRI research program and investigated how recruiters and patients discussed randomization in recruitment appointments. The findings illuminated the reasons why patients find the concept difficult to understand and identified opportunities for improvement. This article presents how randomization is communicated by health professionals and how patients respond to their descriptions, using data from five RCTs with actual or anticipated recruitment difficulties.

2. Method

2.1. Sampling

Data were taken from RCTs that included a QRI to support recruitment. For this analysis, data were available from five trials, all experiencing, or anticipated to have, recruitment difficulties. They included a wide range of specialisms (e.g., orthopedics, oncology, and general surgery), types of trials (e.g., surgery vs. nonsurgery vs. sham surgery, chemotherapy vs. surveillance, and two- or three-arm trials), and recruiters (surgeons, oncologists, research nurses [RNs], and physiotherapists). The analysis included all available recorded appointments from the five trials. The recordings were all made before the RCT receiving any feedback or training related to the recruitment intervention. Clinicians and patients were aware that the purpose of undertaking audio recording was to assist with trial recruitment and to improve information delivery. In total, 73 recruitment appointments, with 56 different patients and 27 different recruiters across five RCTs were audio-recorded. Recordings took place between 2010 and 2014. The QRI element of the studies was approved as part of the main trial Research Ethics Committee application in trials 1, 3, 4, and 5 and as a separate Research Ethics Committee application for trial 2.

Table 1 provides summary information of the participating trials and the range of recruiters providing information.

2.2. Data analysis

The qualitative analysis software package NVivo 10 (QSR international) was used to support data storage and analysis. M.J. listened to all of the recordings, following an approach of content analysis, and screened them to identify any discussion related to randomization. All references to randomization were extracted, transcribed, and coded. Documentation was also done where there was no reference to randomization. In keeping with Jenkins' analysis [18], we included explicit mentions of randomization, for example, where the word ''randomization'' or phrase ''randomly allocated'' was used as well as implicit mentions, for example, ''you'll be allocated to either treatment x or treatment y''. D.E. and C.C. listened and independently coded a subset of 12 recordings. M.J., C.C., and D.E. met to compare coding and interpretation. Differing interpretations were discussed and resolved. The data presented in this article are transcribed excerpts from these consultations that provided an insight into what recruiters actually said to patients about randomization and also how patients responded. To preserve recruiters' anonymity, individual and trial identifiers have not been included. However, the