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Original Paper

How Do Doctors Explain Randomised Clinical Trials to their Patients?

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As part of a larger study designed to improve doctor–patient communication in randomised clinical trials (RCT), we audiotaped the discussions between doctor and patient in which consent was being obtained for a RCT. This paper reports on 82 discussions conducted by 5 clinical oncologists in both District General and University Hospital outpatient departments. When introducing the subject of trials, uncertainty about treatment decisions was expressed by the doctors in the majority of cases (79, 96.3%). This was most often stated in a general sense (78, 95.1%), but some mentioned personal uncertainty (12, 14.6%), an approach which helps to maintain a trusting doctor–patient relationship. The word randomisation was mentioned in 51 (62.2%) consultations, although the process itself was usually described implicitly (78, 95.1%), e.g. by telling the patient that they would be allocated either one or other treatment. Analogies were used in 28 (34.1%) cases to describe the randomisation process. In addition, although treatments and side-effects were described frequently, (68, 82.9%) and (72, 87.8%) respectively, information leaflets about the trials were not given to 23 (28%) patients. The study shows that U.K. clinicians adopt individual methods when providing information and eliciting consent to trials.

Key words: clinical trials, randomised doctor–patient, communication, cancer, audiotape, informed consent

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INTRODUCTION

RANDOMISED CLINICAL trials (RCT) are an essential component in the validation of new cancer treatments. Low levels of recruitment are a major problem in some cancer trials and it is necessary to find methods which will help to increase the recruitment of patients [1–5]. In the U.K. the recruitment rate is between 5 and 10% for all trials, with lowest rates for patients with common tumours, i.e. 1–2% for lung and 2% for colorectal [6]. These figures cause great concern as low or slow recruitment threatens the validity of the trial. It has also been suggested that patients involved in trials may have better clinical outcomes. Whether this is due to the treatment or the expertise of institutions and individuals committed to trials or other factors such as age and health status has yet to be established [7].

A number of factors have been identified that hinder the entry of patients into trials. These are discussed in detail elsewhere [8–10] but can be divided into those affecting the clinician and those affecting the patient. The main difficulties facing the clinician include time pressures, no support staff, having to explain randomisation and obtain informed consent [8]. Giving complex information to patients about trials and describing the concept of randomisation in simple terms were the primary problems highlighted in a postal survey of 357 clinicians that established their attitudes to clinical trials of cancer therapy [11]. These communication difficulties were emphasised also by senior U.K. oncologists during communication skill training courses [12].

The patients' difficulties include an overall lack of information, uncertainty about personal benefit, poor comprehension about the value of trials and an aversion to randomisation [9]. The concept of randomisation is a difficult one for many patients newly diagnosed with cancer to comprehend [13]. It emerged as a major barrier in a study that examined patients' attitudes to the randomised clinical trial [14]. Results showed that the majority of cancer patients (287, 91.1%) believed that patients should be asked to take

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part in medical research. Yet when treatment was randomised only 141 (44.8%) said that they would take part. However, as further information was provided about the randomisation procedure the percentage of patients who would consider participation increased to 260 (82.5%). These results suggest that patients are willing to consider trial entry when they are provided with sufficient information about randomisation. It also implies that low recruitment rates are not entirely due to patient refusal. In a review of the clinical trial literature, Cook-Gotay [15] suggests that the major block in recruitment to trials is the physician. One reason suggested is that clinicians have a preference for a specific treatment option. Another is that they have received little formal training in how to obtain informed consent from patients.

The Helsinki Declaration provides clinicians with guidelines on the information patients should receive when considering entry to a clinical trial. Information needs to be presented in an understandable way so that the patient can make an autonomous decision regarding trial entry. It has been argued elsewhere that full information about clinical trials may depreciate the doctor–patient relationship [8] and that it may be 'needlessly cruel' to burden patients with too much information at the point of diagnosis or relapse [3]. Simes and colleagues [1] examined the issue of information giving by comparing two approaches to consent for trials. One approach used individual consent based on the doctor's discretion, the other total disclosure of information. The results showed that some patients were able to handle detailed information about trials but others were made overly anxious which implies that consultations tailored to a patient's individual needs are best.

There is little evidence that doctors intuitively know which of their patients would require more or less information, consequently a study is being undertaken using a patient preference and attitude profile to help clinicians understand the concerns of individual patients before discussing randomisation into a treatment trial. As part of this study interviews are tape recorded. The present paper reports the results of an analysis of these recorded interviews.

PATIENTS AND METHODS

Patients

The subjects were 100 cancer patients eligible to participate in randomised clinical trials. They comprised newly diagnosed and relapsed patients referred to senior clinical oncologists at two district general hospitals and a university teaching hospital. There were 10 tape failures and eight questionnaires were not returned, leaving a total of 82 tapes available for analysis. Table 1 shows the characteristics of the patients, with breast cancer patients forming 50% of the total sample. Ninety-five per cent of the patients had not had any previous trial experience.

Table 1. *Age and sex distribution*, n = 82

	All *n* (%)	Male *n* (%)	Female *n* (%)
Age range			
25–44 years	7 (8.5)	1 (1.2)	6 (7.3)
45–64 years	46 (56.7)	13 (15.9)	33 (40.2)
Over 65 years	29 (35.4)	14 (17.1)	15 (18.3)
Cancer site	*n* (%)		
Breast	41 (50)		
Prostate	15 (18.3)		
Ovarian	10 (12.2)		
Lung	6 (7.3)		
Colorectal	5 (6.1)		
Melanoma	2 (2.4)		
Lymphoma	2 (2.4)		
Testicular	1 (1.2)		

Method

Patients were invited to participate in the communication study and were given an information sheet to read prior to signing the consent form. Before the consultation they completed three questionnaires, a Patient Information Needs questionnaire and a Patients' Attitudes to Randomised Clinical Trials questionnaire (which together form the Patient Profile, see Appendix 1) and the Speilberger Stait Trait Anxiety Inventory (STAI). Each clinician saw 20 patients who were eligible for trials over a period of between 6 and 12 months. The clinician performed his or her usual Standard Consent (SC) procedure for half of the patients and had access to the Patient Profile (PP) to provide an Individual Consent (IC) for the others. The order in which the clinician used the profile depended on the group to which he or she was randomly allocated following the first five SC discussions. Clinicians in Group A had access to the PP for the final 10 patients, i.e. patients 11 to 20 and those in Group B for patients 6 to 15. The consultations were audiotaped and the patient was subsequently given two further questionnaires to complete and return by post. One of these questionnaires examined patients' satisfaction with the consultation and the other their reasons for accepting or declining to enter a clinical trial. In addition, clinicians completed a short assessment of their own satisfaction with the consultation using a visual analogue scale.

The audiotapes were content analysed by one researcher against a grid matrix developed by the authors. This consisted of the main items that a clinician and patient would cover when discussing randomised trials of cancer therapy (Appendix 2). A random sample of 18% ($n = 15$) of the tapes was double coded by a second researcher to assess intercoder reliability. Pearson correlation coefficients between the two coders were calculated for all items on the grid and the average correlation was 0.78. An analysis of the intervention will not be performed until at least 15 clinicians have completed the study. Therefore, the following results are of a descriptive nature based on the audiotaped consultations and offer an insight into what clinicians actually say to patients regarding randomised clinical trials.

RESULTS

General findings

Contrary to the general belief that explaining a clinical trial is time consuming, the consultations were concise with 86.6% (71/82) taking place within 15 min (mean 10.31 min, S.D. 5.7 min, mode 8 min, range 3–35 min). The concept of the trial was usually introduced by clinicians describing the uncertainty that exists about treatment decisions (96.3%, 79/82). In almost every case it was in a general sense (95.1%, 78/82) but some mentioned personal uncertainty (14.6%, 12/82), e.g. "we are not sure which treatment is best" compared with "I am not sure which treatment is best."

All the clinicians used the word 'trial' in the consultations, yet the word 'randomisation' was mentioned less frequently (62.2%, 51/82). Overall the preference was to describe the randomisation process implicitly (95.1%, 78/82) but some were also explicit (25.6, 21/82), with only 1/82 (1.2%) being only explicit. Three (3.7%) were neither. An explicit discussion of the randomisation process consisted of a description of randomisation in layman's terms plus the reasons why treatment has to be chosen at random in a phase 3 trial. Below are examples of implicit and explicit descriptions of randomisation for the same type of trial.

Implicit. "... to try and create a body of evidence that will guide us in the future there is a national trial running .... If women agree to enter this study ... umm ... are allocated either to have chemotherapy or not to have it. That isn't my decision, that wouldn't be your decision, it would be sort of decided for you whether or not you took it, if you wished to enter the study".

Explicit. "... where knowledge needs to be gained in the use of chemotherapy we will randomise patients so that half will get chemotherapy and half won't and you won't make that choice and I won't make that choice because that would introduce bias. You know we could say, well she looks a fit young lady who could cope with chemotherapy, we'll give her it and the next lady who comes we could say she doesn't look quite as good, we won't give it to her and that would introduce bias and we mustn't do that so it has to be randomised. Now I've explained that because a lot of patients and relatives think, of if someone else is choosing how do they know what's best for you? No one is choosing—it's a random process so that we don't inflict this bias, that we don't skew the results, otherwise you'd only have only fit ladies having chemotherapy and all the unfit ones not. You see?".

The use of analogies to describe the randomisation process occurred in 34.1% (28/82) of cases. The most common were "like the toss of a coin", "like the lottery", and "picking a number from a hat". Also it was found that patients were rarely asked whether they fully understood or even had a moderate understanding of the concept or reasons for randomisation. The usual pattern was that the patient's understanding was either never checked (82.9%, 68/82) or only checked a little (15.9%, 13/82).

Clinicians described treatment choices and side-effects in the majority of cases (82.9% ($n = 68$) and 87.8% ($n = 72$) respectively), yet information leaflets about the trial were given only in 67.1% ($n = 55$) of cases. This figure has been adjusted for those patients (4.9%, $n = 4$) who decided during the consultation that they did not want to take part in a clinical trial.

Finally, whilst only a small percentage of patients in our study were actively encouraged to take part in the trial (29.3%, $n = 24$), two thirds (64.6%, 53/82) were not told they could leave the trial at any time. Despite this, in 50% of the consultations patients were asked if they could make a decision there and then regarding trial entry. Furthermore many patients (43%, $n = 35$) did not have a partner or friend present during the consultation whom they could turn to for support and discussion about the information given and treatment options available.

Patients

The focus of the discussions was doctor directed, in that they provided patients with information about the trial, treatments and side-effects. None the less 85.4% ($n = 70$) of patients raised general questions about the trial. These ranged from a fear of being experimented on, such as "does this mean I will be a guinea pig?" to reservations that the treatments within the trial would be at least as good as each other. In addition 46.3% ($n = 38$) of patients specifically questioned the potential side-effects of treatments.

For many patients the need to get better was an overriding factor in whether they considered trial entry; remarks such as "I'll go for anything as long as I get better" and "do what you want to do, I just want to get better" highlight this issue. Very few patients vocalised their concern about randomisation (8.5%, $n = 7$) but a third expressed uncertainty in treatment choices (32.9%, $n = 27$), with 6% ($n = 5$) concerned about both. It could be argued that randomisation and uncertainty regarding treatment are synonymous, implying that over 40% of patients were disturbed by the concept of randomisation.

Only 14.6% ($n = 12$) of patients mentioned during the consultation that the research may benefit other patients in the future. This is perhaps to be expected when confronted with a life threatening illness. Yet altruism was found to be one of the top three reasons (in the post consultation questionnaire) for agreeing to join the trial (26.4%, $n = 22$). Few expressed fixed views regarding treatment choices during the consultation (22%, $n = 18$), but neither did they express a wish for the doctor to choose whether they should participate in the trial (84.1%, $n = 69$). Those who wanted the doctor to make a decision said things such as, "I'm in your hands doctor" and "do what you think would be best". However, 8 (9.8%) patients were clearly disturbed by the fact that the doctor did not choose the treatment even when the clinician had tried to explain the reasons for the trial. The following quote is from a 69 year old man contemplating entry into a trial of chemotherapy in lung cancer. The clinician has discussed the reasons for the trial, the various treatment options and side-effects and the patient has acknowledged that he understands what the doctor has told him. Towards the end of the consultation the doctor asked the patient how he felt about participating in the trial and received the following reply, "... well the only strong view I've got, obviously I'm not a medical man, so I'm going to put the ball in your court, from your point of view, you're the doctor and knowing my case, what would you advise? I'm not holding you to anything, it's on tape ... but in your expert opinion?"

Type of trial

The trials were divided into five broad categories. 40 consultations were chemotherapy versus standard treatment, 23 were hormone versus standard treatment, 15 were hormone versus placebo, two were radiotherapy versus standard treatment and the fifth category was other (two interferon trials). Because of the small numbers in the latter two trials the analysis only includes data from the first three categories. For all discussions the clinician's explanation of the trial was examined according to the type of trial on offer.

First, the time taken to discuss trials differed significantly between trial categories ($F(2.77) = 8.92$, $P = 0.003$). A Student Newman's test (significance held at $P = 0.05$) indicated that the chemotherapy discussions took significantly longer than the hormonal trials. This is probably due to the intrinsic nature of chemotherapy trials, where treatment and side-effects are discussed in detail. There was a difference in acceptance rates to the trials. The highest refusal rate was

found in the chemotherapy versus standard therapy (52.5%, 21/40), compared with 21.7% (5/23) and 6.7% (1/15) in the hormonal studies. This is not surprising as chemotherapy has the worst reputation of all cancer treatments as it is often associated with severe side-effects and can involve prolonged hospital visits.

Turning to the consultation itself, the word randomisation was used more often in the chemotherapy (37.2%, $n = 15$) and hormone versus placebo trials (15.4%, $n = 2$) than hormone versus standard treatment (9%, 2/23). Doctors discussing chemotherapy trials were more explicit in describing the randomisation process (16.7% ($n = 13/78$) compared with 9% ($n = 7/79$) and 1.3% ($n = 1/78$) for endocrine trials) and used analogies more often (21.8% ($n = 17/78$) compared with 3.8% ($n = 3/78$) and 7.7% ($n = 6/78$)). However, the differences reported are confounded by the doctor's specialty, in that one clinician discussed only hormone trials whilst another focused mainly on chemotherapy.

DISCUSSION

The findings from this preliminary study provide us with information as to how clinicians actually present information about randomised clinical trials to their patients. Overall the standard is high, as one might expect from senior clinicians working in oncology, but there were areas of discussion that could be improved.

The introduction of the subject of trials usually began with the clinician expressing uncertainty about treatments. This was usually in a general sense describing the uncertainty amongst experts in the field as opposed to a personal uncertainty about the type of treatment to give. Our findings are very similar to Slevin and colleagues [13] who suggested that doctors often appear reluctant to admit publicly that they do not know which treatment is best for fear of damaging the relationship with the patient and losing the patient's trust.

Patients may perceive a conflict between a doctor's role as a physician and as a researcher [12, 16] and that this dilemma may be more acute when treatment is based on random allocation. Cockburn and colleagues [17] examined some of the major issues for women considering entry into trials of breast cancer and suggested that random allocation could make women feel that clinicians are more concerned with research than with ensuring that they receive the best possible care. This suggests the need for clinicians to explain in detail why randomisation of treatment is necessary and to check that the patient understands what this means. If a patient's understanding is never checked they may leave the clinic with a number of wrong interpretations. Among these may be a belief that a computer is actually choosing the treatment for the patient based on personal details or that people at the trial centre will tell the doctor what the best treatment is for them. The doctor can never be sure that a patient understands what they have been told unless they check comprehension effectively [18]. The issue is highlighted in a current study [11] examining oncologists' communication skills. To date, 70 doctors have had their consultations videotaped and preliminary findings show that it is extremely rare for a clinician to check explicitly a patient's understanding of either their treatment or illness.

The majority of clinicians in our study discussed the process of randomisation implicitly using analogies at times to describe the concept. The argument for explicitly describing the process has been given but explicit descriptions could also lead to confusion for the anxious patient. This suggestion is implied from results of a survey by Corbett and colleagues [19]. In the study subjects were presented with descriptions of proposed randomised medical trials and their views sought on different aspects of the trial. Interestingly, of the seven statements explaining randomisation, favour was found for the less explicit explanations, the ones that played down the role of chance. These opinions were from the 'healthy' public and may be different from people with life-threatening disease experiencing anxiety about the future.

One communication problem highlighted in the study was that patients were rarely told they could leave the study at any time and still be treated. The result is similar to that reported by Lynoe and colleagues [20] showing that approximately 40% of patients did not recall being informed that they could withdraw from a gynaecological trial. The findings relied heavily on women's memories of the event (18 months later) and as such figures may be unreliable and underestimated. It appears that once clinicians embark on a description of a trial, the possibility of leaving the trial is rarely raised. Yet this piece of information could influence a patient's decision about trial entry. In a paper examining patients' attitudes to clinical trials [13], knowledge that the patient could always leave the study for any reason encouraged 73.1% of previous dissenters to take part. Although patients were responding to a hypothetical situation, the study showed that patients who had difficulty with the concept of randomisation altered their attitude when presented with key pieces of information.

Another area of concern was that in just under a third of cases, clinicians failed to give patients written information about the trial. Yet the clinicians were the only providers of trial information, as opposed to some units where additional information is provided by research nurses and trial co-ordinators. These figures are, however, much better than those reported by Williams and Zwitter [21]. They examined the standard of consent giving in clinicians from 12 European trial centres and reported that, although 58% of clinicians said they gave full information about treatment options and the randomisation process, only 21% provided written information. Whilst discussions are reported to be the most important source of information, patients find written information to be a valuable reinforcement, an additional source of information and a simple way of informing family members about the trial [22].

The acceptance rate, and reasons why patients joined a trial, appeared to be influenced by the type of trial on offer. Chemotherapy trials had the lowest acceptance rate and the main reasons why patients agreed to participate was that they believed the trial offered the best treatment coupled with a high degree of trust in the doctor. Although not examined in this study, others [22] found that many patients hoped for better personal treatment by receiving the experimental arm of a trial. In contrast, patients in the hormone based trials often gave an altruistic response.

A factor which could influence acceptance rates is the degree to which a patient may experience unpleasant side-effects. Clinicians discussing hormonal trials may understate the potential severity of the treatment, whereas discussion of 'serious' side-effects such as nausea, vomiting and hair loss are discussed more frequently for the chemotherapy treatments. Jensen and colleagues [22] reported that a fear of specific side-effects was the main reason patients gave for declining trial entry. In contrast, our results showed that,

independent of the type of trial on offer, a fear of randomisation together with wanting the doctor to choose the treatment were the main reasons for declining.

The findings from this study showed that despite the stated requirements of trial protocols, clinicians adopt individual methods when providing trial information to patients. Although the majority of clinicians discussed the treatments on offer and associated side-effects in great detail, the reasons for randomising treatment was kept to a minimum. There is some evidence that this practice mirrors the feelings among the general public, as one small study reported that they prefer an explanation of randomisation that is less explicit [19]. Whether this is true for patients with cancer, who usually prefer detailed information, has yet to be formally examined, but data from our intervention study may throw further light on the issue.

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APPENDIX 1

Patient profile comprising information needs and patients' attitudes to randomised clinical trials questionnaires

CONFIDENTIAL ID.....

The Information Needs of Patients

Patients differ in the amount of information that they need to know about their diagnosis and treatment—some want to know everything, others want to know very little. Are you the sort of person who prefers to have? (Please tick one of these)

a) all possible information, good or bad ☐
b) only to have good information ☐
c) as much or as little information as the doctor thinks necessary ☐

Below is a list of different kinds of information about illness and treatment which patients might need at some stage. Please tick whether you think you are the kind of person who would ABSOLUTELY NEED this information, WOULD LIKE TO HAVE it, or WOULD PREFER NOT TO HAVE this information.

	absolutely need	would like to have	would prefer not to have
a) The likelihood (in percentage terms) that the treatment offered would cure you completely	☐	☐	☐
b) Whether the treatment offered would control but not cure (eliminate) the disease	☐	☐	☐
c) Whether the treatment offered would reduce the symptoms but not control the disease	☐	☐	☐
d) All the possible treatments that are available	☐	☐	☐
e) All the possible side-effects of the treatment	☐	☐	☐
f) Exactly how the treatment works to treat the illness	☐	☐	☐
g) The research evidence that the treatment being offered works	☐	☐	☐

Confidential ID.....

Patient Attitudes to Trials Questionnaire

Part 1

Please tick one of the boxes

	Yes	No	Do Not Know
1) Do you think that patients should be asked to take part in medical research?	☐	☐	☐

Suppose that you were asked to take part in a research study comparing two treatments both of which were suitable for your illness.

	Yes	No	Do Not Know
2) Would you be prepared to take part in a study comparing different treatments?	☐	☐	☐

Usually the only scientific way to compare one treatment with another is for the choice between the two to be made randomly, rather like tossing a coin.

	Yes	No	Do Not Know
3) Would you be prepared to take part in a study where treatment was chosen at random?	☐	☐	☐

Part 2

You answered "No" or "Do not know" to Question 3, so we would now like to ask you a bit more about this. (Please tick one of the boxes)

In a randomised study a choice would be made between two treatments, either of which would be suitable for you. Your doctor and experts in the field do not know for sure if one treatment is better than the other, or if they are both the same, that's why they want to do the study.

	Yes	No	Do Not Know
4) Would knowing that encourage you to take part?	☐	☐	☐

In a random choice study, if the treatment you were receiving did not suit you for any reason you could always leave the study. Your doctor would then give you whatever other treatment might be appropriate for you.

	Yes	No	Do Not Know
5) Would that encourage you to take part?	☐	☐	☐

Before you agreed to enter a random choice study the doctor would tell you all about the two treatments being compared, including any side-effects before you were allocated one or the other.

	Yes	No	Do Not Know
6) Would that encourage you to take part?	☐	☐	☐

If you knew that the following were taken into account
a) that either treatment was completely suitable;
b) that you could leave the study if the treatment did not suit you;
c) that there is plenty of information before the random choice was made;

	Yes	No	Do Not Know
7) Would all these things together mean that you would change your mind and agree to take part?	☐	☐	☐

Thank you for your help.

APPENDIX 2

Grid matrix comprising the main items that a clinician and patient would cover when discussing randomised trials of cancer therapy

1 = not at all; 2 = mentions it or (a little); 3 = a lot (details, repeated inf.); 4 = fully; 5 = n/a
Note order of discussion, i.e. uncertainty > word trial > randomisation discussion > treatments > side-effects

Age		Sex		Leaflet Given	

Clinician/Patient Code	Trial Time	Name and Type of Trial

CLINICIAN (TRIAL)

Does the clinician		
mention the word trial or study explicitly?	y	n
actively encourage the patient to enter the trial? (1–4) explicitly (4)		
refer to the profile? (1–5)		
discuss the right not to enter? (1–4)		
tell the patient they can leave the study at any time? (1–4)		
Does the clinician ask for an answer immediately or later that day?		
Does the clinician refer the patient to the research nurse? (1–4)@		

@1 = none available 2 = research nurse 3 = trial co-ordinator 4 = breast nurse

RANDOMISATION

Does the clinician		
use the word randomisation?	y	n
Explain randomisation Implicitly: e.g. 1/2 will get tablet, 1/2 not	y	n
Explain randomisation Explicitly: e.g. most of the details	y	n
Does the clinician check the patient's understanding of randomisation? (1–4)		
Does the clinician use an analogy to describe the randomisation process? e.g. flip of a coin	y	n

TREATMENT CHOICES

Does the clinician		
express uncertainty about treatment decisions?	y	n
Personally?	y	n
Generally?	y	n
a) Are choices discussed in detail? (1–4)		
Chemotherapy (1–5)		no to (a)
Radiotherapy (1–5)		no to (a)
Hormone Therapy (1–5)		no to (a)
Surgery (1–5)		no to (a)
No treatment arm (1–5)		no to (a)

SIDE EFFECTS

b) Are side effects discussed? (1–4)		
Nausea/Vomiting (1–5)		no to (b)
Tiredness (1–5)		no to (b)
Loss of hair (1–5)		no to (b)
Other (1–5)		no to (b)

PATIENTS' RESPONSES

Does the patient	
raise questions about the trial? (1–4)	
raise questions about side effects (1-4)	
Express a willingness to join the trial? (1–4)	
Express concerns over randomisation? (1–4)	
Express concerns over uncertainty in treatment? (1–4)	
Express views regarding benefit to others? (1–4)	
leave the decision to participate up to the doctor? (1–4)	
choose one or other treatment? (1–4)	
refer to the profile? (1–4)	
does the relative raise questions about the trial? (1–5)	
does the reviewer understand the trial? (1–4)	

Comments, e.g. type of analogies, patient's comments, etc.