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Information and communication in the context of a clinical trial

P. Hietanen [a,*], A.R. Aro [b], K. Holli [c], P. Absetz [b]

[a] *Department of Oncology, University Hospital of Helsinki, PO Box 180, Fin-00029, Finland*
[b] *Department of Epidemiology and Health Promotion, National Public Health Institute, Helsinki, Finland*
[c] *Department of Oncology, University Hospital of Tampere, Finland*

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Abstract

The aim of this study was to determine the communicative needs of the patients in the context of being invited to participate in a clinical trial. A questionnaire was sent to 299 patients with breast cancer randomised in a trial of adjuvant therapy. It was returned by 261 (87%) of them. Ninety-one per cent (231/255) of the patients regarded the information provided as easy or quite easy to understand. However, the method of treatment allocation was unclear to most patients: 51% (128/251) thought that the doctor had chosen the treatment while only 23% (57/251) knew that they had been randomised. Younger and better educated patients had a better understanding. For 55% (125/226) of the patients written information had been helpful in decision making. This correlated highly with the education of the patient. Sixty-eight per cent (174/255) of the patients thought that they had enough time for decision-making. Less educated patients and older patients had needed more time. Eighty-seven per cent (218/251) were happy with their decision to participate. While most patients are satisfied with the information received, there is a poor understanding of how treatment is allocated. Information should be modified for older and less-educated patients. The needs of the patients when offered participation in a clinical trial are clear information, enough time to consider the options and psychological support.

Keywords: Information; Communication; Clinical trial; Randomisation; Sociodemographics

1. Introduction

Ethical guidelines concerning the information that patients should receive before consenting to enter a clinical trial have evolved continuously since the early 1930s, when the first regulations were established which protected the rights of volunteers in clinical trials [1]. The primary purpose of informed consent is to protect subjects and to give them the opportunity to make an informed choice when deciding whether to participate in a clinical study [2].

True informed consent depends on the patient receiving adequate information for decision making, understanding how treatment is chosen and being able to make a deliberate decision about participation. Evidence from empirical research indicates that the ideals of informed consent are difficult to achieve in practice [3,4]. Ganz has reviewed what is known about attitudes toward clinical trials among patients and the public and has suggested that their concerns must be addressed if clinical trials are to be successful in the recruitment of subjects to answer important clinical research questions [5].

In previous studies, most patients have found the information provided about a clinical trial easy to understand [6,7]. However, when the patients have been asked about details, they have often had poor recall or poor understanding of the information [8,9]. Many patients who have participated in clinical trials have been unaware about the method of treatment allocation or that the best treatment is unknown [7,10,11].

Despite the requirement for informed consent in clinical research, few studies of the decision-making process have been performed to determine the communicative needs of the patients and whether these are related to demographic factors. The aims of the present study were to determine: (i) Whether the patients had received adequate information for decision making; (ii) Whether they had understood the method of treatment allocation; (iii) Whether they had made an informed decision about participation; (iv) What their reasons for

* Corresponding author. Tel.: +358-94711; fax: +358-947174203.
E-mail address: paivi.hietanen@hus.fi (P. Hietanen).

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participation were; and (5) The type of information that they needed when offered participation in a clinical trial. Our aim was to gather information that would lead to an improvement in the quality of informed consent in clinical trials.

2. Patients and methods

2.1. Patients

A questionnaire was sent by mail in May 1998 to 299 patients with breast cancer who were randomised in 1997 into an adjuvant trial which evaluated different types of oral endocrine therapy (tamoxifen versus toremifene) and was performed in five Finnish university hospitals. It is estimated that more than 95% of the eligible patients accepted randomisation. The mean time from recruitment to completion of the questionnaire was 11 months (range: 5–17 months). The questionnaire was returned by 261 (87%) patients. All patients had signed consent forms when they were asked to participate in the clinical trial. 3 of the patients had died before the survey. Those patients who did not return the questionnaire were kindly requested to give a reason for this in writing and asked to return it anonymously. 14 of them answered. The most common reasons were older age and other medical diseases, tiredness with multiple questionnaires, or just unwillingness to answer. 4 patients had found the questionnaire too difficult.

Demographic characteristics of the 261 patients are given in Table 1. The patients were 48–87 (mean: 65) years of age.

2.2. Questionnaire

A pilot questionnaire with 24 structured and 5 open questions was developed to inquire about the adequacy of the oral and written information given prior to recruitment into the trial, aspects of decision making, satisfaction with and usefulness of information, understanding of how treatment was chosen, reasons for participation, whether the same decision would be taken after the experience, and the interests of the patient when offered participation in a clinical trial (open questions). The draft questionnaire was then mailed and tested on 10 patients with breast cancer who were on follow-up without recurrence and their feedback was incorporated into a final version. The final questions used in the analyses are shown in Tables 1 and 2.

Table 1
Demographic characteristics of the patients ($n=261$) studied after entry into a randomised trial evaluating adjuvant therapy for breast cancer

Characteristics	n (%)
Age	
<60 years	75 (29)
60–69 years	103 (39)
$\geqslant 70$ years	83 (32)
Education[a]	
Secondary school	138 (55)
Post-secondary school	97 (39)
University degree	15 (6)
Marital status	
Married or living with a partner or spouse	132 (51)
Living without partner or spouse	129 (49)

[a] Total does not equal to 261 due to missing values.

2.3. Clinical setting

The consent was sought by a total of 10 doctors, but most patients were randomised by five clinical investigators. There was no standard guideline as to how to give verbal information. However, all doctors were instructed to give an information leaflet to the patients. The leaflet included the standard information required for clinical trials [2]. Specialist nurses also met the participating patients, but provision of information about the trial was the responsibility of the doctors.

The doctors who randomised patients were afterwards questioned about how much time their patients had for decision making about participation in the trial. The doctors in two centres, where one-third of the patients in the present study were randomised, gave information about the trial during the appointment preceding randomisation; this gave the patients 1–7 days to consider their participation. All other patients both received information and were randomised during a single appointment.

2.4. Statistical methods

Associations of age and education with how information was regarded and understood, and with decision-making, were assessed using two-way contingency tables. Contingencies were tested with Chi square tests. Significance tests were not corrected for multiple comparisons. A level of significance of $P<0.05$ was used.

3. Results

3.1. The adequacy of oral and written information

Ninety-one per cent (231/255) of the patients regarded the information provided as easy or quite easy to understand whereas only 2% (4/255) found the information quite difficult or very difficult to understand. For 7/255 patients (3%) the doctor did not explain anything about the trial. Most patients (81%) (203/252) also remembered that the doctor told them about the

Table 2
Questionnaire. Only those questions are shown which were analysed. Questions about demographic factors are also excluded

Please, answer the following questions by ticking the appropriate alternative for each question or by writing the answer on the line/in the box given

1. The doctor's explanation about the trial was
- easily understandable
- quite understandable
- can't tell
- quite difficult to understand
- very difficult to understand
- doctor did not explain anything about the trial

2. The doctor explained the possible side-effects of treatments in a way which was
- easily understandable
- quite understandable
- can't tell
- quite difficult to understand
- very difficult to understand
- I do not remember the doctor having told me anything about side-effects

3. There were two treatment arms in the trial. Do you perceive that your treatment was chosen
- randomly
- my doctor chose it
- I chose it myself
- treatment was chosen in another way, how _____
- I do not know how the treatment was chosen

4. Did you have anything to ask about the trial at that time?
- yes
- no

5. Did you pose questions to the doctor?
- yes
- no
- I did not have anything to ask

6. Did you get the answers you needed?
- yes
- partly
- no
- I did not have anything to ask

7. Did you receive the information leaflet about the trial?
- yes
- no
- I can't tell/I do not remember

8. Did you read the information leaflet?
- yes
- no
- I did not receive it/I do not remember

9. The information leaflet was
- very easy to understand
- quite easy to understand
- I can't tell/I do not remember having read it
- quite difficult to understand
- very difficult to understand

10. Information leaflets can be very detailed. How would you evaluate the leaflet you received?
- it made decision-making easier
- it did not make decision-making easier
- I can't tell

11. Did you have enough time to consider your participation in the trial?
- yes, I had enough time
- I would have liked a bit more time to consider
- I would have liked a lot more time to consider
- I can't tell

12. How would you evaluate your decision to participate?
- I was allowed to decide myself
- the doctor/nurse pressed me to participate
- my family pressed me to participate
- I wanted the doctor to decide on my behalf
- someone else decided on my behalf, who?_____
- I had to decide/I was left to decide on my own

13. Could you influence the decision to participate?
- a lot
- somewhat
- hardly
- not at all
- I can't tell

14. Why did you decide to participate in the trial?
- I wished for more effective treatment
- I wished my participation would benefit future patients
- I wished my treatment would be more carefully followed
- I wished to meet the same doctor more often
- I wished to be allowed to come longer to the check-ups in the same hospital

15. Now that you think back, would you decide again to participate?
- yes
- no
- I can't tell

(continued)

Table 2 (*continued*)

16. If you decided to participate again, why?_____
If you did not decide to participate again, why?_____

17. Would you wish (based on information that you would receive) to decide about participation on your own, or would you wish the doctor to decide about participation on your behalf?
- I would like to decide on my own
- I would like to decide together with my significant others
- I would like the doctor to decide on my behalf
- I would like to decide together with the doctor after having discussed the matter with him/her

We'd also like you to answer the following questions:

18. According to your understanding what is meant by randomisation?

19. Did your experiences of the treatment correspond to the information you received beforehand?

20. Would you like to write freely about what aspects you find important when patients are offered the possibility to participate in clinical trials?

side-effects of the treatments in a way that was easy or quite easy to understand, while 14% (35/252) reported that they did not remember any discussion about the side-effects and 1% (2/252) found this information very or quite difficult to understand. More highly educated patients found the information about side-effects to be more understandable than secondary school-educated patients (88% (97/110) versus 77%, (101/132) $P=0.019$).

Sixty-nine per cent (145/210) of the patients reported that the treatment experience corresponded well with the information they had received beforehand. Those 7% (14/210) whose expectations were not at all met often had more side-effects than expected or felt that the information received had been inadequate.

Most patients (76%; 193/253) remembered having received written information while 8% (19/253) reported that no information leaflet was given. Seventy-nine per cent (197/248) of patients remembered having read it while 6% (15/248) did not read it. For 76% (182/238) of those patients that read the leaflet, this information had been easy or quite easy to understand. Better educated patients reported having received information more often (86% (95/110) of patients with higher education versus 69% (92/133) of secondary school educated patients, $P=0.006$) and read it more often (93% (100/108) versus 70% (91/130), $P=0.001$). Age was also associated with receiving and reading of the written information; 83% (60/72) of the patients under 60 years of age, 81% (83/103) of the patients 60–69 years of age and 64% (50/78) of the patients $\geqslant 70$ years of age remembered receiving written information ($P=0.046$). The respective figures for reading it were 85% (63/74), 84% (85/101) and 67% (49/73) ($P=0.008$). More highly educated and younger patients also found the written information more understandable (Table 3). When different educational groups were studied separately, age seemed to be a factor, which moderated the effect of education (the older the age group, the more education influenced the reading and understanding of the written information).

Additional questions prior to randomisation were asked by 67% (166/248) of the patients, and 77% (185/239) were satisfied or partly satisfied with the answers. Seventy-five per cent (55/73) of the patients under 60 years of age asked questions, the respective figures were 71% (72/101) and 53% (39/74) among the patients between 60–69 and $\geqslant 70$ years of age ($P=0.009$); the oldest patients reported most often that they had had nothing to ask (27% (20/74) versus 12% (12/101) and 18% (13/73)). Younger patients were satisfied with the answers that they received significantly more often than patients $\geqslant 70$ years of age ($P=0.006$).

The educational level of the patients also played an important role in this respect 58% (75/130), 77% (72/93) and 80% (12/15) of the patients with secondary school, post-secondary and university education had asked questions, respectively ($P=0.016$); the effects of age were no longer present when the figures were corrected for the different levels of education. Education was not significantly associated with the patient's perception of whether they had received adequate answers.

3.2. Understanding the method of treatment allocation

All patients were aware that they were on a clinical trial. The method of treatment allocation was unclear to most patients: 51% (128/251) thought that the doctor had chosen the treatment while only 23% (57/251) knew that they had been randomised and were also able to explain what randomisation meant. Worryingly, 7% (18/251) thought they had chosen the treatment. Ten

Table 3
Understanding of the written information and its helpfulness in decision making by education and age[a]

	Written information		
	Understandable *n* (%)	Difficult to understand *n* (%)	Do not know *n* (%)
Education of the patient			
Secondary school ($n=122$)	84 (69)	4 (3)	34 (28)
Post-secondary school ($n=94$)	82 (87)	7 (7)	5 (5)
University degree ($n=12$)	11(92)	0	1 (8)
$P=0.001$			
Age of the patient			
<60 years ($n=70$)	61 (87)	2 (3)	7 (10)
60–69 years ($n=97$)	76 (78)	5 (5)	16 (16)
$\geqslant 70$ years ($n=71$)	45 (63)	6 (8)	20 (28)
$P=0.023$			
	Helpfulness in decision making		
	Helpful *n* (%)	Not helpful *n* (%)	Do not know *n* (%)
Education of the patient			
secondary school ($n=120$)	54 (45)	6 (5)	60 (50)
post-secondary school ($n=86$)	63 (73)	8 (9)	15 (17)
university degree ($n=11$)	7 (64)	0	4 (36)
$P=0.001$			
Age of the patient			
<60 years ($n=68$)	40 (59)	8 (12)	20 (29)
60–69 years ($n=93$)	58 (62)	4 (4)	31 (33)
$\geqslant 70$ years ($n=65$)	27 (42)	3 (5)	35 (54)
$P=0.01$			

[a] Total numbers differ due to missing data.

per cent (26/251) thought treatment had been chosen in another way. Younger patients had better understanding of how the treatment allocation had taken place (Table 4).

Nine per cent of the patients spontaneously expressed their feelings of insecurity by describing randomisation as: 'insecure', 'choosing without reason', 'random shooting — and I'm not necessarily one of those hit', 'patient feels like a pawn in the game', 'blind selection', 'making decisions without rational thinking', 'lottery and I don't like it', 'I wonder if I am the random factor in this study', 'luck of the draw', and 'the incidental success of the treatment results, from taking risks'.

Table 4
Understanding the method of treatment allocation by age of the patient

Characteristics	The treatment was chosen by		
	Randomisation *n* (%)	The doctor *n* (%)	Other methods or do not know *n* (%)
Age			
<60 years ($n=75$)	25 (33)	21 (28)	29 (39)
60–69 years ($n=103$)	18 (17)	57 (55)	28 (27)
$\geqslant 70$ years ($n=83$)	14 (17)	50 (60)	19 (23)
$P=0.001$			

3.3. Decision-making

The information provided for decision making was regarded as adequate for decision making by 72% (184/254) of the patients while 15% (37/254) had found it less than adequate and 4% (10/254) very insufficient. Only 1 patient (0.4%) felt the information provided was too much. Age was not associated with this experience.

For 55% (125/226) of the patients written information had been helpful in decision making while 7% (15/226) did not find it helpful and the rest (38%, 86/226) were not able to say. The association of education with the helpfulness of the written information is shown in Table 3. When studying the association between education and the helpfulness of the written information in the different age groups, it was found to be significant in patients $\geqslant 60$ years of age (data not shown).

Sixty-eight per cent (174/255) of the patients thought that they had enough time for decision making while 17 (43/255) would have liked to have more time to consider. The rest (15%; 38/255) did not know. Seventy-six per

cent (84/111) of the more highly educated patients found the time adequate compared with 63% (84/134) of those with a secondary school education ($P=0.029$). Patients $\geqslant 70$ years of age needed more time for decision making ($P=0.02$). 57% (44/77) found the time adequate compared with 69% (52/75) and 76% (78/103) for patients under 60 years of age and 60–69 years of age, respectively.

Only 3% (7/261) of the patients had felt pressure to participate. Eighty-five per cent (223/261) had felt free to decide about their participation independently. Only 3% (7/261) thought that they were left too much alone with the decision. Ninety-six per cent (72/75) of those under 60 years of age had felt free to decide independently, the respective numbers being 83% (86/103) and 78% (65/83) among the patients aged 60–69 and $\geqslant 70$ years of age ($P=0.005$).

Education played a smaller role: 91% (102/112) of the more highly educated patients had felt free to decide independently compared with 81% (112/138) of the secondary school educated patients ($P=0.03$). Only 12% (32/261) of the patients wished the doctor to decide for them.

When the patients were asked how much they had influenced the decision, 63% (156/247) stated a lot and 23% (56/247) to some degree. Only 4% (9/247) felt that they had hardly or no influence. Seventy-three per cent (55/75) of those under 60 years of age stated that they had a lot of influence on the decision, the respective figures were 65% (64/99) and 51% (37/73) among those aged 60–69 and $\geqslant 70$ years ($P=0.016$). Education played an even more important role: 74% (80/108) among more highly educated and 56% (73/130) of the secondary school educated patients reported that they had a lot of influence on the decision ($P=0.004$). Among those younger than 60 years of age, the more highly educated felt more often that they had a greater influence on the decision to participate.

3.4. The reasons to enrol and the interests of the patients when offered participation in a clinical trial

Major reasons for participation were to benefit future patients (62%, 162/261) and to gain personal satisfaction (39%; 101/261). Sixty per cent (157/261) desired a more effective follow-up. Better continuity of care was also important for many patients: 42% (110/261) expected to see the same doctor more often and for 38% (100/261) it was important that the follow-up would take place in the same hospital as the treatment.

Nearly all (87%; 218/251) patients were happy with their decision to participate and would enrol again. Motivation for future participation was identical with the previous one. Often the reasons were also related to the treatment experience like 'more effective treatment', 'more careful follow-up', 'seeing the same doctor, opportunity for more confident discussions', 'having hope', as well as to altruistic justifications like 'benefiting

Table 5
The interests of the patients when offered participation in a clinical trial. Needs related to information and communication, and attributes referring to personnel ($n=180$)

	Patients mentioning this aspect *n* (%)
Information	
Trial (aim, structure, investigations, etc.)	45 (25)
Side-effects of the treatment	42 (23)
Cost and benefit	27 (15)
The importance of the trial for future patients	19 (11)
Results of the treatment so far	14 (8)
Treatment alternatives	14 (8)
Information that treatment is good in all arms	15 (8)
Written information	10 (6)
Extra financial and time burden	4 (2)
Possibility of stopping	4 (2)
Communication	
Clarity of the explanation (no jargon)	40 (22)
Unhurried discussion (possibility to ask questions, equality, ensuring that the patient understands)	28 (16)
Psychological support, hope, security	14 (8)
Good communication with the doctor	14 (8)
Enough time to consider	12 (7)
Attributes referring to doctors and nurses	
Honesty, openness	18 (10)
Humane qualities (kindness, understanding, warmth, caring)	10 (6)
Calmness	8 (4)
Possession of comprehensive knowledge	7 (4)

future patients like my own daughters and grand daughters'. Only 2% (4/251) reported that they would decline and 12% (29/251) were not sure what their decision would be. The main reason was the side-effects they had suffered.

In response to the question about how they would wish to decide about participation in a clinical trial, the majority (71%; 179/251) wanted to decide about participation together with their doctor. Fourteen per cent (35/251) wanted to make the decision independently and 6% (16/251) preferred the doctor to decide for them. The answers were not significantly associated with age or education.

Answers to the open question on factors considered important when offered participation in a trial were grouped and classified: those related to information and communication, and to attributes referring to personnel are listed in Table 5.

4. Discussion

It is essential that patients participate in the process of deciding whether they should be included in a clinical trial. In addition to knowing about the process of randomisation, the patient should know about all treatment options, their likely efficacy and side-effects [2].

Our clinical experience and previous studies have suggested that this 'gold-standard' of true informed consent is difficult to achieve [3]. In the present study, we investigated the quality of informed consent in a randomised trial of adjuvant hormonal therapy for breast cancer with the goal of improving the informed consent process. Our study is descriptive and gives new information about weak points in the information and communication procedure.

The high response rate to the questionnaire (87%) as well as the high rate of agreement to participate in the trial allows us to generalise our results to postmenopausal patients treated by investigational adjuvant breast cancer protocols during the study period. However, we are aware that the information related to the well-tolerated treatment by oral anti-oestrogens in our study, may have been easier to understand than information about more complex and toxic treatments such as high-dose chemotherapy. The discussion about the treatment decision is emotionally important and it is probable that most patients were able to recall the discussions about the trial when completing the questionnaire nearly a year later. Although some selective loss of memory may have occurred, there is likely to be a correlation between recall and understanding as has been shown in the psychological literature.

Most patients regarded the information about the trial as easy or quite easy to understand. This is consistent with previous studies [6,7]. Two-thirds (69%) also reported that their experiences of treatment were as anticipated, which provides one measure of the success of information that was provided.

Written information was helpful in the decision-making process for only approximately half of the patients. This is consistent with a previous study, which showed that patients had better memory for information provided by their physician compared with any written information [7]. The combination of oral and written information has been shown to be most effective [12]. In the present study, the understanding and helpfulness of the written information correlated significantly with the age and education of the patient suggesting that the text was too complicated for older and less educated patients. The written information sheet consisted of 11/2 single-spaced pages written in quite complicated language according to the judgement of the Research Institute for the Language of Finland. It has been shown previously that consent forms are often written at a level that is too difficult for most patients to read or understand [13–16]. It is, therefore, not surprising that better educated and younger patients, who are more familiar with written information, read the leaflet more often in our study.

Younger and better educated patients took a more active role in communication: they asked more questions and younger patients also received satisfactory answers more often. This has also been shown in a previous study based on the analysis of audio-visual recordings of physician–patient consultations [17]. Bochner has argued that more educated patients are more active in communication because they are less 'culturally distant' from the doctor and thus experience fewer difficulties when interacting with physicians [18].

The method of treatment allocation proved to be unclear to most patients. Many doctors who randomise patients in clinical trials may believe that total disclosure is not always in the patient's best interest [19,20]. Doctors may also be sceptical of the patients' ability to comprehend the study design [6]. In a study which examined the standard of consent used by investigators in European randomised clinical trials, 38% of clinicians reported that they did not always tell patients that they had been assigned to their treatment randomly [21]. However, in the present study the most frequent needs of the patients were information about the trial, its aim, structure, nature of treatments and side-effects, and clarity and intelligibility of the explanation.

In the present study, randomisation was described in the information leaflet as follows: 'The medicine you will be given has been randomly chosen'. Of course, there will be individual variation among physicians as to how they amplify and illustrate this concept verbally with individual patients. However, our purpose was to identify the net effect of this information on the understanding of patients in a real trial setting. In the study of White and colleagues two-thirds or more patients

remained unaware that the best treatment is unknown, even though this point was included in the forms [10]. Education and age have been analysed previously as predictive variables for the effectiveness of communication in the context of a clinical trial only in one small study, where survivors of myocardial infarction were interviewed 2 weeks to 15 months after joining the trial [22]. These results also suggested that age and education were associated with the degree of awareness of the fundamental aspects of the trial.

The literature suggests that providing more information about a trial can lead to a better understanding of the concept of randomisation [22–25]. Aaronson and colleagues showed that the fundamental aspects of a trial were understood significantly better by those receiving a supplementary interview with a nurse [11].

The spontaneous interpretations of randomisation of some patients like 'lottery and I don't like it' reveal that the patients had not known that treatment allocation was to one of two alternatives considered to be among the best available treatments. Telling the patient that the treatments are pretested and good alternatives in all arms is very important to create security and confidence.

Less educated and older patients needed more time for decision making. It has been reported previously that doctors typically spend more time with, and give more information to, patients perceived to be from higher socio-economic backgrounds [26]. This is in contrast with the needs of less educated patients who may need more time to understand the various aspects of the trial and to make their decision.

Patients made a distinction between the way information should be provided and the content of information disclosure. Intelligible information about the trial, about side-effects of the treatments, about the cost and benefits and treatment alternatives was requested most often, as well as the current results obtained using the treatments. These requirements have also been described by Slevin and colleagues [27]. In the present study many patients emphasised the need for unhurried discussion and time to consider the decision.

A remarkable amount of time and effort is put into the design of a research protocol and to make the study function in practice, but very little attention is paid to the randomisation procedure and the communication skills of the doctors who recruit patients to the trial. In a study undertaken by Albrecht and colleagues there was strong evidence indicating that patients were more likely to participate in a trial when their physician behaved in a reflective, patient-centred, supportive and responsive manner [28]. Teaching doctors the best ways of informing patients and helping them deal with the emotional burden of such an approach results in a better informed patient [29].

Although not all participants will recall detailed aspects of a trial, the quality of informed consent would be improved if clinicians who recruit them used more time and adjusted their language according to the patient. Communication should be modified, especially for older and less-educated patients. More research is needed to determine the optimal way of informing these patients.

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