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Results of an intervention study to improve communication about randomised clinical trials of cancer therapy

A. Fleissig, V. Jenkins *, L. Fallowfield

CRC Psychosocial Oncology Group, Department of Oncology, Royal Free and University College London Medical School, 3rd Floor, Bland Sutton Institute, 48 Riding House Street, London W1P 7PL, UK

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Abstract

We report results from an intervention study to improve communication during consultations about randomised clinical trials of cancer therapy. Patients, eligible for a trial, completed questionnaires about information preferences and attitudes to trials prior to seeing their doctors, who were either shown these questionnaires (intervention) or not (control). Fifteen doctors participated and invited 265 patients to join one of 40 different randomised clinical trials. Most patients (77.4%) agreed to trial entry and this was predicted by the Patient's Attitudes to Trials questionnaire with an 80.4% accuracy. Accrual, length of consultation, doctor and patient satisfaction were not associated with the intervention. Further research to explore the potential use of written interventions to facilitate communication and accrual to randomised clinical trials is recommended.

Keywords: Neoplasms; Randomised clinical trials; Informed consent; Communication; Physician–patient relations

1. Introduction

Research findings suggest the information given to patients invited to join trials is often inadequate or ineffectively communicated [1–4]. Doctors can also be reluctant about broaching the subject of clinical trials with eligible patients [5,6]. Explaining randomisation and obtaining informed consent have been acknowledged as primary problem areas by oncologists attending communication training courses [7].

Deciding how much information to give to patients for consent to be truly informed is controversial [8–10], especially as patients with cancer can have widely differing preferences for both the type and format of information received regarding prognosis and therapy [11]. British oncologists claim they allow patient reaction to influence the content of information given when obtaining informed consent to clinical trials [5], yet many doctors have styles of communication that are largely unaffected by their patients' characteristics [12]. The challenge is to develop ways to meet individual needs [11,13,14], at the same time as ensuring all prospective clinical trial participants are given adequate information, as recommended in the Helsinki Declaration of 1964 [15].

A few studies have investigated the outcomes of different approaches to seeking consent. In one study, patients were randomised either to total disclosure of all possible relevant information or to an individual approach at the discretion of each doctor [16]. Patients in the total disclosure group had a greater understanding of their treatment and of the research aspects of the trial, but at the expense of increased anxiety. The individual approach was based on the doctors' intuition as to what patients wanted. However, it is often difficult for doctors to assess how much detail to disclose as patients may not express their needs for information and explanation [17].

This paper describes a study in which doctors were shown the information requirements and attitudes to trials questionnaires of half their patients prior to discussions about trial entry. It was hoped that these stated preferences would help doctors to discuss specific concerns early on in the consultation. Previous work demonstrated that the Patient Preferences for Information Questionnaire discriminates the amount of

* Corresponding author. Tel.: +44-20-7504-9293; fax: +44-20-7636-6151.

E-mail address: v.a.jenkins@ucl.ac.uk (V. Jenkins).

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information patients require about their cancer and treatment [18,19] and the Patients' Attitudes to Trials Questionnaire distinguishes amongst: patients who are comfortable with the concept of randomisation, those who have some concerns, and those firmly against participation in randomised trials [20].

It was hypothesised that providing the doctors with the patient questionnaires prior to a discussion about trial participation would: increase patient and doctor satisfaction, improve recruitment and reduce consultation time. A secondary aim of the study was to examine the validity of the Patients' Attitudes to Trials Questionnaire as a predictor of patient behaviour.

Although doctors in the intervention group were expected to provide information according to individual preferences, patients would not be misinformed or denied any information that they subsequently requested. The study had the approval of the Trent Multi-Regional Ethic Committee and Local Ethics Committees of participating hospitals.

2. Patients and methods

2.1. Study design

Doctors at District General and University Teaching Hospitals involved in an earlier phase of the study were invited to participate. The aim was to recruit at least 20 doctors and 20 eligible trial patients per doctor. All patients completed questionnaires about information preferences and attitudes to trials prior to discussion about trial entry, but only half (those completed by the intervention group) were shown to the doctors. To detect any learning effects, doctors were randomised into two groups (A or B), which varied the order of intervention and control group consultations:

Consultations:	Group A	Group B
1–5	Control	Control
6–10	Control	Intervention
11–15	Intervention	Intervention
16–20	Intervention	Control

2.2. Clinic procedure

Clinic staff identified patients with cancer (aged 16 years or older) eligible for a randomised clinical trial (RCT). These patients were invited to participate in a communication study and given an information sheet to read before they gave written consent. (The information sheet described what involvement was required from the patient should he or she decide to participate and also that the focus was on how doctors explain different treatments.) Prior to their consultation, which was audiotaped, participants completed: the Patient Preferences for Information Questionnaire and Patient Attitudes to Trials Questionnaire and the Spielberger State Trait Anxiety Inventory [21] to evaluate anxiety proneness. After the consultation, two questionnaires were given to be returned by post: a 17-item questionnaire primarily addressing satisfaction with doctor–patient interaction, adapted from the Medical Outcomes Study PSQIII [22], and a 16-item questionnaire describing reasons for accepting or declining treatment within a clinical trial, based on the work of Penman and colleagues [3]. After each consultation, doctors assessed the interview and rated patient distress using visual analogue scales.

2.3. Analysis

The audiotapes of the consultations were timed and assessed against a grid matrix devised for a preliminary analysis of the main items covered [23], to check whether doctors altered their consent procedure. Thirty randomly selected tapes were rated again by an independent assessor, who did not know whether or not the patients' questionnaires had been shown to the doctor.

For doctors in group B, the control group consultations carried out before (26/55) the intervention group consultations and afterwards (29/55) were compared. Length of consultation (18.5 min versus 16.3 min, $t = 0.91$, degrees of freedom (df) = 49, $P = 0.368$) and the items covered were similar, so data from all the control group consultations were combined in the analyses and contrasted with the intervention group data. Questionnaire data were analysed using Statistical Package for the Social Sciences (SPSS) and attention was drawn to differences which were significant at the 5% level or less. The numbers on which percentages are based vary because missing or inadequate data have been excluded.

3. Results

3.1. Recruitment and response rate

Of the 43 doctors invited, 27 initially agreed to participate but 12 withdrew before conducting any intervention consultations (three changed teams and nine saw insufficient out-patients eligible for RCTs to make data collection feasible). Thus, data were collected from the consultations of 15 self-selected doctors (eight clinical/radiation oncologists, six medical oncologists and one surgeon). 10 of the doctors were male and five were female. Although the group was self-selected, there did not appear to be any obvious differences between the doctors who participated and those who did not, according to sex, seniority or specialty. Of the 16 who were not interested in participating, all were consultants

(nine male and seven female) employed in University Teaching Hospitals (two surgeons, six clinical/radiation oncologists, two medical oncologists) and District General Hospitals (two surgeons, four clinical/radiation oncologists).

Patients were recruited between April 1997 and February 2000. The aim was to recruit 20 patients per doctor, but only 15 were recruited from one of the medical oncologists before she took maternity leave. Recruitment from clinics was time-consuming, with a maximum of 5 eligible patients recruited at a single session. The length of time it took to recruit 20 patients per doctor varied from 6 to 18 months. Amongst the patients who were approached, 9.2% (30/325) declined to take part. The most common reasons given for non-participation were a lack of English, poor eye-sight and concerned relatives. Of the 295 patients who agreed to participate, 30 did not return their postal questionnaires following the consultation.

3.2. Patient characteristics

The patients in the control and intervention groups were well matched for age, gender, marital status, trait anxiety, site of cancer and previous participation in clinical trials (Table 1). Participants' ages ranged from 19 to 83 years. Nearly three-quarters of the participants were female, the majority of whom were aged between 45 and 64 years. Over three-quarters of the female patients had breast cancer. Amongst males the most common cancer was testicular cancer. Only 10.6% (28/265) of patients had taken part in clinical trials previously and almost all (26/28) were female. Trait anxiety scores were similar to the published norms (21); only 16.5% (43/261) had high scores (trait anxiety >44). There was a weak correlation between a patient's trait anxiety score and the doctor's assessment of patient distress during the consultation ($r=0.27$, $P<0.001$). Assessment of patient distress did not differ between patients in the control group (mean rating = 2.3 out of 10) and the intervention group (mean rating = 1.9 out of 10).

3.3. Trial characteristics

The study included 40 trials involving different types of treatment (chemotherapy, radiotherapy, endocrine treatment and immunotherapy) or different screening regimens (Table 2). Two thirds (27/40; 68%) of the trials involved chemotherapy and these were offered to 57.0% of patients (60.8% (79/130) control, 53.3% (72/135) intervention). Twenty-three trials (discussed with 89.8% (238/265) of the patients) were offered to participants in both the control and intervention groups. The toxicity and side-effects of treatments and the differences between treatment arms varied considerably. Thirteen trials (involving 106/265; 40.0% of patients) included an inactive (placebo or 'no treatment') arm.

Table 1
Characteristics of participants

	Total ($n=265$) *n* (%)	Control ($n=130$) *n* (%)	Intervention ($n=135$) *n* (%)
Age (years)			
26–44 (range: 19–44 years)	44 (16.6)	26 (20.0)	18 (13.3)
45–64	143 (54.0)	65 (50.0)	78 (57.8)
65 or more	78 (29.4)	39 (30.0)	39 (28.9)
Gender			
Male	74 (27.9)	36 (27.7)	38 (28.1)
Female	191 (72.1)	94 (72.3)	97 (71.9)
Marital status			
Married/cohabiting	207 (78.4)	99 (76.2)	108 (80.0)
Other	57 (21.6)	31 (23.8)	26 (19.3)
Cancer site			
Breast	146 (55.1)	70 (53.8)	76 (56.3)
Ovary	36 (13.6)	21 (16.2)	15 (11.1)
Testicular	29 (10.9)	14 (10.8)	15 (11.1)
Prostate	20 (7.6)	10 (7.7)	10 (7.4)
Colorectal	14 (5.3)	9 (6.9)	5 (3.7)
Lung	8 (3.0)	3 (2.3)	5 (3.7)
Other	12 (4.5)	3 (2.3)	9 (6.7)
In a previous clinical trial			
Yes	28 (10.6)	15 (11.5)	13 (9.6)
No	237 (89.4)	115 (88.5)	122 (90.4)
Trait anxiety (min = 20, max = 80)	$n=261$	$n=128$	$n=133$
Mean ±standard deviation (S.D.)	35.9±9.66	36.0±9.71	35.8±9.66

Table 2
Trials involved in the study

Cancer site	Trials	Treatment modality	Inactive treatment/ placebo arm	No. doctors	No. patients total (control, intervention)
Breast	ATAC	Endocrine		7	33 (20,13)
	ABC	Chemotherapy	✓	6	26 (15,11)
	aTTom	Endocrine	✓	5	24 (8,16)
	ANGLO-CELTIC	Chemotherapy		4	18 (11,7)
	START	Radiotherapy		2	17 (5,12)
	NEAT	Chemotherapy		4	9 (5,4)
	AB01	Chemotherapy		3	6 (1,5)
	BASOII	Radiotherapy/endocrine	✓	2	5 (3,2)
	THERATROPE	Immunotherapy vaccine	✓	1	5 (2,3)
	STRONTIUM	Injection of radioactive compound		1	2 (2,0)
	TOPIC2	Chemotherapy		1	2 (0,2)
	FEMERA	Endocrine		1	1 (0,1)
	EXEMASTENE	Endocrine		1	2 (0,2)
	13			10	146[a]
Ovary	OV05	Chemotherapy (based on elevated CA 125 levels versus conventional clinical indicators)	✓	2	10 (5,5)
	ICON3	Chemotherapy		2	8 (4,4)
	CARBOMARIMASTAT	Chemotherapy		2	5 (4,1)
	ICON4	Chemotherapy		3	4 (2,2)
	SCOTROC	Chemotherapy		2	3 (2,1)
	TCAOVARY	Chemotherapy (choice based on additional information from tissue sampling versus standard)		1	3 (2,1)
	CAELYX	Chemotherapy		2	2 (2,0)
	ICON1	Chemotherapy	✓	1	1 (0,1)
	8			8	36
Testicular	TE19	Chemotherapy versus radiotherapy		5	23 (11,12)
	TE20	Chemotherapy		1	4 (2,2)
	TE08	Different CT scan surveillance schedules		1	2 (1,1)
	3			5	29
Prostate	CASODEX	Endocrine	✓	1	20 (10,10)
	1			1	20
Colorectal	QUASAR	Chemotherapy	✓	4	6 (3,3)
	CR06	Chemotherapy		3	4 (4,0)
	PANOREX	Chemotherapy		2	2 (1,1)
	CR05	Chemotherapy		1	1 (0,1)
	CEAVAC	Immunotherapy	✓	1	1 (1,0)
	5			7	14
Lung	BLT	Chemotherapy	✓	3	5 (3,2)
	MARIMASTAT	Chemotherapy		1	1 (0,1)
	TAX317	Chemotherapy	✓	1	1 (0,1)
	AGURON	Chemotherapy		1	1 (0,1)
	4			3	8
Bladder	BS06	Radiotherapy		1	4 (1,3)
	1			1	4
Pancreas	GENMAR	Chemotherapy		1	4 (0,4)
	1			1	4
Lymphoma	60PLUS	Chemotherapy		1	1 (1,0)
	LY07	Chemotherapy and radiotherapy (versus standard radiotherapy)		1	1 (0,1)
	2			2	2
Melanoma	AIM High	Immunotherapy	✓	1	1 (0,1)
	EORTC18951	Chemotherapy	✓	1	1 (1,0)
	2			1	2

CT, computed tomography.
[a] 4 patients were asked to join more than one trial: ABC and START (3), ABC and NEAT (1).

Table 3
Specific information requirements

Would like to have information on: (absolutely need/would like to have)	Total ($n=261$–265) n (%)	Control ($n=127$–130) n (%)	Intervention ($n=131$–135) n (%)
The likelihood (in percentage terms) that the treatment offered would cure you completely	259 (97.7)	126 (96.9)	133 (98.5)
Whether the treatment offered would control, but not cure the disease	258 (97.4)	127 (97.7)	131 (97.0)
Whether the treatment offered would reduce the symptoms, but not control the disease	256 (96.6)	124 (95.3)	132 (97.8)
All the possible treatments that are available	264 (99.6)	129 (99.2)	135 (100.0)
All the possible side-effects of the treatment	251 (94.7)	124 (95.4)	127 (94.1)
Exactly how the treatment works to treat the illness	258 (97.3)	125 (96.2)	133 (98.5)
The research evidence that the treatment being offered works	260 (98.1)	128 (98.5)	132 (97.8)

Following the consultation with the clinician, 40.8% (108/264) of patients were given additional information about the trial by another health professional, for example a trial co-ordinator, research or breast care nurse. At some clinics, the involvement of another health professional depended on which trial a patient was asked to join, at some clinics patients only discussed trial entry with a doctor and at others patients always saw a research nurse or trial co-ordinator as well.

The numbers of patients and doctors involved in each trial varied considerably (Table 2); for example one doctor discussed 11 different trials with patients during the study, whereas another only discussed one particular trial for prostate cancer with all patients. Eleven trials were only offered by one doctor to 1 patient. Women with breast cancer, the most common group in the study, were recruited from 10 different doctors (two were breast cancer specialists) who discussed 13 different breast cancer trials.

3.4. Patient information needs

Most patients (87.1%; $n=230/264$, date missing for 1) preferred to have all possible information about their diagnosis and treatment, 11% ($n=29$) wanted as much or as little information as the doctor thought necessary and 1.9% ($n=5$) wanted to have only good information. These preferences for information were not associated with age, gender or consultation group, but patients who wanted 'as much information as possible, good and bad', were less prone to anxiety than the others (mean trait anxiety of 35.31 compared with 40.0, $t=2.63$, $df=258$, $P=0.009$ (95% confidence interval (CI) 1.180–8.194). Participants were asked seven further questions about specific information requirements (Table 3). The vast majority of patients said they would want to know all the details listed, including 24 of the 34 who stated earlier that they wanted the doctor to use discretion or only to have good information, and there were no significant differences between patients in the control and intervention groups.

3.5. Patients' attitudes to trials

Most participants thought patients should be asked to take part in medical research and over two-thirds said they would be prepared to take part in a study comparing different treatments, but this proportion decreased to approximately a third if treatment was to be chosen at random (Table 4). Patients with previous trial experience were more likely to say they would agree to participate in a randomised study than the others (57.1% (16/28) compared with 32.1% (76/237), $\chi^2=6.95$, $df=1$, $P=0.008$).

The participants who were initially unwilling or unsure about whether they would agree to participate in a randomised study were asked further questions (Table 4). Under certain conditions (i.e. knowing that either treatment would be completely suitable, that they could leave the study if treatment did not suit them and that there would be plenty of information before the choice was made), 68.1% (62/91) of those who initially said no and 72.8% (59/81) of those who were initially unsure (data missing for 1) said they would agree to participate in a randomised trial. Taking these participants into account, 80.7% (213/264 (101 control, 112 intervention)) would be prepared to take part in a randomised trial, 13.3% (35/264 (20 control, 15 intervention)) were unsure and 6.1% (16/264 (8 control, 8 intervention)) would not agree to participate.

3.6. Participation in trials

Questionnaires completed after the consultation showed that over three-quarters (77.4%; $n=205$) agreed to enter the randomised trials in which they were asked to participate in, 20% ($n=53$) declined and 2.6% ($n=7$) did not know. A decision to participate was not significantly associated with whether or not the doctor had been given the patient's questionnaires (73.8% ($n=96$) of control group accepted and 80.7% ($n=109$) of intervention group accepted, $\chi^2=2.566$, $df=3$, $P=0.463$). Trial participation was not associated with age or gen-

Table 4
Patients' attitudes to trials

Attitudes to trials — 3 preliminary questions for all participants ($n=265$):	Yes n (%)	No n (%)	Do not know n (%)
1. Do you think that patients should be asked to take part in medical research?	244 (92.1)	3 (1.1)	18 (6.8)
2. Suppose that you were asked to take part in a research study comparing two treatments both of which were suitable for your illness. Would you be prepared to take part in a study comparing different treatments?	183 (69.1)	14 (5.3)	68 (25.7)
3. Usually the only way to compare one treatment with another is for the choice between the two to be made randomly, rather like tossing a coin. Would you be prepared to take part in a study where treatment was chosen at random?	92 (34.7)	92 (34.7)	81 (30.6)
Patients ($n=173$) who were not prepared to take part in a randomised study at question 3 were asked further questions:	Yes n (%)	No n (%)	Do not know n (%)
4. 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. Would knowing that encourage you to take part?	97 (56.6)	27 (15.6)	48 (27.7)
5. 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. Would that encourage you to take part?	118 (68.8)	22 (12.7)	32 (18.5)
6. 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. Would that encourage you to take part?	123 (71.7)	17 (9.8)	32 (18.5)
7. 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. Would all these things together mean that you would change your mind and agree to take part?	121 (70.3)	16 (9.3)	35 (20.3)

der, but it was associated with the type of treatments involved in the trial. Patients were less likely to agree to participate in chemotherapy trials which involved a 'no treatment' arm than the other trials (55.6% (25/45) versus 85.6% (178/208) $\chi^2=21.0$, df = 1, $P<0.001$, (excludes 12 patients (8 did not know if agreed, 2 were offered more than one trial, 2 were offered screening not a treatment trial)).

Table 5 shows the reasons patients gave for accepting or declining trials. There were differences between the acceptors and decliners which are discussed elsewhere [24], but the factors that influenced patients' decisions about trial entry were not associated with whether they were in the control or intervention groups and almost all patients agreed with the statement 'the doctor told me what I needed to know about the trial'.

Responses to the Patient Attitudes to Trials Questionnaire were compared with the patients' actual decisions about trial participation. 83.1% (79.2% (80/101) control, 86.6% (97/112) intervention) of the patients who said they would participate in a randomised trial on the attitude questionnaire joined the specific trial offered to them, 30 (18 control, 12 intervention) declined and 6 (3 control, 3 intervention) did not know. Just under half (7/16) of those who said they would decline to be part of a randomised study on the attitude questionnaire did decline, but the other 9 changed their minds (5 in the control group and 4 in the intervention group) and accepted the randomised trial discussed with them. Approximately half the patients (10/20 control, 8/15 intervention) who were unsure on the attitude questionnaire participated in a randomised trial, approximately half declined (9/20 control, 7/15 intervention) and the remaining patient was still undecided. Thus, excluding the 35 'unsure patients', the attitude questionnaire predicted the behaviour of participants (whether or not they would agree to take part in a randomised study) with 80.4% accuracy (true acceptors and true decliners as a proportion of all results).

3.7. Satisfaction with the consultation

Most patients were highly satisfied with their consultation, even though approximately a third said they had waited too long in the clinic beforehand (Table 6). Few patients criticised the communication skills of the doctor, yet approximately 1 in 6 patients felt unclear about some of the things they had been told by the

Table 5
Reasons for accepting or declining trials. Proportion of respondents in control and intervention groups who agreed with statements about clinical trials[a]

Statement: agreed (strongly/to some extent)	Acceptors		Decliners	
	Control % (n=91–94)	Intervention % (n=105–108)	Control % (n=25–27)	Intervention % (n=22–23)
I was satisfied that either treatment in the study/trial would be suitable for me	85.1	83.0	11.1	13.6
I thought the trial/study offered the best treatment available	83.0	79.6	7.4	17.4
I wanted to help with the doctors' research	94.7	95.4	44.4	47.8
I believed benefits of treatment in trial/study would outweigh any side-effects	73.9	80.6	11.1	13.0
I feel that others with my illness will benefit from the results of the trial	98.9	98.1	61.5	60.9
Others, e.g. family/friend wanted me to join the trial/study	50.5	46.7	3.8	8.7
I wanted the doctor to choose my treatment rather than be randomised by computer	51.6	42.6	77.8	69.6
The idea of randomisation worried me	37.2	40.7	59.3	65.2
I was given enough information to read about the trial study	87.1	83.2	69.2	63.6
I knew I could leave the trial/study at any time and still be treated	98.9	99.1	88.9	95.7
The doctor told me what I needed to know about the trial	94.7	98.1	88.0	91.3
The doctor wanted me to join the trial/study	50.0	49.5	33.3	43.5
I trusted the doctor treating me	97.9	100	96.3	95.7
I did not feel able to say no	10.6	9.3	18.5	13.6
I was worried that my illness would get worse unless I joined the trial/study	13.8	15.7	11.1	13.0
I was given too much information to read about the trial/study	8.5	9.4	7.7	13.6

[a] Number who responded varies as 13 participants were excluded (5 did not fill questionnaire adequately, 8 did not know if they were on a trial) and 23 others missed occasional items.

doctor. There were no significant differences in satisfaction associated with consultation group (control versus intervention).

The small proportion of participants with a high trait anxiety score (>44) were generally as satisfied as the others, although there was a difference on one of the 17 items; 10% (4/40) of the patients with high anxiety scores said they disagreed with the statement 'The doctor told me what I wanted to know' compared with 2.8% (6/216) of the others ($\chi^2=4.69$, df=1, $P=0.03$). There were too few patients with high anxiety scores to examine the differences associated with consultation group.

In general, doctors were highly satisfied with their consultations. There was no association between the doctors' ratings of the consultation and whether they had seen patients' questionnaires. The average rating for control group consultations was 7.8 out of 10 (range

Table 6
Patient dissatisfaction with the consultation

Negative statements: % agreed: strongly/to some extent	Total % (n=259–262)	Control % (n=128–129)	Intervention % (n=131–132)
The doctor seemed to lack experience	2.3	3.9	0.8
The doctor was too impersonal/businesslike	8.0	6.2	9.8
I felt doctor would be irritated if I asked too many questions	5.0	3.9	6.1
The doctor used medical terms that I didn't understand	4.2	3.9	4.5
The doctor made me feel awkward	1.9	1.6	2.3
More attention should have been paid to my privacy	1.9	0.8	3.1
I feel unclear about some of the things the doctor told me	16.2	19.5	13.0
The doctor I saw could have been more respectful	1.9	2.3	1.5
I waited too long in the clinic before seeing a doctor	31.7	33.1	30.3
Positive statements: % disagreed: strongly/to some extent	**Total % (n=258–262)**	**Control % (n=127–130)**	**Intervention % (n=131–132)**
I am satisfied with the medical treatment I received today	2.3	2.3	2.3
I felt the doctor told me all there was to know	4.2	5.4	3.0
In general I felt the doctor handled the consultation well	3.4	5.4	1.5
The doctor told me what I wanted to know	3.9	4.7	3.1
The doctor I saw seemed sympathetic	4.6	5.4	3.8
The doctor did his/her best to keep me from worrying	5.4	5.4	5.3
The doctor answered all my questions	1.6	1.6	1.5
The doctor seemed to know what he/she was doing	2.7	1.6	3.8

between 2.5 and 10) and the average for intervention group consultations was 8.1 (range between 1.6 and 10) ($t = -1.26$, df = 263, $P = 0.21$, 95% CI −0.684, 0.151). Patients' age, gender, trait anxiety and whether they agreed to take part in the trial were not associated with the doctors' ratings of the consultation, but ratings varied between doctors (their average ratings ranged from 6.4 to 9.6, F ratio = 8.6, df = 14, $P < 0.001$).

3.8. Length of consultation

The majority of consultations were audiotaped (91.5% (119/130 including 1 of poor quality) control, 93.3% (126/135) intervention). Most consultations (64.1% 157/245) lasted 15 min or less (range: 15–30 min), 32.2% (79/245) were between 16 and 30 min and 3.7% (9/245) took longer than 30 min. Consultation times varied between doctors, the average duration per doctor ranged from 3.4 to 25.8 min (F ratio = 13.15, df = 14, $P < 0.001$). Length of consultation was not associated with whether the doctor had been given the patient's questionnaires to read (average consultation time was 14.7 min for control group (range: 2–38 min) versus 13.9 min for intervention group (range: 1–35 min)). Patients who later discussed the trial with another health professional (e.g. research nurse or trial co-ordinator) spent a similar amount of time with the doctor as the others (average of 13.9 min (range: 1–37 min) compared with 14.6 min (range: 3–38 min)).

3.9. Use of the patient preference questionnaires during the intervention group consultations

In the random sample of consultations assessed by the independent researcher, none of the doctors in the intervention group consultations (16 out of 30) referred to patients' preferences when giving information and it was not possible to tell which group patients were in from the content of the consultation. This reflected the use of the questionnaires in the entire study as the patient questionnaires were referred to by only a third of the doctors in approximately a fifth (28/126) of the audiotaped intervention group consultations. Doctors varied in the way they used the questionnaires, but this was not associated with the personal and clinical characteristics of the patients or their information preferences and attitudes to trials. Although they may have read through their patients' responses, five doctors (four medical oncologists and one clinical oncologist) never discussed patients' questionnaires with them during consultations. Of the other 10, five only mentioned the questionnaires briefly in a few consultations. Five doctors discussed patients' answers in more depth, but most did this occasionally. Only one doctor always referred to the patient preference questionnaires during the intervention group consultations ($n = 8$) and went through each response in detail, tailoring the information given to meet the patients' requirements. Length of consultation was not related to whether the questionnaires were discussed openly.

4. Discussion

Providing doctors with their patients' information requirements and attitudes to trials questionnaires, did not have a measurable impact on their consultation style or outcome. Similar proportions of patients agreed to take part in randomised controlled trials in both the intervention and control groups. Length of consultation and doctor and patient satisfaction were not associated with whether or not doctors had been given their patients' questionnaires beforehand. There are a number of possible explanations for these findings which are explored below. Ideas for further research using patient questionnaires to prompt discussion are also discussed.

When doctors were given patient questionnaires, they rarely referred to them during the consultation. Indeed, most doctors adopted an idiosyncratic style of communication when discussing trial entry with patients [23] and it may have been difficult for them to deviate from these patterns of explanation. Alternatively, they may not have wanted to change their standard method of explanation because the use of a routine helped to ensure all the details were covered. The intervention might have a greater effect if doctors are given guidelines or a workshop on how to use the questionnaires within the consultation to facilitate discussion.

A formal evaluation of the doctors' views about the intervention was not performed; for example, whether or not they found the additional information from the questionnaires useful, or if they thought they altered their behaviour as a result. However, anecdotal comments suggest the information about their patients' preferences for information and attitudes towards participating in research trials did have a positive effect. One doctor said she felt more confident and found it easier to broach the subject after reading patients' questionnaires.

The success of the intervention depended in part on the capacity of the questionnaires to discriminate between patients, to enable doctors to tailor the amount of explanation given. Although the Preferences for Information Questionnaire did not distinguish between patients, the responses were useful in reinforcing the message to the doctors, that most patients with cancer want specific details about their illness and treatment.

In contrast, the Patient Attitudes to Trials Questionnaire was effective in differentiating between patients. The questionnaire concerned views about research and trials in general, but was accurate in predicting which patients would take up the specific trials they were offered. These findings confirm the validity of the instrument. Doctors who find it particularly difficult

to broach the subject of clinical trials, might find it a helpful tool to use to approach patients. One way to increase the questionnaire's potential for facilitating the exchange of information, would be to provide space for patients to write down any additional individual concerns and questions they have about randomisation or participating in a research trial (c.f. question prompt sheets used in other studies [25,26]).

Recruitment to the study was very time-consuming and slower than anticipated by the doctors participating. This may be because they overestimated the numbers they recruited [27], or included discussions by all members of the team and the recruitment of in-patients in their original predictions. There were, therefore, insufficient numbers to investigate the complex interactions between the potential influences on participation: the characteristics of the patients (eg. time since diagnosis, disease site, stage and prognosis), the trials (e.g. potential side-effects, whether or not the patient or doctor were blind to treatment given) and the doctors (e.g. specialty, seniority).

Over three-quarters of the patients agreed to treatment within a randomised controlled trial, which highlights the importance of approaching all eligible patients. This rate of accrual is higher than the percentages generally quoted [28] and may reflect the sample of doctors who participated, the nature of the trials included or the patients involved. The doctors participating were a research-orientated sample who knew their practice was being scrutinised. It would be interesting to conduct further research using the intervention with other doctors who are less enthusiastic about recruiting patients to clinical trials. The toxicity and side-effects of treatments and differences between treatment arms varied amongst trials, but most compared different active treatments. The trials involving chemotherapy which had a 'no treatment' arm were the least popular. It is known that some trials are more difficult for doctors to describe and for patients to accept than others and these include RCTs that compare radically different treatments or treatments with major differences in possible side-effects [6] and trials involving a placebo or 'no treatment' arm [29,30]. The high uptake of trials may also be partly due to the written information given to patients participating in the communications study. All patients completed the Preferences for Information and Patient Attitudes to Trials questionnaires before their consultation, which contained information about treatment choices, decision-making and randomisation. As a consequence, any differences between the outcomes of the intervention and control group consultations may have been reduced.

The reasons patients gave for accepting and rejecting treatment within a RCT were different [24], but there were no differences between patients in the intervention and control groups. Providing doctors with additional information about the patients' main concerns may have made a difference to the explanations given, but this was not detected, as the majority of patients reported they had been told what they needed to know about the trial by the doctor. Being well informed, however, did not necessarily prevent them from continuing to worry about the idea of randomisation.

In general, patients were highly satisfied with the doctor they had seen, the manner in which the consultation was conducted and the information given to them, whether or not the doctor had seen their questionnaires. Nevertheless, 16.2% felt unclear about some things the doctor told them. The inclusion of some extra open-ended questions would have been useful in detecting any questions or concerns patients still had after the consultation. The audiotapes are another rich source of data and it is hoped that further systematic analysis of them using qualitative methodology will provide additional information, as to how doctors explain trials and respond to patients' queries concerning randomisation or uncertainty of treatments.

It was hypothesised that the intervention might speed up the process of informed consent, as the doctor had already acquired background information about the patient's views. Using the overall length of the consultation was a crude measure, as the nature of the consultations varied. Sometimes the doctor and patient had met before and sometimes the patient's history, test results, diagnosis and treatment options were discussed in addition to the trial itself or the trial had been mentioned previously. Measuring the time spent discussing the trial itself was too complicated as this was rarely confined to one part of the consultation.

This study focused on the role of the doctor, but the part other professionals play in explaining and recruiting patients to trials should also be examined. Their role and influence should not be ignored and further research should investigate ways in which they might clarify the concept of randomisation or other aspects of trial participation that patients want more explanation about.

In conclusion, providing doctors with a copy of their patients' requirements for information and attitudes towards participating in research trials questionnaires before asking them to participate in a trial made little difference to the outcomes measured in this study. Further research to explore the potential use of written interventions to facilitate communication and accrual to randomised clinical trials is recommended.

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