FULL PAPER

BJC

British Journal of Cancer (2013) 108, 1402–1407 | doi: 10.1038/bjc.2013.113

Keywords: randomised; trial participation; communication

Drivers and barriers to patient participation in RCTs

V Jenkins*[,1], V Farewell[2], D Farewell[3], J Darmanin[4], J Wagstaff[4], C Langridge[1] and L Fallowfield[1] on behalf of the TTT Steering committee

[1]*Sussex Health Outcomes Research and Education in Cancer (SHORE-C), Brighton and Sussex Medical School, University of Sussex, Falmer, Brighton BN1 9QG, UK;* [2]*MRC Biostatistics Unit, Institute of Public Health, University Forvie Site, Cambridge CB2 0SR, UK;* [3]*Cochrane Institute of Primary Care and Public Health, Cardiff University, Heath Park, Cardiff CF14 4YS, UK and* [4]*Wales Cancer Research Network, NISCHR Clinical Research Centre, 3rd Floor, 12 Cathedral Road, Cardiff CF11 9LJ, UK*

Background: Recruitment of patients into randomised clinical trials (RCTs) is essential for treatment evaluation. Appreciation of the barriers and drivers towards participation is important for trial design, communication and information provision.

Method: As part of an intervention to facilitate effective multidisciplinary team communication about RCTs, cancer patients completed two study-specific questionnaires following trial discussions. One questionnaire examined reasons why patients accepted or declined trial entry, the other perceptions about their health-care professionals' (HCPs) information giving.

Results: Questionnaires were completed by 74% (358/486) of patients approached; of these 81% (291/358) had joined an RCT, 16% (56/358) had declined and 3% (11/358) were undecided. Trial participation status of the 128 patients not returning questionnaires is unknown. Trial acceptance was not dependent on disease stage, tumour type, sex or age. Satisfaction with trial information and HCPs' communication was generally very good, irrespective of participation decisions. The primary reason given for trial acceptance was altruism (40%; 110/275), and for declining, trust in the doctor (28%; 12/43). Decliners preferred doctors to choose their treatment rather than be randomised (54% *vs* 39%; $P<0.027$). Acceptors were more likely to perceive doctors as wanting them to join trials (54% *vs* 30%; $P<0.001$). Trial type, that is, standard treatment *vs* novel or different durations of treatment, also influenced acceptance rates.

Conclusion: The drivers and barriers to trial participation are partly related to trial design. Unease about randomisation and impact of duration on treatment efficacy are barriers for some. Altruism and HCPs' perceived attitudes are powerful influencing factors.

Patients with cancer have benefited from the introduction of new drug and treatment regimens that have been tested within randomised clinical trials (RCTs). Recruitment to trials worldwide remains fairly low, impeding early introduction of efficacious treatment into the clinical setting. Slow recruitment may be owing to several factors at a health-care professional (HCP), institutional or patient level. Not all patients join RCTs; understanding some of the reasons for rejecting participation is useful to inform future information and communication needs and trial design.

Some trials have multiple treatment arms, and this complexity can be quite overwhelming. Knowing that uncertainty about the best treatment extends to three, four or even five arms can cause considerable anxiety. Also, many new trials include substudies that require extra tumour samples or additional imaging. Some of these tests are done perioperatively or may delay the start of treatment. Taking part in these types of trials may be more burdensome in terms of time spent visiting hospitals for the extra tests.

Patients may also be involved in numerous interactions about the trial with other members of the multidisciplinary team (MDT), not just a research nurse and oncologist, and not all HCPs may be cognisant of, enthusiastic or knowledgeable about the study.

*Correspondence: Dr V Jenkins; E-mail: val@sussex.ac.uk

Received 4 December 2012; revised 14 February 2013; accepted 20 February 2013; published online 19 March 2013

Therefore, trials with more complex designs may present more recruitment challenges.

Earlier surveys reported that patients enter RCTs primarily for altruistic reasons, in order to benefit future patients (Penman *et al*, 1984; Jenkins and Fallowfield, 2001). More recent studies have questioned whether altruism *per se* is a primary motivation (McCann *et al*, 2010; Locock and Smith, 2011). Although willingness to help others and contribute towards furthering medical knowledge featured strongly in these studies, gaining personal benefit emerged as an important driver. Different types of trials and stage of disease also influence trial decisions, and this is most noticeable in early phase studies where expectation of some personal medical benefit far outweighs altruism as a reason for participation (Daugherty *et al*, 1995; Catt *et al*, 2011).

One of the most difficult aspects of discussing RCTs is explaining randomisation clearly. Most HCPs are well aware of the necessity for randomisation but for patients without any background in scientific methodology and in the context of life threat, it can seem a rather strange way to determine treatment. The concept of randomisation emerged as a major barrier in a large survey that examined patients' attitudes towards a hypothetical two-arm RCT (Jenkins *et al*, 2010). Results showed that the majority of cancer patients (91%; 967/1066) believed that patients should be invited to participate in medical research. Yet, when told treatment allocation was determined by randomisation, only 55% (589/1066) would take part. If HCPs are not comfortable or competent explaining randomisation and the scientific logic for it, this may cause disquiet for patients wanting certainty about optimal treatments.

A large Cancer Research UK-funded prospective study (paper in press) examined MDT members' communication about clinical trials and the involvement of individual team members in trial recruitment. The attitudes of patients and clinicians to RCTs were collected to provide evidence-based arguments that might encourage HCPs to approach more patients about trials (Jenkins *et al*, 2010; Ford *et al*, 2011). The data presented here examine reasons why patients accept or decline to participate in clinical trials and the clarity of HCPs' information giving about the trial on offer.

MATERIALS AND METHODS

Questionnaires

Reasons for accept/decline. Patients' motivations for accepting or declining trial participation were recorded via a study-specific 16-item questionnaire (Supplementary online Material 1) modified from the one designed by Penman *et al* (1984) and used in previous research examining reasons why patients participated in Phase 3 trials (Fallowfield *et al*, 1998). The questionnaire comprises an initial question establishing whether or not the patient had agreed to trial entry. For each of the 16 statements, patients registered their agreement or disagreement on a scale of 0 to 4 (0 = strongly agree; 1 = agree to some extent; 2 = unsure; 3 = disagree to some extent; and 4 = strongly disagree). Finally, patients indicated from the options available the most important reason for their decision.

Clarity of HCP communication about the trial. This 15-item questionnaire asked patients to rate the clarity of the trial information provided by the HCP. First, patients indicated who had spoken with them about the trial (e.g., research nurse or clinician) and where possible the trial name. Thereafter, patients rated their agreement with statements using a scale of 0 to 4 (0 = not at all clear; 1 = a little bit clear; 2 = somewhat clear; 3 = quite a bit clear; and 4 = very clear). These statements included clarity about explanations of randomisation, side effects of treatments and voluntary nature of a trial (see Supplementary online material 2). They were also asked whether they were likely to join the trial (no, yes and uncertain). Space was provided for additional free text comments. This questionnaire had been used in a previous communication study with simulated patients (Fallowfield *et al*, 2012).

Sample. Patients with cancer, identified by members of the team as eligible for clinical trial discussions and attending the teams' clinics in Wales, were invited to join the Cancer Research UK MDT communication study.

Both questionnaires were given to patients by the research nurse in clinic following the trial discussion. Patients completed the questionnaires at home once they had decided whether or not they would participate in the clinical trial, and returned questionnaires by post to the co-ordinating centre. Each MDT provided monthly information regarding the number of patients who were given questionnaires, their sex and age, together with a contact telephone number that could be used to remind patients to return the questionnaire if they had not already done so. The study had multicentre ethical approval (South East Wales Local Research Ethics Committee Ref: 07/WSE03/17) and local NHS R&D permissions.

Statistical analyses. Summary statistics were generated for the descriptive data: counts, percentages and averages. Chi-square tests with continuity corrections as appropriate were conducted on comparison data.

Trial type (placebo, e.g., REACT; perioperative, e.g., POETIC; standard *vs* standard therapy given at different duration, e.g., PERSEPHONE or *vs* a different agent, e.g., SPIRIT2, and standard *vs* standard + new agent, e.g., STAMPEDE) was categorised by entering the name of the trial from the patient questionnaires into the NCRN portfolio and CRUK trial databases. If there was any difficulty categorising the trial, the co-ordinating centre contacted WCTN for a description of the trial. Of the 56 different trials offered, most were for breast ($n = 15$), urological ($n = 14$) and haematological cancers ($n = 14$). Trial type also allowed us to categorise the patients as receiving treatment for adjuvant or advanced disease.

RESULTS

Table 1 shows patients' characteristics. 358/486 (74%) patients completed the questionnaires, 291/358 (81%) indicated they had agreed to join a trial and 56/358 (16%) had declined. 11/358 (3%) were uncertain and were omitted from the analyses. The trial participation status of the 128 patients who did not return questionnaires was unknown. The table shows that more women (40; 71%) than men (16; 29%) declined trial participation.

Reasons for accepting or declining trial entry. Table 2 displays the frequency (expressed as percentage) of agreement to each statement according to whether responders accepted or declined trial entry. Data were dichotomised; the categories 'strongly agree' and 'agree to some extent' were combined and taken to indicate agreement.

Table 2 shows that a majority of patients were aware that they could leave the trial at any time, trusted the doctor and had received sufficient information about the study. However, certain key factors differed significantly between the responders who accepted and declined trial entry, in particular issues to do with treatment efficacy, positive attitudes towards research in general and external influencing factors. Noticeably, acceptors were more likely than decliners to agree that the trial offered the best treatment (84% *vs* 36%), that all treatments would be suitable

Table 1. Demographics

	Total	Acceptors	Decliners	Do not know
	N = 358	***N*** = 291	***N*** = 56	***N*** = 11
Sex				
Male	139 (39%)	120 (41%)	16 (29%)	8 (73%)
Female	207 (58%)	159 (55%)	40 (71%)	3 (27%)
Missing	12 (3%)	12 (4%)		
Age groups				
29–50 years	40 (11%)	29 (10%)	7 (12%)	4 (36%)
51–69 years	183 (51%)	155 (53%)	28 (50%)	0
⩾70 years	75 (21%)	58 (20%)	12 (21%)	5 (45%)
Missing	60 (17%)	49 (17%)	9 (16%)	2 (18%)
Cancer site				
Breast	152 (42%)	113 (39%)	31 (55%)	8 (73%)
Urology	78 (22%)	74 (25%)	3 (5%)	1 (9%)
GI (upper and lower)	74 (21%)	56 (19%)	16 (29%)	2 (18%)
Haematological/ lymphoma	35 (10%)	34 (12%)	1 (2%)	
Gynaecological	12 (3%)	9 (3%)	3 (5%)	
Lung	7 (2%)	5 (2%)	2 (4%)	
Treatment				
Adjuvant	173 (48%)	137 (47%)	32 (57%)	6 (55%)
Advanced	150 (42%)	134 (46%)	12 (21%)	4 (36%)
Missing	35 (10%)	20 (7%)	12 (21%)	1 (9%)
Trial Type 1				
Placebo	57 (18%)	44 (16%)	7 (16%)	6 (60%)
Perioperative	18 (5%)	15 (6%)	3 (7%)	0
Standard *vs* different therapy or durations of treatment	90 (28%)	68 (25%)	20 (44%)	2 (20%)
Standard *vs* Std + new agent	134 (41%)	121 (45%)	11 (24%)	2 (20%)
Other	26 (8%)	22 (8%)	4 (9%)	0

Abbreviation: GI, gastrointestinal. Reasons for accepting/declining a clinical trial. The patient data are based on those who returned both questionnaires ($n = 358$).

Table 2. The frequency of agreement (strongly agree/agree) to each statement according to trial decision.

Statement	Acceptors, ***n*** = 291	Decliners, ***n*** = 56	Chi square
1. I thought the trial offered the best treatment available.	245 (84%)	20 (36%)	<0.001
2. I believed the benefits of treatment in the trial would outweigh the side effects.	254 (87%)	21 (38%)	<0.001
3. I was satisfied that either treatment in the trial would be suitable.	245 (84%)	28 (50%)	<0.001
4. I was worried that my illness would get worse unless I joined the trial.	85 (29%)	4 (7%)	<0.001
5. The idea of randomisation worried me.	74 (25%)	19 (34%)	<0.159
6. I wanted a doctor to choose my treatment rather than be randomised by computer.	113 (39%)	30 (54%)	<0.027
7. The doctor told me what I needed to know about the trial.	282 (97%)	53 (95%)	<0.648
8. I trusted the doctor treating me.	285 (98%)	54 (96%)	<0.841
9. I was given too much information to read about the trial.	35 (12%)	6 (11%)	<0.503
10. I was given enough information to read about the trial.	277 (95%)	51 (91%)	<0.173
11. I knew I could leave the trial at any time and still be treated.	286 (98%)	53 (95%)	<0.068
12. I did not feel able to say no.	19 (6%)	3 (5%)	<0.521
13. I wanted to help with the doctor's research.	286 (98%)	33 (59%)	<0.001
14. I feel that others with my illness will benefit from the results of the trial.	286 (98%)	45 (80%)	<0.001
15. The doctor wanted me to join the trial.	158 (54%)	17 (30%)	<0.001
16. Others, for example, family or friends, wanted me to join the trial.	187 (64%)	8 (14%)	<0.001

(84% *vs* 50%), that the benefits would outweigh the side effects (87% *vs* 38%) and that their illness would worsen unless they joined the trial (29% *vs* 7%). Altruistic motivations were less likely in decliners compared with acceptors, who wanted to help doctors with research and thought that others would benefit from trial results. Acceptors felt more influenced by doctors (54% *vs* 30%) or by others (64% *vs* 14%) about trial entry. Decliners more often preferred the doctor to choose their treatment rather than be randomised (54% *vs* 39%).

The primary reasons (available on the questionnaire) for trial acceptance were altruism (110/275; 40%), followed by trial offered best treatment (50/275; 18%), whereas trust in the doctor (12/43; 28%) and wishing the doctor to choose (6/43; 14%) were main reasons for declining. These reasons for trial acceptance were the same irrespective of disease stage, cancer site, sex and age group (data not shown). However, 44% (20/45) of responders who declined trials did so when the trial in question compared novel or different durations of treatment, compared with 25% (68/270) among acceptors. For trials with new treatments in addition to the standard treatment, the percentages were reversed: 24% (11/45) *vs* 45% (121/270). The percentages of acceptors and decliners for the other trial types, placebo, perioperative and 'other' were similar.

Clarity of HCP communication about the trial. Patients indicated that trials were discussed more often by research nurses (224/345; 65%) rather than clinicians (101/345; 29%) or both (20/345; 6%). Most (330/358; 92%) patients could recall the name (or approximation) of the trial discussed.

Table 3 shows responses to questions 1–15 eliciting patient feedback about the HCPs' clarity of communication concerning the trial. Data were dichotomised conservatively with 'very/quite a bit' interpreted as good or clear and 'somewhat, a little, not at all' as not clear. All items were positively framed except statements 7, 11 and 15. Irrespective of a decision to decline or accept a clinical trial, the quality of communication was viewed as good by the patients.

Extra comments about the HCP's trial discussion were recorded by 112 patients, and were categorised into six themes: trust in the doctor, wanting to help others and self, randomisation, explanation

Table 3. Quality of communication: the frequency of clarity (very clear/quite a bit clear) to each statement according to trial decision

Statement	Acceptors, $n=291$	Decliners, $n=56$	*P*-value
1. The HCP used clear and understandable language.	284 (97%)	56 (100%)	<0.585
2. I understood that entry into the trial was voluntary.	290 (99%)	56 (100%)	–
3. I understood that if I agreed to join the trial I could leave at any time.	289 (99%)	54 (96%)	<0.69
4. I understood the HCP's explanation of randomisation.	275 (94%)	54 (96%)	<0.51
5. I felt the HCP was sensitive to my concerns.	288 (99%)	56 (100%)	<0.70
6. I was given the opportunity to ask questions.	286 (98%)	56 (100%)	<0.70
7. I was left confused.	4 (1%)	1 (2%)	<0.589
8. I felt the HCP listened to what I had to say.	286 (98%)	55 (98%)	<0.705
9. I understood the treatment options available to me outside the trial.	263 (90%)	50 (89%)	<0.418
10. I was informed about the possible side effects of the different treatments.	267 (92%)	48 (86%)	<0.074
11. The HCP seemed to favour one treatment over another.	29 (10%)	3 (5%)	<0.197
12. I felt that the HCP gave me all the information I needed to make a decision.	281 (96%)	53 (95%)	<0.437
13. I felt that the HCP created an atmosphere of trust and support.	283 (97%)	55 (98%)	<0.653
14. I felt that the HCP gave me time to consider entry into the trial.	286 (98%)	54 (96%)	<0.409
15. I still have unanswered questions.	9 (3%)	3 (5%)	<0.296

Abbreviation: HCP, health-care professional.

of trial; time burdens and other comments. Examples are shown in Table 4.

DISCUSSION

The majority of patients returning questionnaires had accepted trial entry. They cited altruism or a belief that the trial offered the best treatment as their main drivers for participation, as reflected in the following quote: 'I am happy to take part in any trial that may benefit not only me but others who may need to have treatment for cancer'. The fact that most patients believed the trial offered the best treatment perhaps allows them to feel more altruistic, this was true for those offered adjuvant or palliative trial treatments. Likewise in early phase studies, patients with metastatic disease often express hope and expectations of benefit, despite being told explicitly that the likelihood of personal treatment benefit was small. In an interview study involving 40 Phase I trial patients, only one said that wanting to help others was the primary reason for taking part (Catt *et al*, 2011). This contrasts with the results from a study examining the willingness of patients with primary colorectal cancer and patients with colorectal liver metastases to enter a trial involving oral consumption of a diet-derived agent with unknown therapeutic action. Findings revealed that those with primary colorectal tumours were motivated more by self-interest than patients with hepatic metastases who appeared more altruistic (Garcea *et al*, 2005).

While it is possible that many patients with cancer are genuinely selfless, social desirability may influence endorsement of altruistic statements if these are provided as options on a questionnaire. The authors of one study coined the term 'conditional altruism' to describe the situation where people agree to randomisation as an opportunity to help others but hopefully themselves or at least not do themselves harm from participation (McCann *et al*, 2010). A similar theme was pursued in another interview study examining drivers to trial participation (Locock and Smith, 2011). Patients participated anticipating personal benefit and declined anticipating personal detriment, especially if receiving a placebo was a possibility.

Although 'I trusted the doctor treating me' was endorsed as a reason both for joining and not joining, it was the main driver for those who had declined participation. This has been reported previously and thought to reflect the HCP's equipoise during the discussion (Jenkins and Fallowfield, 2001). Most patients in the current study rated the clarity of the trial information as good and agreed that the HCP did not favour one arm of the trial over another, or that the doctor wanted them to join the study. This suggests that patients recognised authentic and even-handed communication by their HCP about clinical equipoise and felt that trial entry really was voluntary. Of interest was the finding that many (44%; 20/45) declining trial entry had been offered a trial comparing standard treatment with novel drugs or different duration of standard treatment; for example, the 12 months (standard) *vs* 6 months (novel) treatment with Herceptin in HER 2 + ve women with breast cancer. Such trials comparing shorter duration can evoke anxiety about efficacy. In contrast, trials that had a standard drug plus or minus a new drug appeared more attractive, perhaps because the patient would not feel they were losing out and may even gain an extra treatment.

Of course patients who participate in questionnaire research may be more positively inclined to research in general, including clinical trials. Notably, the 128 patients who failed to return questionnaires may have also declined clinical trial entry. The difficulty in obtaining data from decliners is highlighted in a US study (Buss *et al*, 2008). They collated responses from 896 patients with advanced cancer and their caregivers who declined to participate in a web-based support system study for patients with advanced cancer and their carers; 452 (50.4%) patients declined to participate, a further 96 were deemed to be ineligible and 108 did not give a reason. This resulted in only 27% (240/896) of decliners responding giving a potentially biased sample. Although the questionnaire does cover many of the key issues associated with RCTs patients' reasons for accepting or declining the trial were limited to the list of options available, other important factors, for example, the extra burdens associated with some complex trials, were not listed on the questionnaire, but were cited by patients in their free text comments.

The overall rating of clarity by the patients of the HCPs' communication about trials was high. Research and specialist breast care nurses had a primary role in many of these trial discussions reflecting common practice in the United Kingdom. In addition, the HCPs involved in trial discussions were all participating in a study to improve communication about trials with both patients and members of their team. It is possible that improvements and good communication were partially explained

Table 4. Comments (acceptors to the trial: explanation of trial; wanting to help others and themselves; decliners to the trial: trust in the HCP time burden, randomisation, other)

Joined the trial
Explanation of the trial
Very thorough explanations given, I felt I had all necessary information to base my decision upon. Did not feel pressured to agree to join study.
I was advised at the first consultation that I was considered a suitable candidate to take part in the trial. The trial was explained in detail.
I was told it was voluntary and that I could leave at any time.
I read all the information, wrote down questions which I asked and they were explained back, the concerns I had, in a lovely and understandable manner.
The information and support offered by the specialist nurse was invaluable in understanding the trial and coming to a decision. By the time I spoke to I was very well prepared and most of my questions had been answered.
Wanting to help others and themselves
I'm interested in doing the trial because I hope it will help other people with cancer in the future.
I suppose I felt that this trial was a chance to get the drug after hearing about it on the TV news, a few weeks before I was offered the chance of becoming part of the trial. I believed that if I got the drug rather than the placebo, I would benefit greatly. I feel much better and my PSA has dropped dramatically so I do seem to be benefitting very much. All the staff and doctors I have seen have been excellent. I'm very pleased to be on the trial. Many thanks.
I'm pleased that I've been invited to participate in this trial. I'm grateful that my CA125 will be closely monitored, and also if my cancer is found to be sensitive to oestrogen, being offered the blocking mechanism of tamoxifen could slow the growth and spread of the disease and delay the use of a third chemotherapy.
I believe that doing the trial will keep the doctors more in touch with my condition.
I am happy to take part in any trial that may benefit not only myself but others who may need to have treatment for cancer.
After reading all the information about the trial I decided with the help of my family to say yes, as it could be a help not only to me but other patients in the future.
Declined the trial
Time burdens
I felt that the extra journeys to the hospital would be too much for me as well as having chemo. I also have to rely on my husband taking me to the hospital and he has to take a lot of time off work unpaid.
I was willing to take part in the trial, however, on the 2 occasions I went for an appointment I was kept waiting in excess of 1 hour each time. My condition gives me terrible mood swings and I can neither physically or mentally wait around indefinitely. I rightly or wrongly assumed that the trial would be a separate part from patient appointments. I felt that the consultant was fitting me in between patients. I ended up walking out, no apologies and no reason given for the delay.
I gave this a lot of thought but the reasons for declining were my age 81 yrs. The treatment would have been over a longer period and which would have meant travelling approx. 25 miles several times. The radiotherapy, which I have accepted, means 12 days in hospital for treatment then hopefully it will be over and done with.
I feel as though I need a break from treatment and tests at this moment in time as I have only just finished herceptin, perhaps in the future.
Randomisation
I feel the choice of treatment should be left to the consultant, and not to randomisation.
Wanted tablets, didn't want to attend hospital due to transport problems so opted to have tablets instead, as the trial couldn't guarantee that I would be on tablets as it would be chosen randomly.
Trust
Although very, very, busy, nurses are the back bone to the specialist doctors, everyone gave me full support and understanding.
The trial nurse was very understanding of my circumstances and had such a calm quiet way that she put me completely at ease, she explained everything to me and when I did ask her a question to do with previously diagnosed conditions, she immediately found the answer.
All staff have been very supportive and helpful. I have been very happy with my care and treatment.
Other
I was quite happy about the way I was asked to consider taking part in the trial. Decided not to participate in view of (1) injections/drip once every 3 weeks for 12 months, (2) possible side effects.
I did not wish to have a pump in situ for 3 or 6 months. I was worried that if I had been given 3 months of chemotherapy, as opposed to 6 months, I would not be giving myself the best possible chance.

by the 'Hawthorn effect', in which subjects in behavioural studies change their performance in response to being observed. Nevertheless, these findings present a very positive picture of the communication received by patients in the United Kingdom about clinical trial participation, treated by the MDTs being studied. Poor communication did not seem to be a determining factor as to whether or not patients joined a trial, but trial design, especially if one arm appeared to be offering less treatment, did seem to deter some.

ACKNOWLEDGEMENTS

We wish to thank the patients, and all the research and clinic nurses engaged in the study, and members of the Steering Committee: Libby Batt, Jayne Caparros, Ty Francis, Jane James, Jayne Jones, Kathy Malinovsky, Tim Maughan, Fergus Macbeth, Margaret Moore, Jackie Morris, Sara Shankland, Lucy Seago and John Wagstaff. We also thank the supportive MDT leaders: Richard Adams, Peter Barrett-Lee, Michael Chare, Derek Crawford, David Edwards, Alan Evans, Mererid Evans, Eve Gallop-Evans, Simon Gollins, Neil Fenn, Simon Holt, Saad Al Ismael, Mike Jamieson, Richard Johnson, Tibor Kovacs, Howard Kynaston, Simon Leeson, Seamus Linnane, Bill Maxwell, Andrew Maw, Diane Parry and Clare Rowntree. Cancer Research UK funded the study, Professor Fallowfield, Dr Jenkins and Mrs Langridge. The study was sponsored by Brighton & Sussex Medical School. MRC (UK) support was provided for VF (U105261167) and DF. Neither the funding body nor the sponsor had any role in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

REFERENCES

Buss MK, DuBenske LL, Dinauer S, Gustafson DH, McTavish F, Cleary JF (2008) Patient/caregiver influences for declining participation in supportive oncology trials. *J Suppor Oncol* **6**(4): 168–174.

Catt S, Langridge C, Fallowfield L, Talbot DC, Jenkins V (2011) Reasons given by patients for participating, or not, in Phase 1 cancer trials. *EJC* **47**(10): 1490–1497.

Daugherty C, Ratain MJ, Grochowski E, Stocking C, Kodish E, Mick R, Siegler M (1995) Perceptions of cancer patients and their physicians involved in phase I trials. *JCO* **13**(5): 1062–1072.

Fallowfield LJ, Jenkins VA, Brennan C, Sawtell M, Moynihan C, Souhami RL (1998) Patients' attitudes to randomised clinical trials of cancer therapy. *EJC* **34**(10): 1554–1559.

Fallowfield LJ, Solis-Trapala I, Jenkins VA (2012) Evaluation of an educational program to improve communication with patients about early phase trial participation. *Oncologist* **17**(7): 377–383.

Ford E, Jenkins V, Fallowfield L, Stuart N, Farewell D, Farewell V (2011) Clinicians' attitudes towards clinical trials of cancer therapy. *BJC* **104**(10): 1535–1543.

Garcea G, Lloyd T, Steward WP, Dennison AR, Berry DP (2005) Differences in attitudes between patients with primary colorectal cancer and patients with secondary colorectal cancer: is it reflected in their willingness to participate in drug trials? *EJCC* **14**(2): 166–170.

Jenkins V, Fallowfield L (2001) Reasons for accepting or declining to participate in randomised clinical trials for cancer therapy. *BJC* **82**(11): 1783–1788.

Jenkins V, Farewell D, Batt L, Maughan T, Branston L, Langridge C, Parlour L, Farewell V, Fallowfield LJ (2010) The attitudes of 1066 patients with cancer towards participation in randomised clinical trials. *BJC* **103**: 1801–1807.

Locock L, Smith L (2011) Personal benefit, or benefiting others? Deciding whether to take part in clinical trials. *Clin Trials* **8**(1): 85–93.

McCann SK, Campbell MK, Entwistle VA, Smith D (2010) Reasons for participating in randomised controlled trials: conditional altruism and considerations for self. *Trials* **11,** art. no 31.

Penman DT, Holland JC, Bahna GF, Morrow G (1984) Informed consent for investigational chemotherapy: patients' and physicians' perceptions. *JCO* **2**: 849–855.

Supplementary Information accompanies this paper on British Journal of Cancer website (http://www.nature.com/bjc)