A Randomised Controlled Trial of an Audiovisual Patient Information Intervention in Cancer Clinical Trials

Volume II of II

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CHAPTER SEVEN: DEVELOPING AND TESTING A QUESTIONNAIRE TO ASSESS PATIENT UNDERSTANDING ABOUT RESEARCH

7.1 Introduction

Chapter 3 includes a discussion of informed consent and the importance of knowledge and understanding prior to decision making. This chapter will build on that by discussing the difficulties in assessing understanding, and by providing a justification for the approach chosen in this study. It will then address in detail the development and testing of a new questionnaire to assess patient understanding in the randomised cancer trial setting.

7.2 Background

7.2.1 Challenges in assessing understanding

Assessing patients' understanding of the information given to them concerning treatment options is in itself challenging, owing to lack of agreed definitions of 'understanding' and inconsistent approaches to measuring it. This is compounded when the information given is of a technical nature, like the information patients receive when asked to consider taking part in a randomised clinical trial. In the cancer setting, this information is often given at a time when patients are very vulnerable and anxious after receiving a diagnosis of cancer or news of its recurrence.

It is essential that health care professionals caring for and supporting patients, prior to consent, are able to assess and determine what patients *do* know and understand about the trial that they are being asked to participate in, so that they can correct any misconceptions and provide additional information to enable patients to make an informed choice about whether or not to participate.

There is a lack of validated measures to assess patients' understanding of randomised trials. As discussed in Chapter 3 (Section 3.14.2), the relationship between knowledge and understanding is unclear, with much of the literature using the terms interchangeably. This has led to difficulties in assessing studies and comparing approaches. As already discussed in previous chapters, this study does not attempt to distinguish between the terms, and will use them synonymously when referring to previous research and describing the AVPI study. For example, in discussion of informed consent theory, the term 'understanding' was mainly used, and the questionnaire discussed in this chapter was called 'Questionnaire: Patient Understanding of Research'. However, for ease of discussion it is usually referred to as the 'knowledge questionnaire'.

7.2.2 Assessment of understanding

As discussed in Chapter 3, understanding (also referred to as knowledge) does seem to be related to patients' decision making concerning clinical trials (Ellis *et al*. 2001; Comis *et al*. 2003). However, determining patient understanding in relation to health care and treatment generally is notoriously difficult. A complication exists in the assessment of understanding when one considers that there may be a difference between what patients think they understand and what they actually do understand. This has been found in several studies, for example work by Sutherland *et al*. (1990), Miller *et al*. (1996) and Hietanen *et al.* (2000). Sutherland *et al*. (1990) developed a consent form for a hypothetical trial and studied patients' interpretations of clinical trial information. They found that there was considerable misunderstanding of information presented in the consent form and that, depending on the particular statement, between 26 and 54% of the interpretations were correct. In a study by Hietanen *et al.* (2000) of 255 patients with breast cancer invited to take part in a randomised clinical trial, 91% reported finding the information provided as easy or quite easy to understand. However, only 23% knew that they had been randomised, with 51% believing that the doctor had chosen the treatment for them. This demonstrates the need for an objective approach to measuring

understanding – in effect, a knowledge test – rather than asking patients for their perceptions of the issues on a self-report basis.

7.2.2.1 Studies to assess patient understanding for informed consent

Much of the work reported in the literature has been carried out to assess knowledge or understanding pre and post the introduction of an intervention designed to increase knowledge or understanding about a specific treatment or clinical trial. Assessment is usually by means of a questionnaire designed for that purpose. For example, Mason *et al*. (2003) investigated the effect of using video information in obtaining consent for female sterilisation. In this case knowledge was assessed through specific questions, with true/false answers: patients were randomised to receive the standard consultation or the video intervention, and knowledge levels were compared. A similar approach has been taken by other groups, including the Diabetes Control and Complications Trial Research Group, in assessing a multi-component process for informed consent. They used a 14-item, multiple-choice knowledge test, based on information given to patients via slides and a handbook, as part of the consent process (Diabetes Control and Complications Trial Research Group 1989).

Kruse *et al.* (2000) assessed the impact of written information on out-patients' knowledge of, and attitudes towards, randomised clinical trials. Knowledge was assessed by a 17-item multiple-choice questionnaire, and included some general questions to assess knowledge about clinical trials, in addition to a specific focus on randomisation. The questionnaire related to studies being carried out in Denmark and could not be generalised to the UK for this reason; there are also difficulties in complex terminology that may have been compounded by the English translation of the questionnaire. However, it does provide a good starting point for the assessment of understanding in the randomised cancer trial setting in the UK, and it was considered as a tool for this study, following modification. The modification was achieved by simplifying some of the wording

in order to address the issue of complex terminology. Also, by removing questions which were specific to Danish clinical trial regulations. This modified version was discussed with the ethics committee and was considered to be 'too difficult for the patients to complete'. An additional problem was that, for some of the questions, there could be more than one correct answer.

Miller *et al.* (1996) evaluated the Deaconess Informed Consent Comprehension Test (DICCT), which is an assessment tool for clinical research subjects, focussed on the required elements of informed consent in the USA at the time of initiating the study (1994/1995). This was one of the first attempts to develop a standardised assessment tool for consent in clinical trials. The DICCT consists of 14 open-ended questions with three scoring options: 2 points for correct answer, 1 point for partially correct and 0 points for incorrect or no answer. As part of the evaluation of the tool, 275 adults completed the test, in addition to the revised Weschler Adult Intelligence Scale (WAIS) and the reading subtest of the revised Wide Range Achievement Test (WRAT-R), as part of validity testing. Scores were then correlated. There was moderate correlation between the DICCT and the WAIS-R, and the DICCT and the WRAT-R. Interrater reliability for the DICCT was determined for the first 50 patients, and was good at 0.84. The DICCT appears to be worthy of further investigation, but was not appropriate for the AVPI study since it did not assess understanding of trial design.

More general approaches which aim to assess the quality of the informed consent process (of which understanding was part) include work by Joffe *et al*. (2001a) in cancer, and outwith cancer, but in the randomised trial setting, by Sugarman *et al.* (2005), Guarino *et al.* (2006) and Länsimies-Antikainen *et al.* (2007).

7.2.2.2 Assessment of the quality of informed consent

7.2.2.2.1 Cancer setting

Joffe *et al.* (2001b) developed and evaluated the 'Quality of Informed Consent Questionnaire (QuIC)', which was designed to assess actual understanding (20 questions) and perceived understanding (14 questions). It incorporates the basic federal requirements for informed consent in the USA, assesses the therapeutic misconception, and uses the language and structure of the National Cancer Institute (NCI) template for informed consent documents. The QuIC was sent to 287 adult cancer patients enrolled in phase I, II or III clinical trials, and was completed by 207 patients. A random sample of 32 patients was selected to assess test-retest reliability, with 17 completing the questionnaire again. Test-retest reliability was shown to be good with intraclass correlation coefficients of 0.66 for objective understanding and 0.77 for subjective understanding. Content validity was assessed via two independent expert panels. Nine patients were involved in testing for time and ease of administration. The questionnaire was found to take an acceptable amount of time to complete, at an average of 7.2 minutes.

The QuIC has since been tested in several small scale studies, such as that by Barrett (2005) with oncology patients in a small community hospital, and appears to be a useful tool for a generic evaluation of the informed consent process in cancer trials; but it is not specific to the randomised cancer trial setting, and does not address in any detail, the difficult issues associated with the randomisation design. Joffe *et al.* (2001b) acknowledge that, because of the nature of the questions, the QuIC may be more sensitive to the therapeutic misconception, than to other areas of subject misunderstanding. In addition, the QuIC is focussed on federal requirements for informed consent in the USA, which may not be directly transferable to the UK. Despite this, the QuIC is receiving interest from other countries, and has now been translated and adapted for use in France, where it has undergone preliminary validation work (Paris *et al.* 2006)

7.2.2.2.2 Non-cancer trial setting

Sugarman *et al.* (2005) developed the Brief Informed Consent Evaluation Protocol (BICEP) as a practical and general means of evaluating the quality of informed consent to research. BICEP is a telephone assessment, where the interviewer is called after patients have completed the consent process for a trial with the investigator. The telephone assessment was completed by 632 patients who took an average of 8.8 minutes to complete. During the two-year study period, the interview schedule was further developed and refined as a result of patient responses. This was an interesting study, focussed on the whole informed consent process rather than just on understanding, and its approach that was shown to be acceptable to patients and research staff. However, the study sample was American veterans, many of whom were enrolled in trials of preventative therapies rather than treatments, and it is unknown how transferrable the results are to other settings. This approach was not an option for our study since it was too general, without any attention to misconceptions associated with randomisation. Questions that assessed understanding were only a small part of the interview, which also included personal perceptions of issues such as satisfaction and voluntariness.

Guarino *et al.* (2006) developed an Informed Consent Questionnaire (ICQ) for assessing patients' own perceptions of understanding of informed consent. This was evaluated in a Department of Veterans Affairs randomised clinical trial of cognitive behavioural therapy and aerobic exercise for Gulf War veterans, involving 1092 subjects. Again this study used self–report and did not address objective understanding at all. It claimed to focus on assessing self-perceived understanding; however, the content was similar to the Sugarman *et al*. (2005) study, which addressed the informed consent process in general.

An interesting qualitative approach to evaluating informed consent was undertaken by Länsimies-Antikainen *et al.* (2007), and involved patients with a metabolic syndrome who were taking part in a trial to evaluate an intervention on cardiovascular risk factors in

Finland. The aim of the study was to describe and analyse the use of informed consent in clinical research from the perspective of patients (n=26), in order to develop and test an interview schedule for the evaluation of informed consent. The study found the key elements of informed consent to be information, understanding and decision making, with competence an essential factor throughout. The interview schedule has now been refined as a result of the study, and is currently undergoing further testing. It contains five sections containing a total of 44 questions about informed consent, and appears to be a promising approach for future informed consent evaluation. The main limitation of the study was that the interview schedule was tested with small numbers of clinically well patients, who had high levels of subjectively and objectively assessed understanding (as delineated by questions in the interview schedule). It is difficult, therefore, to determine the generalisability of the findings.

Due to the lack of validated measures to assess understanding of research for randomised cancer trials, and the limitations of the instruments discussed, the decision was taken to develop and test a new tool specifically for this purpose. Due to the wealth of information already available in the literature on the informational requirements for informed consent, and the challenges of assessing patient understanding – in addition to the need to comply with the requirements of a study design necessary (RCT) to meet the primary endpoint – a quantitative approach was adopted. To develop and test this new questionnaire, a separate study was set up, which will be referred to as the questionnaire development (QD) study, and will now be discussed.

7.3 Aims of the QD study

The objectives of this study were to:

- Develop a questionnaire to assess understanding (also referred to as knowledge) of randomised clinical trials, to be used in the cancer setting.
- Test the acceptability, reliability and validity of the questionnaire.

7.4 Development of the questionnaire

7.4.1 Introduction and content of the questionnaire

As discussed in Chapters 2 and 3, misconceptions are common in relation to the concept of randomisation and the value of the standard treatment arm within this setting (Harris Interactive 2001). Therefore, the questionnaire was developed to focus mainly on these topics, and was derived from the literature, patient and professional consultation. Thirteen items were included in the tool, 'Questionnaire: Patient Understanding of Research', each with a 4-part, multiple-choice option for response. Demographic questions were also included to determine age, education status, deprivation category and previous experience of clinical trials. (The questionnaire is shown in Appendix 7.1). Guidance on questionnaire structure and design was taken from Bryman (2001, pp128-136) and Robson (2002, pp228-268).

7.4.2 Patient involvement

Four patients were involved in the design of the questionnaire. A patient with lung cancer, who had previously participated in several randomised cancer trials, and a patient who was currently part of a randomised cancer trial met on one occasion in a facilitated meeting to contribute to the questionnaire development. They provided comments on subsequent drafts in relation to format, content and wording. Following this, the final draft was sent to two more patients with cancer in other treatment centres, which resulted in minor changes to wording.

7.4.3 Professional consultation and review

Clinical experts were involved in the development of the questionnaire through an advisory group set up for the purpose of the project. The advisory group included members of the steering group for the main study (Appendix 5.1) in addition to the lead for patient information within the department. The process was similar to that for patient consultation, and the group advised on several drafts.

The questionnaire was then reviewed by the Ethics Committee which resulted in some changes to the wording. It was assessed for readability using the Flesch Reading Ease score through Microsoft ® Office Word SP2 (2003). Text is rated on a 100-point scale: the higher the score, the easier it is to understand the document, with a score of 60-70 considered acceptable. The Flesch Reading Ease score for the questionnaire was good at 67.5.

7.5 Testing of the questionnaire

7.5.1 Sample

The total sample for the study was 78: 26 clinical trial nurses, 26 patients who had previously taken part in a randomised clinical trial (RCT), and 26 patients who had no previous clinical trial experience. The patients were purposively sampled to ensure that there was an equal mix of patients with colorectal, breast and lung cancer in both patient groups. For the nurse group, all cancer research nurses from The Beatson West of Scotland Cancer Centre were included; a total of 8. The remainder of the sample was selected to represent a range of specialty areas, with all the nurses recruited being involved with patients in randomised trials. The sample size was determined to provide 80% power to detect a standardised difference of 0.8 (conventionally regarded as a large effect) between the groups based on the overall questionnaire score (the percentage of correct answers out of 13). The sample size above was also estimated to be able to provide a 95% confidence interval of width 0.2 for the Cronbach alpha coefficient, assuming the true coefficient is 0.7 (Donner and Eliasziw 1987).

7.5.2 Measures

7.5.2.1 Questionnaire: Patient Understanding of Research

The knowledge questionnaire (Questionnaire: Patient Understanding of Research) was developed as described above and is shown in Appendix 7.1.

7.5.2.2 *Assessing acceptability of Questionnaire: Patient Understanding of Research*

This is a short questionnaire, shown in Appendix 7.2, which was designed to assess acceptability of the knowledge questionnaire. Areas assessed included time to complete, clarity, and format. Subjects were also requested to provide any additional comments about the questionnaire that they felt were relevant.

7.5.3 Data collection and recruitment

7.5.3.1 Patients

Data was collected over a period of three months by the Research Practitioner (RP) under the guidance of the Cancer Consultant Nurse (CCN), who also undertook the function of data collection during periods of absence of the RP. Potential patients for the study (both the 'previous trial' and 'no previous trial' groups) were identified by the RP/CCN during attendance at the out-patient clinic, while present on the wards, and from case-notes and discussions with clinical staff. Verbal permission to approach patients about the study was granted from the relevant medical consultants. Patients' medical notes were used to confirm diagnosis and previous participation in a clinical trial.

Patients attending the hospital for the first time were not approached as it was considered that they would have too much other information to comprehend. Patients were also not approached if it was clear from their medical notes that they were symptomatic from brain metastases, or if they were expected to receive bad news - for example, that their disease had worsened - during that clinic visit. A recruitment log was kept to record age, diagnosis and previous clinical trial participation, and to identify non-responders.

If, after an initial discussion of the study, the patient was keen to participate, he/she was given an information sheet to read (Appendix 7.3) and an opportunity to ask questions, prior to obtaining written consent (Appendix 7.4). Participants were then asked to complete the questionnaires while they were waiting to be seen in the out-patient clinic.

Seventeen of the 52 patients wanted to take the questionnaires home to complete, and they were given a stamped addressed envelope for return. Of these 17, 3 did not return the questionnaires, and additional patients were recruited to replace them. One of the 17 returned the questionnaires late and had been replaced in the meantime. Of those who had taken part in a previous RCT, 1 patient returned a blank questionnaire and another returned the questionnaire late (mentioned above). Both were replaced. Of those who had not previously taken part in an RCT, 1 returned a questionnaire where only the first page was completed. A further 2 patients had previously been employed in roles working directly with patients in trials/organisation of trials and were considered atypical for this reason. An additional 3 patients were asked to participate in order to replace them.

Of the patients approached, all of those who had been in a previous RCT agreed to participate. Of those who had not been in a previous RCT, 5 refused to participate. Recruitment summaries for the two patient groups are shown in Figures 7.1 and 7.2.

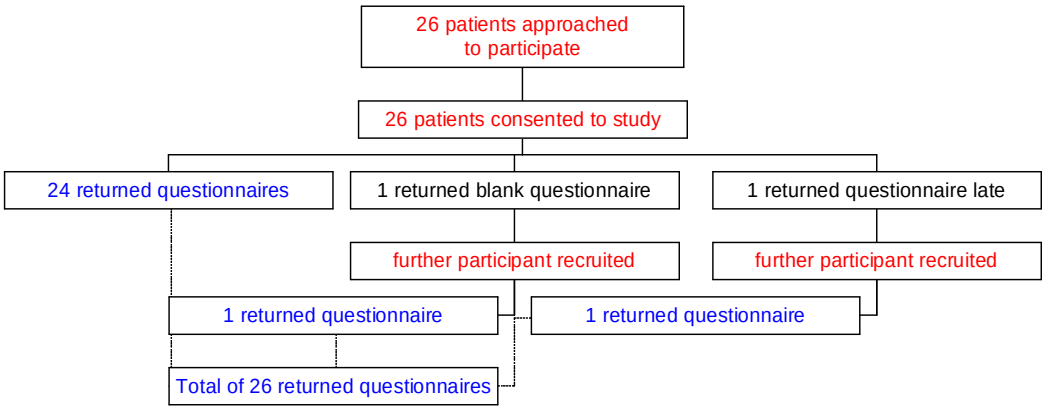

Figure 7.1. Recruitment summary for patients in a previous clinical trial

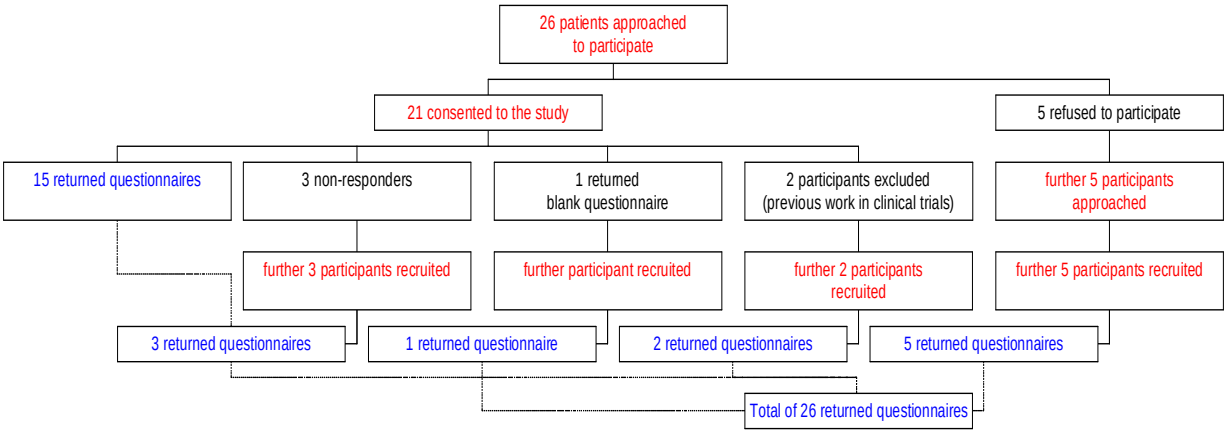

Figure 7.2. Recruitment summary for non clinical trial patients

7.5.3.2 Nurses

Nurses were identified through job titles on the global address list for NHS Greater Glasgow and Clyde, and through the Clinical Research Forum database. They were invited to participate by telephone; and, if verbal agreement was obtained at this stage, a covering letter, study information sheet, questionnaires, consent form and return envelope were posted to the participant via internal mail. The participant was requested to return the signed consent form to the RP, who then signed it, photocopied it and returned the original to the participant. A recruitment log was kept in order to identify non-responders. Of the 26 research nurses approached, all were willing to participate. Of these, 22 nurses returned the questionnaires. The 4 who did not return the questionnaires were reminded via e-mail. Only 2 of them subsequently responded, and a further 2 research nurses were contacted in order to invite them to participate; both subsequently returned the questionnaires. A recruitment summary for the research nurses is shown in Figure 7.3.

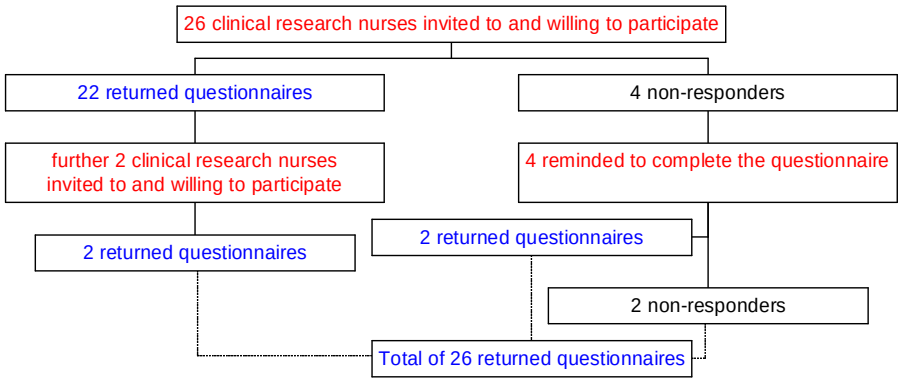

Figure 7.3. Recruitment summary for clinical research nurses

7.5.4 Analysis

Data were entered by the Cancer Consultant Nurse into SPSS (version 11, running on Wndows XP) and Cronbach's alpha was used to estimate the internal consistency reliability of the questionnaire (Cronbach 1951; Bryman 2001, p71). The Chi-square test for trend was used to assess whether the percentage of patients answering a particular question correctly increased or decreased approximately linearly across the three ordered study groups (ordered 'Patients NOT previously in RCT'; 'Patients previously in RCT'; 'Research nurses'). In order to allow for small patient numbers, the exact version of the test was used. The Mann-Whitney U test was used to compare the questionnaire scores between the groups; multiple comparisons were allowed for using a sequential testing procedure (Holm 1979). The association between educational status and deprivation categories was assessed using Spearman's rho (r_s) non-parametric correlation coefficient.

7.5.5 Ethical considerations

Full ethics approval for the study was obtained as part of the larger study testing the AVPI intervention (Chapter 5, Section 5.10). Patients were allocated a study number on all paperwork in order to maintain anonymity.

7.5.6 Results

7.5.6.1 Demographics

There were equal numbers of patients with lung, breast and colorectal cancer recruited into each of the study arms: previous RCT; no previous RCT. Subjects in both of the patient groups were similar in terms of age, with the majority in both groups being female. In the nurses' group, subjects were also predominantly female. Demographic details of the total sample are shown in Table 7.1

Table 7.1. Demographic details of the sample (patients and nurses)

	Age		**Sex**		**Diagnosis**		
	Mean (yrs)	Range (yrs)	M (n)	F (n)	Lung (n)	Breast (n)	Colorectal (n)
Patients (Previous RCT)	57	38-76	10	16	8	9	9
Patients (No previous RCT)	63	43-81	8	18	8	9	9
Research nurses	41	28-57	2	24	N/A	N/A	N/A

The 26 research nurses came from a total of 12 different specialties, including diabetes, cardiac, rheumatology, and renal. Eight of the sample worked specifically with cancer clinical trials.

Similar to the data fields used in the Census of Population (Census Dissemination Unit, 1991), level of qualifications was recorded as a measure of education status/level of education. Education level was classified as: 'No educational or vocational qualifications', 'Qualification below degree level', 'Degree, degree level vocational qualification or above'. Deprivation was measured by the Carstairs scores for Scottish postcode sectors (Carstairs and Morris 1991) using data from the 2001 census (McLoone 2004). Each postcode is classed as one of seven categories with categories 1-2 identified as affluent, 3-4 as the middle category and 5-7 as deprived.

7.5.6.2 Testing of the questionnaire

Table 7.2 shows the percentage of respondents in the 3 study groups who answered the questions correctly. For all questions, except 4, 7, 8 and 13, there is a statistically significant trend across the 3 groups in the expected direction, using the Mann-Whitney U test.

Table 7.2. Response to questions by group

		Percentage with correct response				
		Patients NOT previously in RCT (%)	Patients previously in RCT (%)	Research nurses (%)	P-value for linear trend	Corrected item total correlation
Q1	The main reason for carrying out research with patients is..	76.9	92.3	100.0	0.009	0.287
Q2	Research with patients is carried out to...	69.2	80.8	100.0	0.003	0.490
Q3	In a randomised clinical research trial/study...	23.1	42.3	100.0	<0.001	0.617
Q4	The main aim of a randomised trial is to..	88.5	92.3	100.0	0.101	0.246
Q5	When a trial is randomised...	50.0	65.4	100.0	<0.001	0.601
Q6	Drawing a blank in a randomised trial..	38.5	38.5	73.1	0.008	0.327
Q7	It is justified for doctors to carry out a randomised trial when..	57.7	34.6	69.2	0.240	0.369
Q8	If best supportive care or symptom control is one of the randomisation options in the trial, it means that..	61.5	46.2	80.8	0.076	0.190
Q9	Patients are chosen for a trial..	57.7	61.5	100.0	<0.001	0.586
Q10	Taking part in the trial..	69.2	80.8	100.0	0.003	0.476
Q11	You can leave a trial..	61.5	84.6	100.0	<0.001	0.328
Q12	If you do not want to take part in a trial..	53.8	88.5	100.0	<0.001	0.405
Q13	Doctors involved in clinical research trials/studies... (financial incentives)	53.8	53.8	65.4	0.413	0.313

An overall questionnaire score was constructed (the percentage of correct answers out of 13), and the distribution of this is illustrated in Figure 7.4. The difference between the nurse and the patient groups is highly statistically significant (U=115.5, z=-5.935, p<0.001); the difference between the patient groups is not (U=273, z=-1.199, p=0.231).

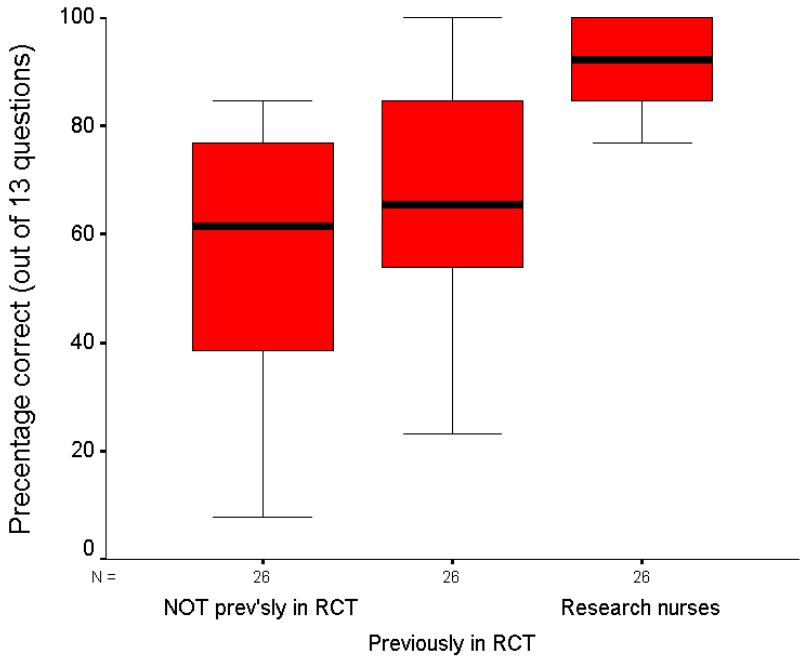

Figure 7.4. Patients' and nurses' percentage scores based on all 13 questions

Table 7.2 also shows the corrected item total correlation between individual questions and the overall questionnaire score; for some questions this is quite low (<0.4) indicating that these questions have poor convergent reliability. Despite this, the overall questionnaire score has a high Cronbach's alpha of 0.77 (95% confidence interval (CI) 0.69-0.84). The questions with poor convergent reliability are also those that tend to discriminate less well between the 3 groups.

A new questionnaire score was therefore constructed using the 6 questions that had item total correlations greater than 0.4; the distribution of this new score is shown in Figure 7.5. The differences between the nurse and the patient groups are still highly statistically significant (U=117, z=-6.249, p<0.001) and the difference between the patient groups is now also statistically significant (U=220, z=-2.206, p=0.027). Cronbach's alpha for the new score is 0.78 (95% ci 0.70-0.85).

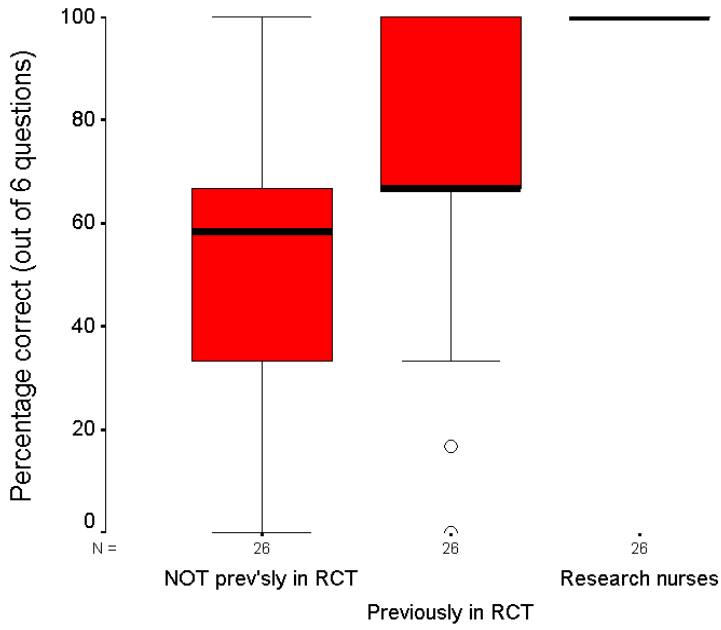

Figure 7.5. Patients' and nurses' percentage scores based on 6 questions with corrected item total correlations >0.4

Both questionnaire scores demonstrated a strong positive association with educational level (whole questionnaire score r_s=0.542 [p<0.001], 6 question score r_s=0.635 [p<0.001]). Both questionnaire scores demonstrated a moderate negative association with deprivation category. Whole questionnaire score r_s=-0.317 [p=0.005]; 6 question score r_s=-0.346 [p=0.002]. The observed association with the 6 question score is stronger than that with the whole questionnaire for both educational level and deprivation category.

7.5.6.3 Acceptability of the questionnaire

Patients and nurses were asked how long it took them to complete the questionnaire, and for their comments in relation to format and clarity. Their responses are shown in Table 7.3., along with the percentage of patients who were happy with the format and clarity. Those who did not feel that the questionnaire was clear, or who did not like the format, gave specific comments on how they felt it could be improved. The majority of comments came from the research nurses, but all groups focussed mainly on wording and

terminology in a few specific questions. Both nurses and patients found question 6, which focussed on explaining placebo-controlled trials and the concept of randomisation, particularly problematic. This question was considered unclear, ambiguous and difficult to understand. Question 8 discussed 'supportive care' as one of the randomisation options in a trial, and, although some of the non-cancer nurses were unsure of the meaning of this term, the majority answered the question correctly.

Table 7.3. Patient acceptability of knowledge questionnaire (Questionnaire: Patient Understanding of Research)

	Time to Complete (mins)		**Clarity** (numbers who agreed)				**Format** (numbers who liked)			
	Mean	Range	Yes	No	N/S	N/R	Yes	No	N/S	N/R
Patients (Previous RCT)	8.8	5-20	22	3	1	0	21	2	3	0
Patients (No previous RCT)	10.6	5-20	18	2	3	3	16	2	5	3
Research Nurses	8.8	5-20	17	6	3	0	20	3	3	0

N/S = Not sure, N/R = No response
Median time to complete for all was 10 minutes

7.5.7 Discussion

This study focussed on the development and testing of a new tool to assess patient understanding of randomised clinical trials in the cancer setting. The development phase was multi-professional, involving experts whose contribution and breadth of expertise strengthened the work. Patient involvement in the development phase, as well as in the testing of the tool, was invaluable: patients in the study generally found the tool user-friendly.

Recruitment was good, and the study generated much interest among both patients and staff, which provided good preparation for the main study. Patients participating in the QD study were from the same patient population that were involved in the main study of the

intervention. They had three of the most common cancer diagnoses - lung, breast and colorectal cancer - with a typical mean age and range. Nurses had a good working knowledge of randomised trials, as would be expected, and came from a wide range of specialties.

Results of the testing phase revealed a number of useful areas for further development, in addition to providing information on reliability and acceptability of the tool within the cancer setting. The questionnaire was found to be acceptable to patients in terms of time taken to complete, format and content; and useful suggestions were given for minor changes to improve clarity.

In the nurses group, there were no obvious differences between specialties, except in some of the verbatim comments in the questionnaire assessing acceptability. For example, cancer research nurses appeared to be more familiar with some of the wording in one of the questions (Q8) around palliative care trials, specifically the term 'supportive care'. Interestingly, patients did not comment on the term, which may have been because many were familiar with it, or because for some it was not relevant. The purpose of this question was to assess the principle of randomisation, where supportive care was one of the treatment options, rather than to assess an understanding of the term itself. This could explain why the majority of nurses answered the question correctly, despite claiming not to understand the term.

Although the general questions setting the scene in relation to clinical trials (Q1 and Q4) had poor convergent reliability, it was agreed to retain these questions for the main study, in order to frame the questionnaire and introduce the issues to patients. Similarly Q11, which also had poor convergent reliability, was retained as it provides information on a key aspect of patients' understanding: withdrawal from a clinical trial.

The questionnaire discriminated well between patients and nurses, with a very clear difference (as would be expected) between the nurse and patient groups in relation to their understanding about randomised clinical trials. Nurses were much more knowledgeable. It is interesting to note that, although patients who had previous experience of taking part in a randomised trial had slightly higher scores than comparable patients who had not taken part previously in a trial, this was not statistically significant in the initial 13-item scale; however, it was significant when the scale was adjusted to exclude individual questions with poor convergent reliability. If patients taking part in clinical trials had the relevant knowledge, and if they understood more about clinical trials before agreeing to take part, one would expect there to be a clear difference between the two patient groups. However, it could be that the initial scale was not sensitive enough to detect any difference, owing to problems with reliability of some of the questions; or it could be that there is no significant difference between the patient groups as a consequence of the problems and challenges of informing patients adequately about clinical trials, as already discussed. This emphasises the importance of trying to address these issues.

As would be expected, the questionnaire demonstrated a positive association with education level and a negative association with deprivation category. This is consistent with other studies which have shown that better educated patients and those in a higher social class have higher levels of knowledge or understanding of research (e.g. Hietanen *et al*. 2000; Kruse *et al*. 2000; Ellis *et al*. 2001; Joffe *et al*. 2001a).

The internal consistency of the questionnaire as assessed by Cronbach's alpha was acceptable at 0.77. As already discussed, one question (Q6) was found to be problematic by all 3 groups in the sample, in addition to having poor convergent reliability. When the results were analysed again, omitting this question, internal consistency was not reduced, and so this question was removed completely prior to the main study.

Some individual questions correlated better than others with the total scale, and minor changes, as suggested by study participants, were made to the wording of six of the questions (Q2, Q3, Q4, Q7, Q8 and Q13), four of which had poor convergent reliability (Q4, Q7, Q8 and Q13). It was anticipated that by incorporating participants' comments and suggestions for minor changes to the wording of individual questions, individual item correlation would be improved. The revised 12-item tool was rechecked for readability, which remained good with a Flesch Reading Ease score of 68.4. This version, which is shown in Appendix 5.8, is the questionnaire used in the main AVPI study.

Content validity was established through the use of experts at the development stage. It was reassessed, following the analysis, through discussion with the same expert group, who were happy with the changes.

7.5.8 Limitations of the study

It must be acknowledged that it was not possible within this study to re-pilot the questionnaire following slight changes to the wording of some of the questions and the removal of Q6. It is recognised that this would have been useful prior to usage in the main study.

7.5.9 Conclusion

Informed consent will always be a challenge in the randomised cancer clinical trial situation, owing to treatment and disease factors that are not amenable to change. However, an awareness of what patients know and understand following information-giving, prior to their decision making, is essential to enable the health professional to provide relevant additional information, and to correct any misconceptions, in order to achieve 'consent with understanding'. Assessing patient understanding in clinical trials is a difficult area for health care professionals. It is particularly challenging in relation to randomised trials, owing to the lack of validated measures available specifically for this

purpose - which led to the development and testing of this new questionnaire. The new questionnaire has been shown to be a reliable, valid and acceptable tool for assessing patient understanding in the randomised cancer trial setting.

CHAPTER EIGHT: RESULTS

8.1 Introduction

This chapter presents the results of the main study. To avoid confusion with the primary endpoint of the study (recruitment to clinical trials), recruitment to this study has already been discussed in detail within the methods chapter. This chapter presents: participant flow through the study; demographics and baseline characteristics; clinical trial refusal rates; knowledge and understanding; anxiety; and clinical trial decision making which includes reasons for accepting and declining a clinical trial, patients' perceptions of the consent process and acceptability of the intervention.

8.2 Participant flow

Figure 8.1 summarises the flow of patients through the AVPI study, according to the standard revised template of the Consolidated Standards of Reporting Trials (CONSORT) diagram, showing the numbers of participants through each stage of a randomised trial (Altman *et al.* 2001). The reasons for exclusion to the study are discussed in detail in Chapter 5. The 'other reasons' for exclusion shown in Figure 8.1 (n=105) include the 98 patients shown in Table 5.1 (Chapter 5), the majority of whom were receiving care and treatment discussions outwith cancer centre (n=85), and it was not practical to include them, as previously discussed; and also 7 patients who consented to the clinical trial the same day as receiving information about it.

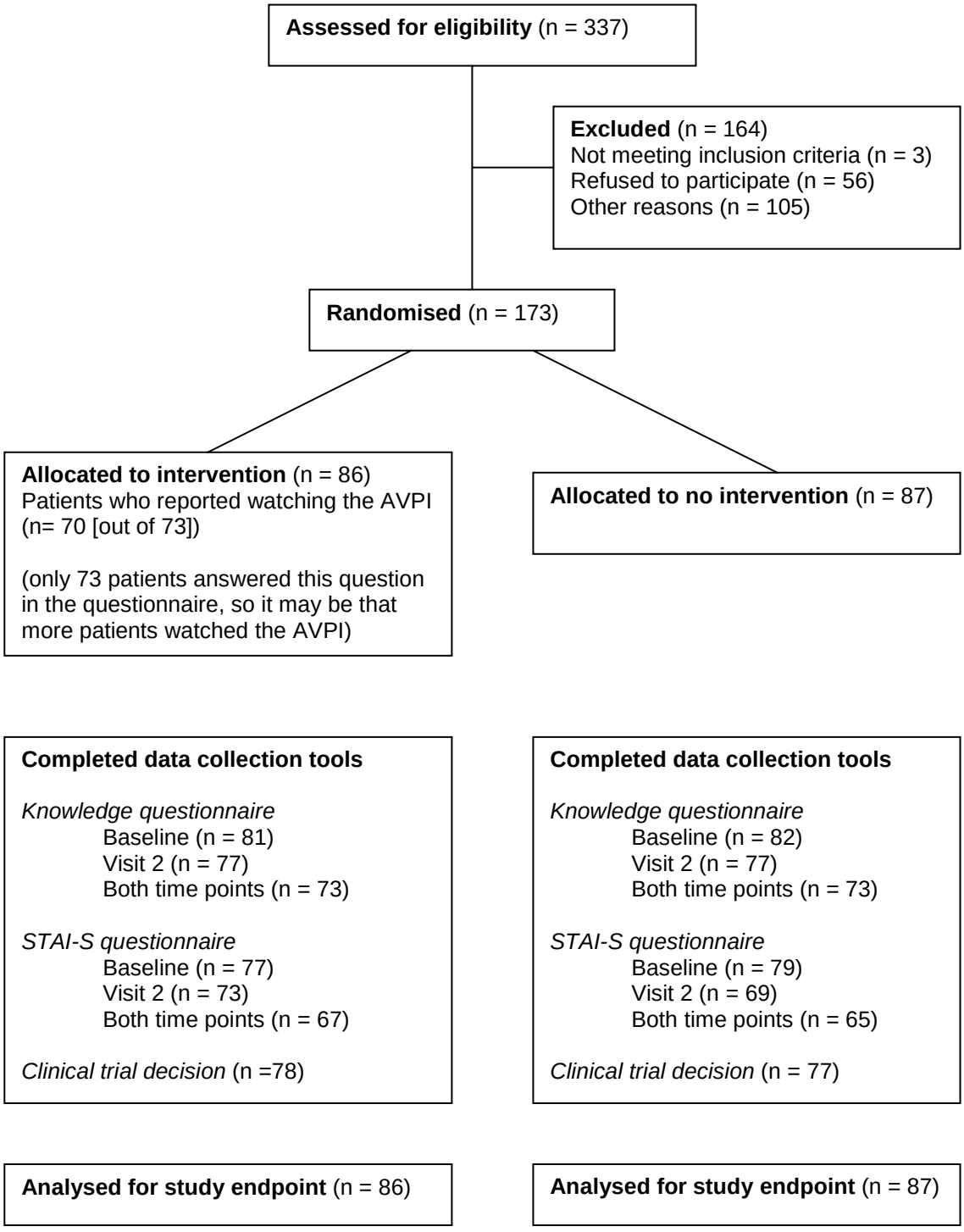

Figure 8.1. Participant flow through the AVPI study

8.3 Demographics and baseline patient characteristics

8.3.1 Patients and trials

Between January 2005 and August 2006, 173 patients were recruited to the study. Patients were entered into a total of 18 different randomised clinical trials during this time, the breakdown of which is shown in Appendix 8.1. As previously discussed in Chapter 5, although the target number was 164, on advice from the statistician 9 extra patients were recruited to allow for the proportion of patients for whom the question of trial entry at visit 2 was no longer applicable, as they were no longer eligible, or where, for administrative reasons, the trial was no longer available. On final review of the study data prior to definitive analysis, the total number of patients recruited to the AVPI study, but not eligible for the clinical trial, or not entered into the clinical trial for reasons other than refusal, was 13. Baseline characteristics of those recruited to the study were well balanced between the arms, as shown in Tables 8.1, 8.2, and 8.3.

It should be noted that information in the categories 'Educational qualifications', 'Previously taken part in research study?', 'Friend/family member been in research study?' and 'Deprivation status', in Table 8.1 is not available for all patients. This is because the data came from the knowledge questionnaire, which was only completed by 163/173 patients at baseline. Another point of note is that this questionnaire was completed twice by patients (at two different time points), so the data about 'Educational qualifications', 'Previously taken part in research study?', 'Friend/family member been in research study?' and 'Deprivation status', were collected twice. This resulted in slight discrepancies in the information that patients gave in these categories. The main question affected was 'Previously taken part in research study?'. It is assumed that when patients ticked 'yes' the second time they completed the questionnaire, they were answering the question within the context of this study. The answers given by patients at baseline were therefore the ones used in the analysis.

Table 8.1. Demographic and baseline patient characteristics

		Study Arm				Overall Total	
		Intervention		No Intervention			
		Col %	Count	Col %	Count	Col %	Count
Gender	F	76.7	66	77.0	67	76.9	133
	M	23.3	20	23.0	20	23.1	40
Group Total		100.0	86	100.0	87	100.0	173
Tumour type	Breast	65.1	56	64.4	56	64.7	112
	Colorectal	31.4	27	32.2	28	31.8	55
	Lung	3.5	3	3.4	3	3.5	6
Group Total		100.0	86	100.0	87	100.0	173
Age group	<50	22.1	19	20.7	18	21.4	37
	50-59	23.3	20	24.1	21	23.7	41
	60-69	39.5	34	37.9	33	38.7	67
	>=70	15.1	13	17.2	15	16.2	28
Group Total		100.0	86	100.0	87	100.0	173
Stage of cancer	Limited	68.6	59	66.7	58	67.6	117
	Advanced	31.4	27	33.3	29	32.4	56
Group Total		100.0	86	100.0	87	100.0	173
Educational qualifications	None	22.2	18	26.3	21	24.2	39
	Below degree level	48.1	39	45.0	36	46.6	75
	Degree level or higher	29.6	24	28.8	23	29.2	47
Group Total		100.0	81	100.0	80	100.0	161
Previously taken part in research study	Yes	8.3	7	15.7	13	12.0	20
	No	91.7	77	84.3	70	88.0	147
Group Total		100.0	84	100.0	83	100.0	167
Friend/family member been in research study	Yes	12.0	10	12.2	10	12.1	20
	No	88.0	73	87.8	72	87.9	145
Group Total		100.0	83	100.0	82	100.0	165
Deprivation status	Affluent	27.4	23	27.6	24	27.5	47
	Middle	46.4	39	37.9	33	42.1	72
	Deprived	26.2	22	34.5	30	30.4	52
Group Total		100.0	84	100.0	87	100.0	171

Of the 173 patients entered into the study, 76.9% were female with 23.1% male. The majority of patients had breast cancer (64.7%), 31.8% had colorectal cancer and 6 patients (3.5%) had a diagnosis of lung cancer. At the beginning of this study, each

randomised trial was identified by the RP and CCN as either a limited or advanced disease trial, (shown in Appendix 5.2). In general, adjuvant trials = limited disease, and trials for metastatic disease = advanced disease. According to this assessment, two thirds of the sample was considered to have limited stage of cancer (67.6%), and one third (32.4%) had advanced cancer.

Almost one quarter of the sample had no educational qualifications (24.2%), with an additional 46.6% having qualifications below degree level. Only 29.2% reported having educational qualifications at degree level or higher. As discussed in Chapter 5, deprivation status was determined according to deprivation categories measured by the Carstairs scores for Scottish postcode sectors (Carstairs and Morris 1991), using data from the 2001 census (McLoone 2004). Each postcode is classed as one of seven categories with categories 1-2 identified as affluent, 3-4 as the middle category and 5-7 as deprived. According to these criteria, 27.5% of patients were classed in this study as affluent, 42.1% in the middle category and 30.4% were considered deprived. There was a wide range of ages from 37 years to 92 years (Table 8.2): 21.4% were less than 50 years old; 23.7% were aged between 50 and 59; 38.7% between 60 and 69; and 16.2% were 70 years of age or older (Table 8.1). The median age of the sample was 60, and the sample was well-balanced between the study arms in terms of age profile.

Table 8.2. Age

		Study Arm	
		Intervention	No Intervention
Age	Maximum	81.00	92.00
	Percentile 75	66.25	68.00
	Median	60.50	60.00
	Percentile 25	52.75	52.00
	Minimum	37.00	38.00
	Valid N	N=86	N=87

Patients were asked about their previous research experience: 12% reported having previously taken part in a research study, and 12.1% reported that a friend or family member had been involved in a research study.

The name of the doctor seeing the patient was recorded for the initial discussion and for the consent visit. On review of the data, this showed that the intervention and no-intervention groups were similar at baseline in terms of seniority of doctor involved in the interaction. In the intervention group, 45 patients saw a consultant and 41 saw a registrar; in the no-intervention group, 44 saw a consultant and 43 saw a registrar. In terms of the patients who consented to a clinical trial, this was also similar in terms of the seniority of doctor involved in the interaction; 59 patients who saw a consultant, and 65 who saw a registrar said yes to a clinical trial (the 13 patients who became ineligible, or were not included in the trial for some other reason as identified in Section 8.4.1 were excluded from this review). Only 55 patients saw the same doctor at both visits. Of these, 41 consented to a trial, 4 refused and 10 were ineligible/not entered (so the decision was not relevant). For the eligible patients seeing the same doctor at both visits, this equates to 91% consenting to the trial (41/45) and 9% refusing (4/45).

Table 8.3 shows the numbers of patients per study arm in terms of the parent clinical trial. The description of the parent trial in the table is taken from each individual protocol title. This table lists the trials according to the numbers of patients in the AVPI study who were being considered for that specific trial (highest numbers first). The top three largest recruiting trials into the AVPI study were all in breast cancer and constituted 59% of the total AVPI study sample. The largest single recruiting trial was of hormone therapy (27.2%) followed by a radiotherapy trial (17.3%), and then a chemotherapy trial (14.5%). Following this, the fourth and fifth ranking top recruiters were chemotherapy trials in colorectal cancer at 9.8% and 8.1%.

Table 8.3. Characteristics according to clinical trial

Study Code and Title		Study Arm				Overall Total	
		Intervention		No Intervention			
		Col %	Count	Col %	Count	Col %	Count
B 88	A phase III randomised controlled trial to determine whether adjuvant Zoledronic acid reduced recurrence in patients with high risk localised breast cancer	27.9	24	26.4	23	27.2	47
B 99	Fast prospective randomised clinical trial testing 5GY and 6GY fractions of whole breast radiotherapy in terms of late normal tissue responses and tumour control	17.4	15	17.2	15	17.3	30
B 104	Trial of accelerated adjuvant chemotherapy with Capecitabine in early breast cancer	15.1	13	13.8	12	14.5	25
GI 103	A phase III trial comparing either continuous chemotherapy plus Cetuximab or intermittent chemotherapy with standard continuous palliative combination chemotherapy with Oxaliplatin and a fluoropyrimidine in first line treatment of metastatic colorectal cancer	9.3	8	10.3	9	9.8	17
GI 101	Open randomised controlled multi-centre phase III study comparing 5FU/FA plus Irinotecan plus Cetuximab vs. 5FU/FA plus Irinotecan as first line treatment for epidermal growth factor receptor-expressing metastatic colorectal cancer	8.1	7	8.0	7	8.1	14
GI 104	A randomised three arm multinational phase III study to investigate Bevacizumab in combination with either intermittent Capecitabine plus Oxaliplatin or a 5 FU/FA with Oxaliplatin vs. Folfox 4 regimen alone as adjuvant chemotherapy in colon cancer	7.0	6	5.7	5	6.4	11
B 91	A randomised phase II study of loading dose Ibandronate schedules in patients with bone metastases from breast cancer	3.5	3	3.4	3	3.5	6
GI 117	A multi-centre open label parallel group randomised phase IIB clinical trial to evaluate the safety and efficacy of co-factor and 5FU vs. Leucovorin and 5FU in subjects with metastatic colorectal carcinoma	2.3	2	3.4	3	2.9	5
GI 119	A multi-centre randomised double blind placebo controlled phase III study of the efficacy of Xaliproden in preventing the neurotoxicity of Oxaliplatin in first line treatment of patients with metastatic colorectal cancer treated with Oxaliplatin/5FU/FA	2.3	2	3.4	3	2.9	5
B 90	Post operative radiotherapy in minimum risk elderly breast cancer	1.2	1	3.4	3	2.3	4
L 76	Phase III randomised study of TLK286 vs. Gefitinib as third line therapy in locally advanced or metastatic Non Small Cell Lung Cancer (NSCLC)	1.2	1	1.1	1	1.2	2

Study Code and Title		Study Arm				Overall Total	
		Intervention		No Intervention			
		Col %	Count	Col %	Count	Col %	Count
L 73	A phase III randomised double blind placebo controlled trial of Carboplatin and Etoposide with or without Thalidomide in Small Cell Lung Cancer (SCLC)	0.0	0	1.1	1	0.6	1
GI 95	A phase III randomised open label multi-centre study of Irinotecan and Cetuximab vs. Irinotecan as second line treatment in patients with metastatic EGFR positive colorectal carcinoma	1.2	1	0.0	0	0.6	1
L 75	A randomised controlled trial of active symptom control with or without chemotherapy in the treatment of mesothelioma	1.2	1	0.0	0	0.6	1
L 78	A randomised phase III study of two doses of Alimta with locally advanced or metastatic NSCLC who have failed prior platinum containing chemotherapy	0.0	0	1.1	1	0.6	1
B 126	Randomised trial testing observation (no radiotherapy) against radiotherapy in women with low risk completely excised ER positive ductal carcinoma in situ (DCIS) of the breast on adjuvant endocrine therapy	0.0	0	1.1	1	0.6	1
GI 108	Chemotherapy or no chemotherapy in clear margins after neoadjuvant chemoradiation in locally advanced rectal cancer. A randomised phase III trial of control vs. Capecitabine plus Oxaliplatin	1.2	1	0.0	0	0.6	1
L84	A BTOG phase III trial of Gemcitabine plus Cisplatin at 80mg/m2 vs. Gemcitabine plus Cisplatin 50mg/m2 vs. Gemcitabine plus Carboplatin AUC6 in stage IIIb/IV NSCLC cancer	1.2	1	0.0	0	0.6	1
Group Total		100	86	100	87	100	173

8.3.2 Type of intervention

Table 8.4. Interventions used by patients in the study

		Col %	Count
Type of intervention	CD	1.2	1
	DVD	55.8	48
	Video	43.0	37
Group Total		100.0	86

As stated earlier, 86 patients were randomised to the intervention arm of the study. The majority of them (55.8%, 48/86), chose DVD as their preferred medium for the intervention with 43% (37/86) choosing video and 1.2% (1/86) CD ROM as shown in Table 8.4.

8.4 Primary endpoint – clinical trial refusal rate

8.4.1 Refusal rate/clinical trial entry

The primary endpoint for the study was the proportion of patients refusing clinical trial entry. The logistic regression, using the likelihood ratio method for deriving the p value in an intention-to-treat analysis, gave an estimated odds ratio for refusal (intervention/no intervention) of 1.19 (p=0.661, 95% ci 0.55-2.58). All patients were included, and adjustments were made for baseline minimisation factors of age and gender. Although patient refusal was the main reason that patients did not enter clinical trials, 3.5% of patients (n=6) became ineligible for the clinical trial and 4% (n=7) did not enter for 'other' reasons. These were mainly for reasons of disease progression as shown in Table 8.5.

Table 8.5. 'Other' reasons that patients were not entered into clinical trials

Patient ID	Study Arm	Entered into trial?	Other reason for not entering clinical trial
17	Intervention	No, other	TREATMENT OPTIONS CHANGED
24	Intervention	No, other	TREATMENT OPTIONS CHANGED: DISEASE PROGRESSION
26	No intervention	No, other	UNKNOWN: PATIENT DID NOT ATTEND X 2 CLINIC APPOINTMENTS, & NO FURTHER APPOINTMENTS MADE.
40	No intervention	No, other	TREATMENT OPTIONS CHANGED: DISEASE PROGRESSION
51	Intervention	No, other	TREATMENT OPTIONS CHANGED: RAPID DISEASE PROGRESSION
101	Intervention	No, other	DRUGS NOT YET AVAILABLE FOR STUDY TO GO AHEAD
119	Intervention	No, other	CLINICIANS OPTED FOR STANDARD TREATMENT BECAUSE OF PATIENT'S ANXIETY & LEVEL OF COMPREHENSION

Excluding patients who were either not eligible for the trial, or could not enter for some other reason, gives an odds ratio for refusal of 1.19 (p=0.664, 95% ci 0.54-2.60). The small odds ratio reflects the small absolute difference between the two groups (2.6% refusal, 3.8% acceptance). Table 8.6 summarises the proportion of patients who subsequently entered into clinical trials. The clinical trial refusal rate in this study of approximately 20% is substantially lower than the clinical trial refusal rate assumed when the study was designed (40%), an assumption which was based on previous literature as discussed in Chapter 2.

Table 8.6. Proportion of patients that subsequently entered into clinical trials

		Study Arm				Group Total	
		Intervention		No Intervention		Col %	Count
		Col %	Count	Col %	Count		
Entered into trial?	Yes	72.1	62	75.9	66	74.0	128
	No, refused	19.8	17	17.2	15	18.5	32
	No, not eligible	2.3	2	4.6	4	3.5	6
	No, other	5.8	5	2.3	2	4.0	7
Group Total		100.0	86	100.0	87	100.0	173

8.4.2 Association between demographics/patient characteristics and clinical trial entry

The association between demographic/baseline patient characteristics of the group and clinical trial entry is shown in Table 8.7; the p-values are from Pearson's Chi-square test (exact version). This was based on the 128 patients who consented to a clinical trial, and the 32 patients who refused. Slightly smaller numbers were used for the categories where data was taken from the knowledge questionnaire (specified in Section 8.3.1). There were no statistically significant (p>0.05) associations between any of the pre-treatment patient characteristics as reported in Table 8.1 and clinical trial entry, i.e. clinical trial entry was not influenced by tumour type, stage of cancer, age, educational qualifications or previous research experience. The only suggestion of an association was with deprivation status, with more patients in the middle category consenting to a trial, followed by deprived, with

affluent patients having the lowest consent rates. However, the level of statistical significance is very modest (p=0.046) and perhaps not too much weight should be attached to it. Multiple factors are being examined in the table, which increases the possibility of a false positive when using conventional levels of statistical significance. None of the variables had predictive value for trial entry when entered in a logistic regression model with the study arm; nor was any statistically significant interaction between the study arm and these variables detected.

Table 8.7. Association between demographics/patient characteristics and trial entry

		Patients entered into trial	
		Col %	Count/Total
Tumour type (p=0.408)	Breast	80.6	87/108
	Colorectal	76.1	35/46
	Lung	100.0	6/6
Stage of cancer (p=0.194)	Limited	77.2	88/114
	Advanced	87.0	40/46
Gender (p=0.231)	F	82.4	103/125
	M	71.4	25/35
Age group (p=0.831)	<50	84.8	28/33
	50-59	80.0	32/40
	60-69	79.4	50/63
	≥ 70	75.0	18/24
Deprivation status (p=0.046)	Affluent	68.2	30/44
	Middle	87.7	57/65
	Deprived	79.6	39/49
Educational qualifications (p=0.928)	None	76.3	29/37
	Below degree level	82.1	55/67
	Degree level or higher	81.8	36/44
Previously taken part in research study (p=0.371)	Yes	89.5	17/19
	No	79.3	107/135
Friend/family member been in research study (p=0.767)	Yes	84.2	16/19
	No	79.7	106/133

8.5 Knowledge/understanding

8.5.1 Knowledge questionnaire

For ease of reporting, the questionnaire used to measure knowledge/understanding (Questionnaire: Patient Understanding of Research) is referred to as a knowledge questionnaire (see Chapter 3 for discussion on why the terms are used synonymously). Seventy-three patients in each arm completed the questionnaire at both time points. Cronbach's alpha was used to estimate the internal consistency of the questionnaire at the pre and post time points, which was shown to be high at 0.773 (pre) and 0.791 (post).

The change in knowledge score from baseline was compared between the two groups using the Mann-Whitney U test. (The knowledge score is the number of correctly answered questions expressed as a percentage mark.) The difference in the change in percentage score is statistically significant between the treatment arms (U=2029, z=2.528, p=0.011, p=0.0072 [multiple imputation]) with improvements in the knowledge score tending to be higher in the intervention arm. The distribution of the percentage knowledge score for these patients is shown in Figure 8.2. Figure 8.2 is a box and whisker plot where the bar represents the median, the upper line of the box is the 75th percentile and the lower line of the box is the 25th percentile; 50% of the data is therefore inside the box. The tails represent the minimum and maximum values, excluding outliers. The circles and stars are individual outlying data points, with the circles being slightly outwith the tails and the stars much further away. All box and whisker plots shown in this chapter follow the same format.

In Figure 8.2, the median knowledge scores prior to the intervention are high at just over 80% with a wide spread, especially when compared to the post intervention scores where the spread is much less and the data is more concentrated. A similar trend is seen in the no-intervention arm although this does not appear to increase as much and the decrease in spread is less.

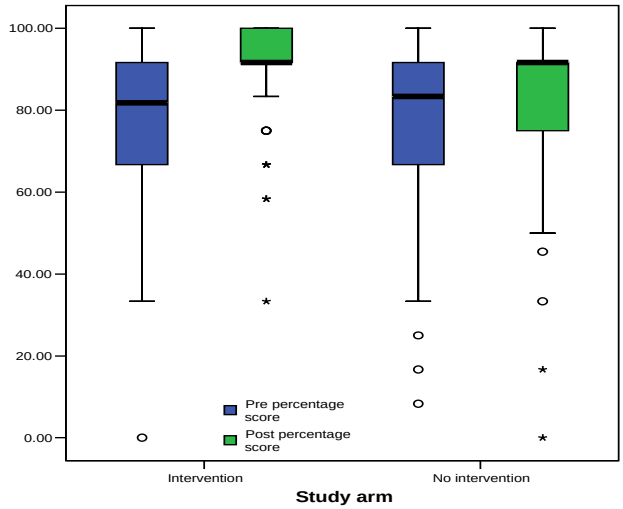

Figure 8.2. Distribution of percentage knowledge score for patients completing questionnaires at both time points

The post knowledge score minus the pre score was calculated for every patient. The statistical significance of within-patient changes in knowledge score in each group was assessed using the Wilcoxon signed-rank sum test. Figure 8.3 shows the within-patient differences in this score between the assessment time points, and Table 8.8 shows the distribution of the within-patient changes. In both arms there is a statistically significant improvement in score from pre to post (z=-0.5773 for intervention group, z=-4.004 for no-intervention group, p<0.001 and p<0.001 [multiple imputation]. The median within-patient change is approximately the same, however, people above the median are increasing more. The 75th percentile and the maximum score are both higher in the intervention arm.

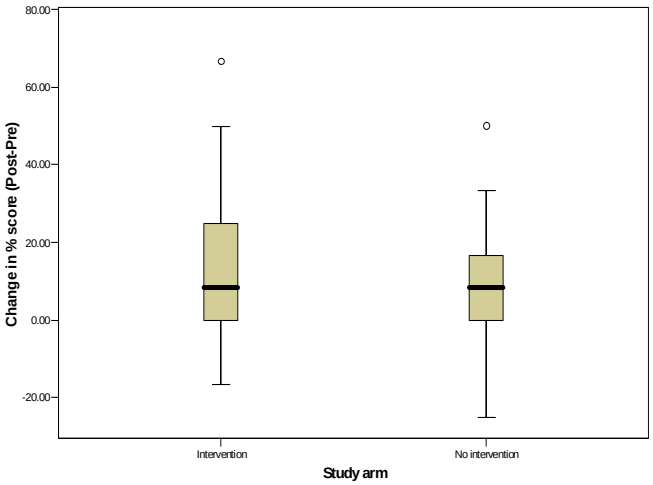

Figure 8.3. Within-patient differences in knowledge score between the two time points

Table 8.8. Distribution of the within-patient changes

		Study arm	
		Intervention	No Intervention
Change in %score (Post-Pre)	Maximum	66.67	50.00
	Percentile 75	25.00	16.67
	Median	8.33	8.33
	Percentile 25	0.00	0.00
	Minimum	-16.67	-25.00
	Valid N	N=73	N=73

Change in knowledge level (post score minus the pre score) was considered in relation to trial entry. There was no evidence that a change in knowledge level was associated with the probability of refusing clinical trial entry, as shown in Figure 8.4.

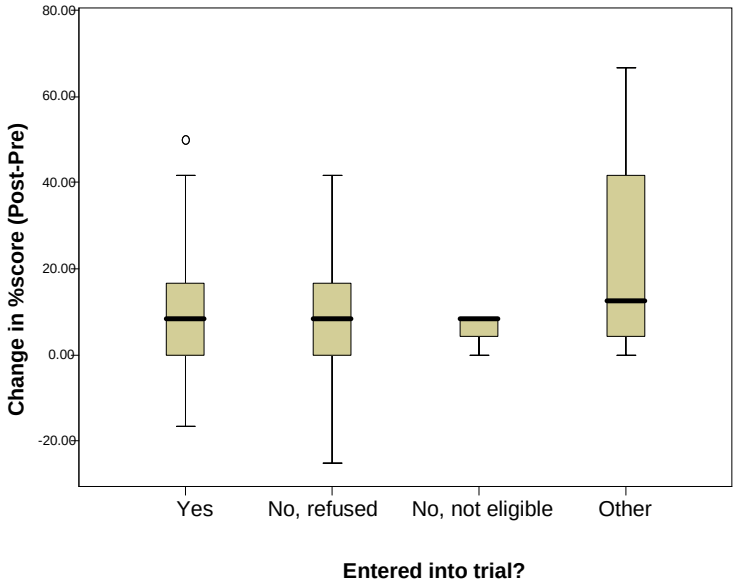

Figure 8.4. Change in knowledge level and clinical trial entry

Knowledge was also examined at the individual question level. A reminder of the content of individual questions is shown in Table 8.9, since question numbers are referred to in the subsequent tables.

Table 8.9. Questions in knowledge questionnaire

Q1	**The main reason for carrying out research with patients** …. is to improve current treatments.
Q2	**Research with patients is carried out** …. when a new treatment is potentially better than the usual, standard one.
Q3	**In a *randomised* clinical research trial/study**…the treatment of the individual patient is decided by chance.
Q4	**The main aim of a randomised trial is to….** find out if a new treatment is better than the commonly used treatment.
Q5	**When a trial is "randomised" …** you have exactly the same chance of receiving the new treatment (or not receiving it), as any other patient taking part.
Q6	**It is justified for doctors to carry out a randomised trial…** when there is genuine uncertainty from expert cancer doctors about which treatment is best.
Q7	**If "best supportive care" or "symptom control" is one of the randomisation options in the trial, it means that…**supportive care or symptom control is the standard usual treatment for that type and stage of cancer.
Q8	**Patients are chosen for a trial…**if they fit the guidelines for selecting patients (developed from previous research work).
Q9	**Taking part in the trial…**is voluntary - there are no conditions.
Q10	**You can leave a trial…**at any time without giving a reason
Q11	**If you do not want to take part in a trial…**you will be offered the treatment which is currently considered the standard treatment for your cancer.
Q12	**Doctors involved in clinical research trials/studies…**do not receive any financial incentives from drug companies.

For each of the two time points, the percentage of patients answering the question correctly was determined and this is listed per question in Table 8.10.

Table 8.10. Percentage correct for each question in the knowledge questionnaire at each time point

		Study Arm							
		Intervention				No Intervention			
		Assessment time				Assessment time			
		Pre		Post		Pre		Post	
		Col %	Count	Col %	Count	Col %	Count	Col %	Count
Q1	Wrong	5.9	5	5.0	4	4.7	4	6.3	5
	Right	94.1	80	95.0	76	95.3	82	93.7	74
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q2	Wrong	14.1	12	5.0	4	19.8	17	10.1	8
	Right	85.9	73	95.0	76	80.2	69	89.9	71
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q3	Wrong	43.5	37	18.8	15	43.0	37	19.0	15
	Right	56.5	48	81.3	65	57.0	49	81.0	64
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q4	Wrong	8.2	7	1.3	1	5.8	5	10.1	8
	Right	91.8	78	98.8	79	94.2	81	89.9	71
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q5	Wrong	27.1	23	13.8	11	26.7	23	15.2	12
	Right	72.9	62	86.3	69	73.3	63	84.8	67
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q6	Wrong	47.1	40	25.0	20	43.0	37	36.7	29
	Right	52.9	45	75.0	60	57.0	49	63.3	50
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q7	Wrong	42.4	36	31.3	25	64.0	55	45.6	36
	Right	57.6	49	68.8	55	36.0	31	54.4	43
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q8	Wrong	23.5	20	10.0	8	25.6	22	20.3	16
	Right	76.5	65	90.0	72	74.4	64	79.7	63
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q9	Wrong	11.8	10	7.5	6	12.8	11	16.5	13
	Right	88.2	75	92.5	74	87.2	75	83.5	66
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q10	Wrong	23.5	20	6.3	5	19.8	17	12.7	10
	Right	76.5	65	93.8	75	80.2	69	87.3	69
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q11	Wrong	20.0	17	3.8	3	19.8	17	13.9	11
	Right	80.0	68	96.3	77	80.2	69	86.1	68
Total		100.0	85	100.0	80	100.0	86	100.0	79
Q12	Wrong	38.8	33	12.5	10	41.9	36	26.6	21
	Right	61.2	52	87.5	70	58.1	50	73.4	58
Total		100.0	85	100.0	80	100.0	86	100.0	79

There is a statistically significant imbalance between the study arms in the proportion of patients getting question 7 correct at baseline (57.6% correct on the 'intervention' arm, as compared to 36.0% correct on the 'no-intervention' arm, p=0.005). This question aimed to

assess the understanding of randomisation by applying the principles in a supportive care setting (see Q7 in Table 8.9). There is no explanation for this, and it may be ascribed to natural variability giving rise to a false positive result due to the number of factors being assessed within this table. At the level of individual questions there is no statistically significant difference between the study arms in the change in the proportion of patients answering correctly from pre to post, as shown in Table 8.11.

Table 8.11. Comparison of change between study arms, per individual question

	P-values for pre versus post comparison (McNemar)		P-value for the comparison of change from pre to post between study arms (Mann-Whitney U test)
	Intervention	No Intervention	
Q1	1.000	1.000	0.594
Q2	0.039	0.039	0.784
Q3	<0.001	<0.001	0.733
Q4	0.125	0.727	0.073
Q5	0.077	0.096	0.969
Q6	0.007	0.523	0.086
Q7	0.189	0.008	0.211
Q8	0.021	0.332	0.400
Q9	0.344	0.804	0.245
Q10	<0.001	0.118	0.157
Q11	0.004	0.424	0.145
Q12	<0.001	0.019	0.112

Only Q2, Q3 and Q12 show statistically significant improvements in both study arms. In the intervention arm, Q6, 8, 10 and 11 also show statistically significant improvements.

8.5.2 Demographics/patient characteristics and knowledge scores

8.5.2.1 Association of demographics/patient characteristics and baseline knowledge score

The graphs in Figure 8.5 show the association between knowledge scores at baseline and patient characteristics (gender, age, tumour type, stage, education status, deprivation status and previous research experience). This was assessed using the Mann-Whitney U test (2 categories), Kruskal Wallis test (>2 categories) or, for age, Spearman's rank correlation. The non-parametric p-values for each association are given on the graphs. Age (p=0.004), stage (p<0.001), friend/family member in research study (p=0.015),

educational qualifications (p<0.001) and tumour type (p=0.028) all have statistically significant associations with knowledge at baseline.

Patients with limited disease had higher baseline knowledge scores than patients with advanced disease. Patients with lung cancer had less knowledge at baseline as compared to patients with breast and colorectal cancer. For education status, the better educated that patients reported themselves to be, the higher their knowledge scores at baseline. If patients reported having previous experience of a friend or family member taking part in research, their baseline knowledge scores were higher, although this trend was not shown for patients who had themselves previously taken part in a research study. In the age diagram in Figure 8.5, patients represent individual points (circles) for age and baseline knowledge scores. The line is a smoothed non-parametric indicator of the average association between age and baseline knowledge. The line shows a statistically significant association using Spearman's rank correlation. As patients' age increases, knowledge goes down. The box and whisker plots for gender and deprivation status show that neither was associated with baseline knowledge scores.

A multivariate logistic regression (knowledge score dichotomized at the median, variables selected by a forward-stepwise method) was undertaken to examine which patient characteristics were independently associated with baseline knowledge. The outcome of this analysis indicated that education and stage of cancer (limited versus advanced) independently were associated with baseline knowledge. This is illustrated in Figure 8.6. Patients who were better educated had higher levels of knowledge (p=0.001). Patients who had limited stage of cancer had higher baseline knowledge when compared with patients with advanced cancer (p<0.001). Within each stage of cancer, knowledge increases across the educational group. When comparing each level of educational qualifications, the advanced cancer group had lower knowledge. This confirms that each has independent influence.

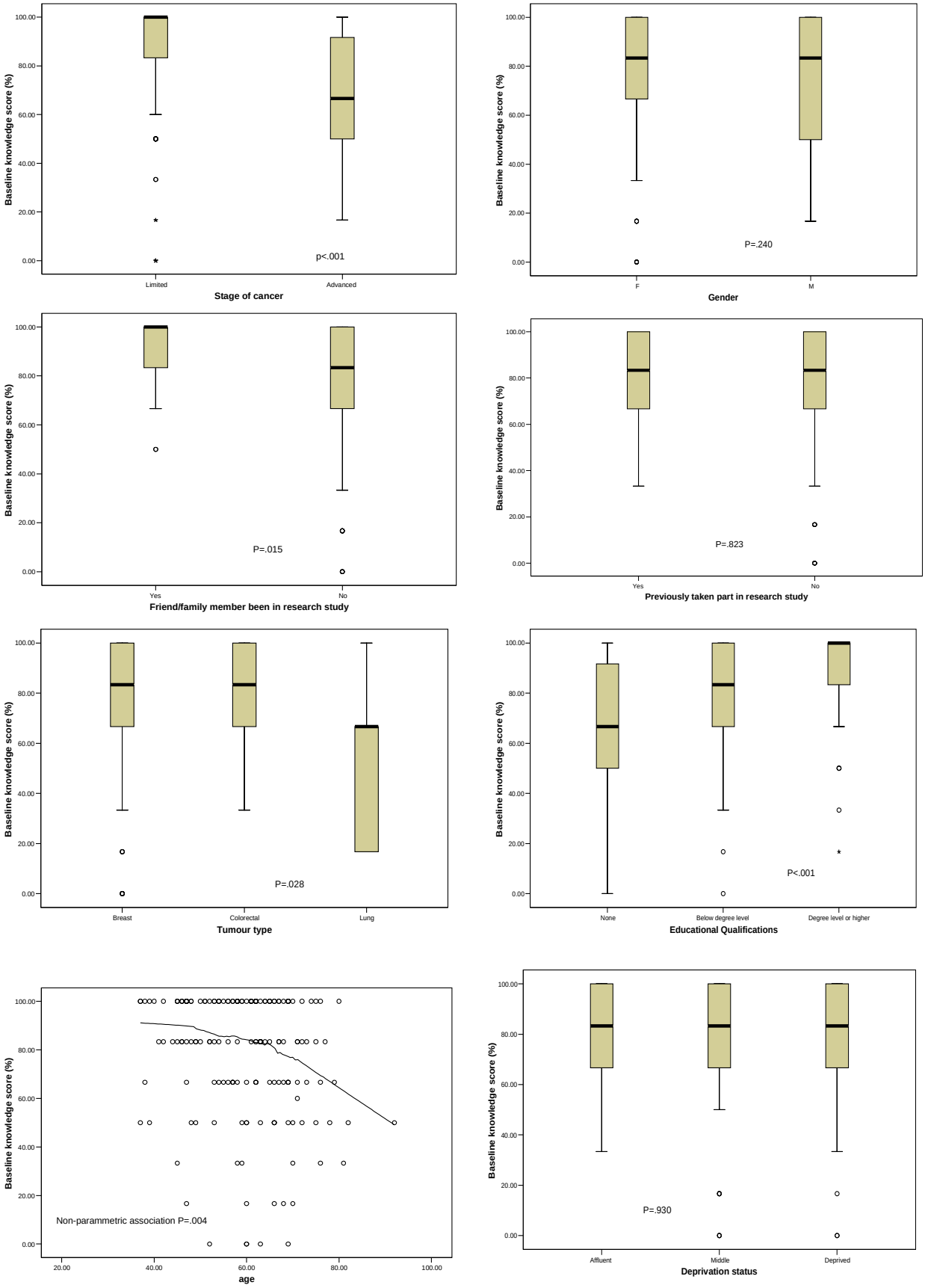

Figure 8.5. Association between various patient characteristics and knowledge score at baseline

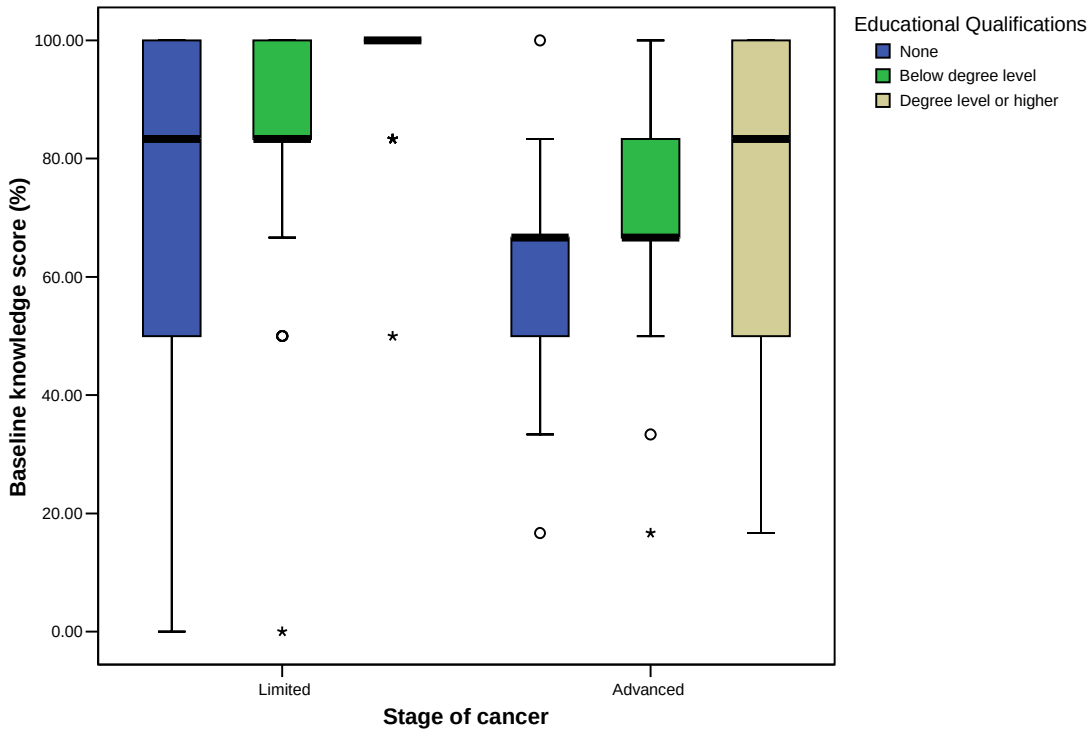

Figure 8.6. Association of education and stage of cancer with baseline knowledge

8.5.2.2 Association of demographics/patient characteristics and change in knowledge score

The association between demographics/patient characteristics and change in knowledge score was examined in the context of a linear model incorporating the study arm; the dependence of the prognostic value on the study arm was assessed by incorporating the appropriate interaction term. None of the above variables had additional predictive value for change in knowledge score over study arm; nor was any statistically significant interaction between the study arm and these variables detected. There was no indication that the effect of the study arm was influenced by any of the baseline characteristics.

8.6 Anxiety

8.6.1 STAI-S questionnaire

In the intervention arm, 77 patients completed the baseline questionnaire and 73 the follow-up questionnaire; the corresponding figures in the no-intervention arm are 79 and

69. Sixty-seven patients in the intervention arm completed the anxiety questionnaires at *both* time points. In the no-intervention arm the number was 65. The change in anxiety score from baseline was compared between the two groups, using the Mann-Whitney U test. There is a statistically significant difference in anxiety score pre-treatment (U=2272, z=-2.727, p=0.006) with patients in the intervention arm appearing to be more anxious than those in the no-intervention arm. The distribution of the anxiety score is shown in Figure 8.7. For data obtained from the STAI-S scale, the highest possible score (which means high levels of anxiety) is 80 and the lowest possible (no anxiety) is 20. In the intervention group, the median anxiety pre-score is 44 and the post score 37, whereas the median appears to be almost the same (38 pre, 39 post) for both pre and post testing in the no-intervention group. The spread is wide in both groups in the pre-test where almost the full range of possible scores is seen (20-78 and 20-79), with slightly less spread at the post-test in both groups

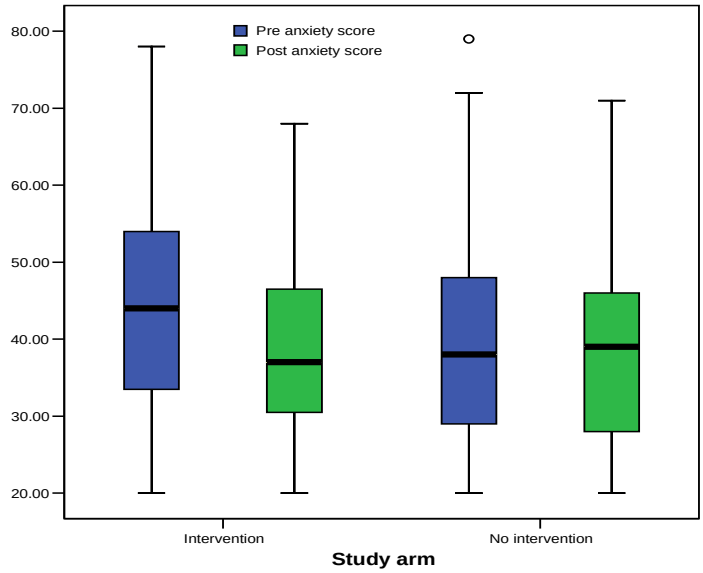

Figure 8.7. Distribution of percentage anxiety score for patients completing questionnaires at both time points

The change in anxiety score between the arms is statistically significant (U=1380, z=-3.634, p<0.001 and p=0.011 [multiple imputation]) with anxiety improving in the

intervention arm more than in the no-intervention arm. The estimated difference in the median anxiety change score between the groups is –4.6 (95% ci –7.0 to –2.0). Because of the elevated anxiety in the intervention group pre-treatment, this means that anxiety levels in the two groups are similar at the 'post' assessment. The statistical significance of within-patient changes in anxiety score in each group was assessed using the Wilcoxon signed-rank sum test. The change from pre to post within the intervention group is highly statistically significant (z=-4.851, p<0.001 and p<0.001 [multiple imputation]); there was no statistically significant change in the no-intervention group (z=-0.626, p=0.531 and p=0.408 [multiple imputation]). Figure 8.8 illustrates the distribution of the within-patient anxiety scores between assessment time points.

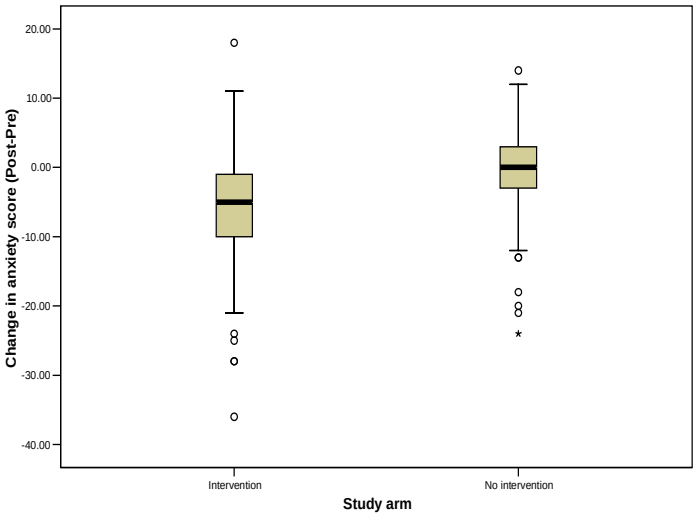

Figure 8.8. Within-patient differences in anxiety between both time points

8.6.2 Association between demographics/patient characteristics and anxiety

The association between demographics/patient characteristics and anxiety was assessed using the Mann-Whitney U test (2 categories), Kruskal Wallis test (>2 categories) or, for age, Spearman's rank correlation. There were no statistically significant associations between baseline anxiety and any of the demographics/patient characteristics. This is shown in Table 8.12.

Table 8.12. Association between demographics/patient characteristics and anxiety at baseline

Characteristic	**P-value**
Tumour type	0.216
Stage	0.873
Gender	0.066
Deprivation status	0.848
Educational qualifications	0.083
Previously taken part in a research study	0.562
Friend/family member been in research study	0.551
Age	0.171

The association between demographics/patient characteristics and change in anxiety score was examined in the context of a linear model incorporating the study arm; the dependence of the prognostic value on the study arm was assessed by incorporating the appropriate interaction term. None of the demographic or pretreatment patient characteristics had additional predictive value for change in anxiety score over the study arm; nor was any statistically significant interaction between the study arm and these variables detected. There was no indication that the effect of the study arm was influenced by any of the demographic/pretreatment patient characteristics (gender, age, tumour type, stage, education status, deprivation status and previous research experience).

8.7 Clinical trial decision making

A total of 148 patients who made a decision about entering a trial completed the Clinical Trial Decision Questionnaire (CTDQ): 73 patients in the intervention group and 75 patients in the no-intervention group. Of the total number, 125 patients had agreed to take part in a clinical trial and 23 had refused. This represented 97.7% of the total sample who said 'yes' to a clinical trial (125/128) and 71.9% of the patients who said 'no' (23/32). The CTDQ included questions about a) who patients discussed their decision with, b) reasons for accepting/declining clinical trial participation, c) patients' perceptions about the consent process, and d) acceptability of the AVPI.

8.7.1 People who patients discussed their decision with

Patients discussed the trial with family members and several health care professionals before making their decision about whether or not to take part; the most common being family (81.8%) (Figure 8.9). The 29 entries in the 'other' category were mainly friends, although sometimes this was specified to be a friend who was involved in health care or research (nurse, radiologist and research scientist). There was no effect of the intervention in terms of numbers of patients having discussion with their family; 83.3% in the intervention group and 79.2% in the no-intervention group.

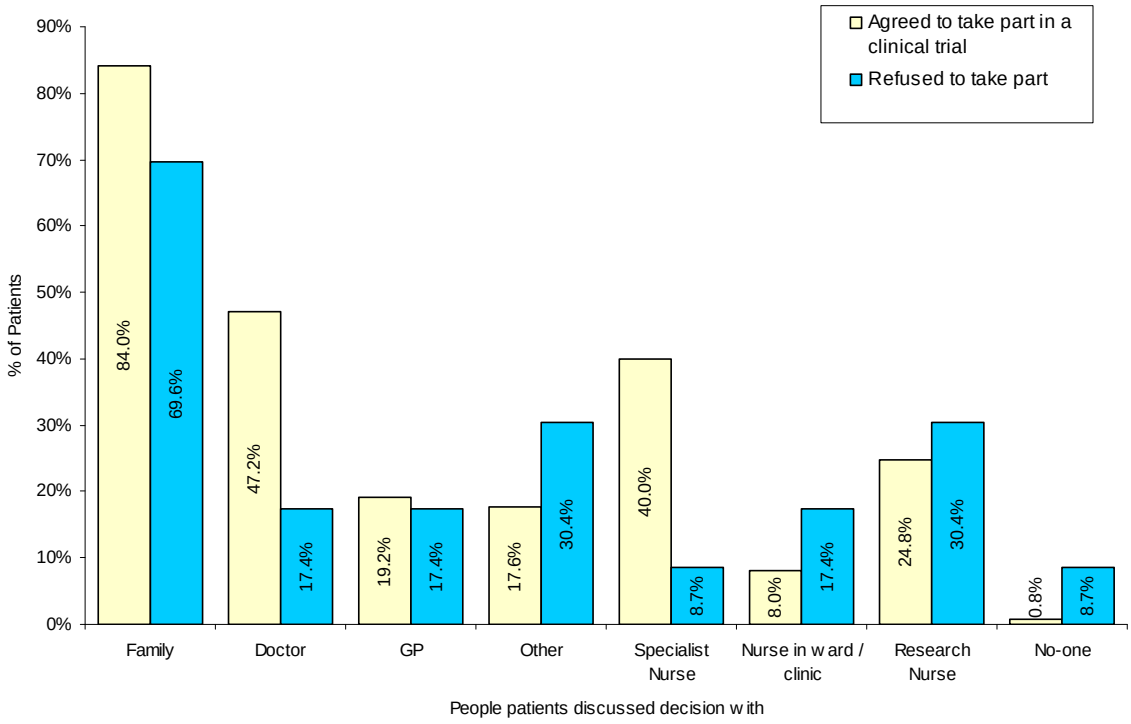

Figure 8.9. People with whom patients discussed their decision to take part in the trial

8.7.2. Reasons for accepting/declining a clinical trial

This largest part of the Clinical Trial Decision Questionnaire focussed on potential reasons for accepting and declining a trial, using the questionnaire developed by Jenkins and Fallowfield (2000). These results are shown in Table 8.13. The number of patients (shown in the table as 'count') is also expressed as a percentage of agreement to each

statement, according to whether patients accepted or declined trial entry. Reasons for accepting and declining clinical trial participation were tabulated. The percentage of patients falling into the categories 'strongly agree' and 'agree to some extent', for each reason, were compared between those who agreed and those who declined to take part using the Chi-square test.

Table 8.13. Patients' who 'strongly agree'/'agree to some extent' to statements which may be related to whether or not they agreed to take part in the clinical trial offered to them

	Agreed to take part in a clinical trial				Group Total	
	Yes (n=125)		No (n=23)			
	%	Count	%	Count	%	Count
Q1. I thought the study offered the best treatment available (p<0.001)	83.2	104	13.0	3	72.3	107
Q2. I believed the benefits of treatment in the study would outweigh any side effects (p<0.001)	77.6	97	13.0	3	67.6	100
Q3. I was satisfied that either treatment in the study would have been suitable for me (p<0.001)	88.0	110	21.7	5	77.7	115
Q4. I was worried that my illness would get worse unless I joined the study (p=0.683)	16.8	21	17.4	4	16.9	25
Q5. The idea of randomisation worried me (p=0.063)	20.8	26	43.5	10	24.3	36
Q6. I wanted the doctor to choose my treatment rather than be randomised by computer (p=0.010)	32.3	40	65.2	15	37.2	55
Q7. The doctor told me what I needed to know about the trial (p=0.006)	94.4	118	73.9	17	91.2	135
Q8. I trusted the doctor treating me (p=0.047)	91.2	114	73.9	17	88.5	131
Q9. I was given too much information about the trial (p=0.861)	8.0	10	8.7	2	8.1	12
Q10. I was given enough information about the trial (p<0.001)	91.2	114	43.5	10	83.8	124
Q11. I knew I could leave the study at any time and still be treated (p=0.878)	96.0	120	95.6	22	95.9	142
Q12. I did not feel able to say no (p=0.455)	9.6	12	17.4	4	10.8	16
Q13. I wanted to help with the doctors research (p<0.001)	95.2	119	52.2	12	88.5	131
Q14. I feel that others with my illness will benefit from the results of the study (p<0.001)	96.0	120	56.5	13	89.9	133
Q15. The doctor wanted me to join the study (p=0.343)	42.4	53	34.8	8	41.2	61
Q16. Others e.g. family & friends wanted me to join the study (p=0.001)	61.6	77	13.0	3	54.0	80

Ten of the 16 questions showed statistically significant differences between those who agreed and those who declined to take part in the clinical trial. Of these 10 questions, 7 were highly significant with a p-value of ≤0.001. This included belief in, and satisfaction with, the study (Q1-3), satisfaction with information, trust in the doctor, and the desire to help others. Reasons given by more than 90% of patients for their decision to say 'yes' to a clinical trial were: satisfaction with information (Q7 and Q10); knowing they could leave the study at any time (Q11); trust in the doctor (Q8); and a desire to help the doctors and future patients (Q13 and Q14). For patients who refused the clinical trial, the only reason that was identified by more than 90% of the sample, was the knowledge that they could leave the study at any time and still be treated. It is difficult to know how patients interpreted this statement in the questionnaire, and it may be that, because they could still receive appropriate treatment outwith the trial, they decided to refuse the trial.

At the bottom of the questionnaire, patients were asked to pick out their most important reason for agreeing or not agreeing to take part in the clinical trial. The results are presented in Table 8.14

By some margin, the two most important reasons for taking part were "I thought the study offered the best treatment available" (Q1) (27 [29.7%] out of the 91 who responded), and "I feel that others with my illness will benefit from the results of the study" (Q14) (26 [28.6%] out of the 91 who responded).

Reasons for not participating were more evenly distributed across questions, with no particular question or questions standing out. There was a high percentage of patients in this group who did not respond (39.1%= 9/23).

Table 8.14. Questions corresponding to the most important reasons given by patients for agreeing or not agreeing to take part in a clinical trial.

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
Question number corresponding to the most important reason	Q1.	21.6	27	0.0	0	18.2	27
	Q2.	7.2	9	4.3	1	6.8	10
	Q3.	6.4	8	0.0	0	5.4	8
	Q5.	0.8	1	4.3	1	1.4	2
	Q6.	0.8	1	4.3	1	1.4	2
	Q7.	1.6	2	4.3	1	2.0	3
	Q8.	5.6	7	4.3	1	5.4	8
	Q10.	0.0	0	8.7	2	1.4	2
	Q11.	1.6	2	8.7	2	2.7	4
	Q12.	0.8	1	0.0	0	0.7	1
	Q13.	4.8	6	4.3	1	4.7	7
	Q14.	20.8	26	4.3	1	18.2	27
	Q16.	0.8	1	13.0	3	2.7	4
	No response	27.2	34	39.1	9	29.1	43
Group Total		100.0	125	100.0	23	100.0	148

8.7.3 Consent process

As part of the Clinical Trial Decision Questionnaire, patients were asked about their perceptions of various aspects of the process, and results are shown below. Table 8.15 tabulates how much of the information received was understood, and shows that the majority of patients reported understanding most of it. When patients were compared in terms of trial entry, using the Mann-Whitney U test, a formal comparison gives p=0.026, showing that those who agreed to take part in a clinical trial thought that they understood more than those who did not (the non-responders were excluded from the p-value calculation).

Table 8.15. Patients' perceptions of their understanding of trial information received, in terms of effect on clinical trial entry

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
How much of the total information you received did you understand?	None of it	0.8	1	0.0	0	0.7	1
	A little	0.8	1	4.3	1	1.4	2
	Some of it	3.2	4	13.0	3	4.7	7
	Most of it	62.4	78	65.2	15	62.8	93
	All of it	28.8	36	13.0	3	26.4	39
	No response	4.0	5	4.3	1	4.1	6
Group Total		100.0	125	100.0	23	100.0	148

Patients' perceptions of their understanding were compared in terms of the study arm, also using the Mann-Whitney U Test. This showed that there were no differences between patients who received the intervention and those who did not, in terms of their perceptions of understanding of the information they received (p=0.509). This is shown in Table 8.16. The full study sample of 155 was used for this calculation, to include the patients who, at the decision making time point, were not in a position to make the choice about trial entry due to reasons such as ineligibility, or drugs not being available.

Table 8.16. Patients' perceptions of their understanding of trial information received, in terms of effect of the study arm

		Study Arm				Group Total	
		Intervention		No Intervention			
		Col %	Count	Col %	Count	Col %	Count
How much of the total information you received did you understand?	None of it	1.3	1	0.0	0	0.6	1
	A little	1.3	1	1.3	1	1.3	2
	Some of it	6.4	5	5.2	4	5.8	9
	Most of it	64.1	50	61.0	47	62.6	97
	All of it	24.4	19	27.3	21	25.8	40
	No response	2.6	2	5.2	4	3.9	6
Group Total		100.0	78	100.0	77	100.0	155

Patient understanding was compared between objectively assessed understanding (knowledge test) and subjectively assessed understanding, according to patients' perceptions. There is a modest association (Spearman's rank correlation coefficient =0.213, p=0.009) as shown in Figure 8.10.

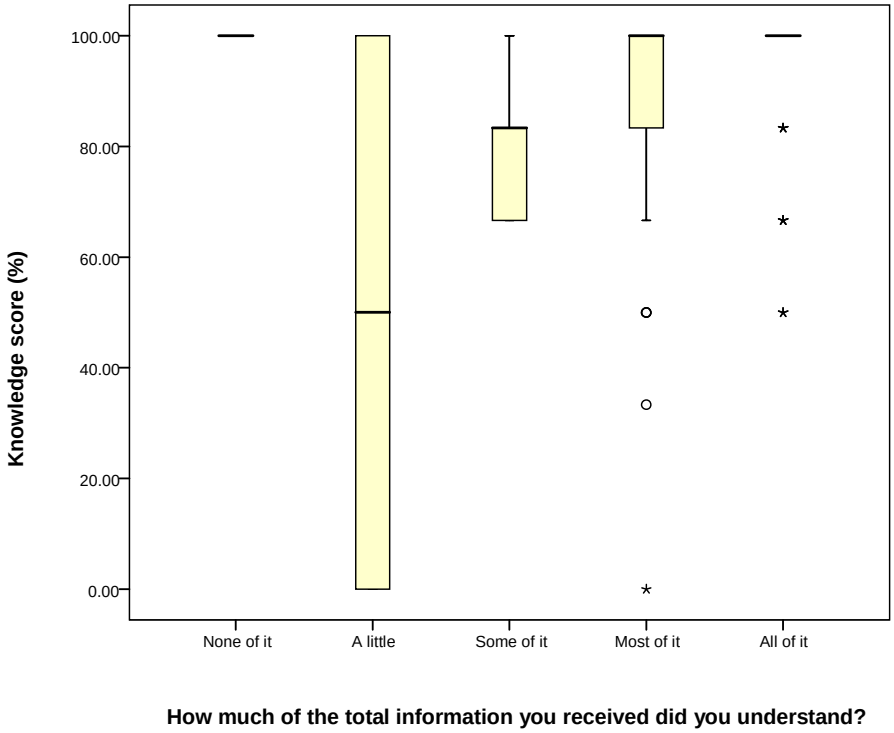

Figure 8.10. Objectively assessed and subjectively assessed understanding

Table 8.17 tabulates whether or not patients felt they had enough time to make a decision about whether or not to participate in a clinical trial. The large majority of patients in both groups thought that they did have sufficient time (93.9%), although 4 patients (2.7%) felt that they did not have enough time to make the decision, and 2 patients were not sure.

Table 8.17. Patients' perceptions of time, prior to decision making

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
Did you have enough time to make your decision?	Yes	95.2	119	87.0	20	93.9	139
	No	2.4	3	4.3	1	2.7	4
	Not sure	0.0	0	8.7	2	1.4	2
	No response	2.4	3	0.0	0	2.0	3
Group Total		100.0	125	100.0	23	100.0	148

Tables 8.18, 8.19 and 8.20 tabulate whether or not patients read the trial-specific patient information sheet, whether or not they found it useful, and the effect on their decision to take part in the clinical trial.

Table 8.18. Numbers of patients who read the clinical trial written information sheet

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
Did you read the written information sheet?	Yes	99.2	124	100.0	23	99.3	147
	No response	0.8	1	0.0	0	0.7	1
Group Total		100.0	125	100.0	23	100.0	148

Table 8.19. Numbers of patients who found the written information sheet useful

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
Did you find the written information sheet useful?	Yes	98.4	122	91.3	21	97.3	143
	No	1.6	2	4.3	1	2.0	3
	No response	0.0	0	4.3	1	0.7	1
Group Total		100.0	124	100.0	23	100.0	147

Table 8.20. Patients' perceptions of effect of information sheet on the clinical trial decision

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
What effect (if any) did the written information sheet have on your decision to take part?	Made me want to take part	68.5	85	4.3	1	58.5	86
	Made me not want to take part	0.8	1	43.5	10	7.5	11
	Had no effect on my decision	29.8	37	52.2	12	33.3	49
	No response	0.8	1	0.0	0	0.7	1
Group Total		100.0	124	100.0	23	100.0	147

Every patient reported having read the information sheet (1 patient did not answer the question). Almost all patients found it useful; only 2 patients who agreed to take part in the clinical trial, and 1 patient who refused the trial, did not find the information sheet useful. For 66% (97/147) the written information sheet was reported as having influenced their decision about whether or not to take part in the trial. The information sheet appeared to have more of an influence in patients who took part in a trial (69%, 86/124) compared to patients who refused a trial (48%, 11/23) (p=0.056).

8.7.4 Acceptability of the AVPI

The next three tables (Tables 8.21, 8.22 and 8.23) tabulate whether or not patients in the intervention arm watched the video/CD ROM/DVD and, if they did, whether or not they found it useful and what effect it had on their decision.

Table 8.21. Numbers of patients who watched the AVPI

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
Did you watch the video/CDROM/DVD?	Yes	96.8	60	90.9	10	95.9	70
	No	1.6	1	9.1	1	2.7	2
	No response	1.6	1	0.0	0	1.4	1
Group Total		100.0	62	100.0	11	100.0	73

Table 8.22. Numbers of patients who reported finding the AVPI useful

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
Did you find the video/CDROM/ DVD useful?	Yes	93.3	56	90.0	9	92.9	65
	No	6.7	4	10.0	1	7.1	5
Group Total		100.0	60	100.0	10	100.0	70

Table 8.23. Patients' perceptions of effect of the AVPI on the clinical trial decision

		Agreed to take part in a clinical trial				Group Total	
		Yes		No			
		Col %	Count	Col %	Count	Col %	Count
What effect (if any) did the video/CDROM/DVD have on your decision to take part?	Made me want to take part	41.7	25	0.0	0	35.7	25
	Made me not want to take part	1.7	1	10.0	1	2.9	2
	Had no effect on my decision	56.7	34	90.0	9	61.4	43
Group Total		100.0	60	100.0	10	100.0	70

Seventy three patients responded to the questions about their perceptions of the AVPI. Of the patients who received it, 96% (70/73) watched it. Of those who watched it, overall 93% (65/70) found it useful. When asked about the effect the AVPI had on their decision about whether or not to take part in the clinical trial, 42% (25/60) of those who entered the trial said that it had made them want to take part. A large proportion of patients overall stated that the AVPI had had no effect on their decision about whether or not to take part in the clinical trial; this was 90% (9/10) of those who *refused* trial entry and 57% (34/60) of those who *entered* the trial.

CHAPTER NINE: DISCUSSION

9.1 Introduction

This thesis has described the development and evaluation of an AVPI intervention designed to improve understanding of research and increase clinical trial recruitment by reducing refusal rates. It has found that:

- AVPI did not reduce clinical trial refusal rates.
- AVPI did increase knowledge/understanding, and this was associated with a reduction in anxiety.
- AVPI was considered by patients to be a useful and acceptable aid to the decision making process for clinical trials.
- the new knowledge questionnaire, developed and tested in the study, was shown to be a reliable and acceptable tool to measure understanding of randomised cancer trials.
- personal benefit and altruism were the main motivating factors for clinical trial acceptance, with reasons for refusal less clear.

This chapter considers explanations for these findings. Implications and recommendations for practice and research will then follow, and finally study limitations and conclusions.

9.2 Refusal rates

The AVPI aimed to increase clinical trial recruitment by improving patient understanding, whilst at the same time meeting the conditions for informed consent, according to ethical theory. There are a number of possible reasons why the intervention did not have an effect on refusal rates, as had been anticipated. These will be discussed in terms of statistical power, relation between refusal rates and knowledge/understanding, interaction, and information content.

9.2.1 Statistical power

The study was designed with an assumed clinical trial refusal rate of 40%, which was based on an average from previous studies (Klabunde *et al,* 1999; Jenkins and Fallowfield 2000; Lara *et al*, 2001). However, the observed refusal rate for clinical trials in this study, approximately 20%, is substantially less than that reported in the literature. Interestingly, the UK study by Jenkins and Fallowfield (2000) reported a refusal rate of 25-28% and, like this study, it focussed on randomised cancer trials; it also had a relatively high proportion of patients with breast cancer. The refusal rate for clinical trials in the AVPI study is comparable with the lowest refusal rate for cancer clinical trials found in the literature (19%), which was reported by a UK cancer network (Corrie *et al.* 2003), following improved clinical trial infrastructure and substantial investment. As discussed in Chapter 1, the cancer centre where the AVPI study was undertaken was, and is, part of a regional trials network, which has also benefited from investment and improved infrastructure. At the time of initiation of this study, the networks were in the process of being established and the resultant effect on clinical trial recruitment was unknown. It is now known that recruitment rates were increased following this initiative in the West of Scotland, but it is not known how much of this increase, if any, was due to a reduction in patient refusal rates. However, it is acknowledged that there may have been some influence on refusal rates to clinical trials in this study as a result of the network.

The relatively low refusal rate to clinical trials in this study can also perhaps be explained within the context of refusal rates for the study itself, where the rate was also low at 24%. It could be, therefore, that the sample was not wholly representative of the population under study. Of those who refused the AVPI study, 73% did not then go into the clinical trial. This is a large percentage of patients; however, it is unknown what proportion was for reasons of patient refusal and how many were because the patient became ineligible for the clinical trial.

Due to the considerable variation in refusal rates to clinical trials, it would have been useful to have used a baseline rate for the cancer centre (study site) as a guide when developing the study protocol. Unfortunately, this was not available since this information is not collected routinely, and consequently a judgement had to be made from the literature, which in retrospect appears to have been too high at 40%. This study was designed to detect a reduction in refusal rates from 40% to 20%; in actuality the no-intervention arm itself was found to have a refusal rate of only 20%.

The sample size recruited for the study means that the study could detect with 80% power a reduction in the refusal rate from 20% to 5.5% (Machin *et al.* 1997). However, such a dramatic 75% reduction in the refusal rate relative to no-intervention would be a very ambitious target for the AVPI intervention; indeed, the results of the study itself confirms that the intervention cannot achieve such a magnitude of change. Using the bottom end of the 95% confidence interval for the estimated odds ratio for the AVPI intervention, the most optimistic effect would only reduce the refusal rate from 20% to 12%. It could be argued that such a small difference may not be clinically useful, as there may be other more effective ways to increase recruitment, and the study therefore counts as evidence against the possibility of the AVPI intervention having a meaningful impact on refusal rates.

9.2.2 Relation between refusal rates and knowledge/understanding

Misconceptions and poor patient understanding are common in randomised cancer trials, due to patients being vulnerable and also due to difficult terminology. This has led to claims that poor understanding is contributing to high clinical trial refusal rates (Ross *et al.* 1999; Lara *et al.* 2001; Curbow *et al.* 2006) and the suggestion that, by improving understanding, clinical trial recruitment rates can be increased (Fallowfield *et al.* 1998a; Ellis *et al.* 2001), which was the approach taken in this study, using AVPI.

The literature is limited concerning AVPI as a tool to increase clinical trial consent rates (and hence reduce refusal rates), and it is important to consider the results of the AVPI study within this context. Several authors have identified the potential of AVPI to increase clinical trial recruitment by increasing patient knowledge/understanding (Fisher *et al.* 1991; Weston *et al*. 1997; Du *et al.* 2008). In addition, the need for further research investigating the role of AVPI in clinical trial recruitment has been highlighted by recent reviews (McLaughlin *et al.* 2002; McDaid *et al.* 2006). Despite this potential, and the attractiveness of the approach in being able to concurrently address ethical aspects of informed consent and hence increase recruitment in an ethically acceptable manner, there are only a small number of studies that have evaluated AVPI in the clinical trial setting; a body of knowledge to which the study now adds. Furthermore, AVPI has sometimes been part of a multifaceted education intervention, where it is difficult to determine the precise benefit of the AVPI aspect of the intervention (e.g. Wallace *et al.* 2006).

The handful of studies which have involved AVPI as the study intervention, and which have shown an increase in consent rates or willingness to participate in a trial, were either undertaken within a hypothetical trial context (Fureman *et al.* 1997; Weston *et al.* 1997) or in a specific patient population (phase I trials) (Daugherty *et al.* 2003). On reflection, it may be inappropriate to generalise these prior study results, because of the differences in the patient population (on the one hand), and the hypothetical context (on the other), which might not translate into actual trial participation (Cassileth *et al.* 1982; Trauth *et al*. 2000). Alternatively, it may be that in these studies, other factors, such as the quality of the interaction (Section 9.2.3), may have influenced consent rates. In the case of the phase I trial (Daugherty *et al.* 2003), increased rates may have been achieved because the information was substantially tailored, as discussed in Section 9.2.4.

There was no evidence in this study that a change in knowledge level was associated with the probability of refusing clinical trial entry; this study suggests that a change to one

(knowledge/understanding) is not necessarily associated with a change in the other (behaviour/decision). There is a widespread assumption that, in order to influence people's behaviour (in this case, to consent to a clinical trial), you have to educate them, by giving them appropriate information. This assumption is connected to rational models of decision making; where decisions are made rationally, and the decision-output (or behaviour) is influenced as a consequence of increasing an individual's knowledge. This has been a common approach in health promotion, and indeed in health care generally, with mixed success, as has been discussed in the literature review. Within health care generally, the rational model is apparent, for example with the ever increasing development of and reliance on clinical guidelines. Another example is the focus on increasing regulation and guidance on the disclosure aspect of patient information for decision making. Although there is evidence to suggest that you can give people guidelines (the knowledge) but they will not necessarily act on them (Lomas *et al.* 1989; Cabana *et al.* 1999), within the health promotion literature an increase in compliance and behaviour change was shown in some randomised clinical trials where patients received an informational video or CD-ROM. This could be because, if patients have more knowledge and understanding about a condition, perceiving it to be severe and their risk/susceptibility to be high, in keeping with the principles of health behaviour theory, they are more likely to comply with preventative measures, although the limitations of predictive power in current health behaviour theory is acknowledged.

The health promotion decision is different to one in which the decision is about a choice of treatments, as in the clinical trial situation, where the decision is whether or not to have treatment as part of a clinical trial, rather than whether or not to have investigations (or treatment, or preventative measures) at all. It may be that in the clinical trial setting, other factors come into play, since it appears that increasing knowledge is not effective in increasing the likelihood of consent.

Consistent with the AVPI study, an improvement in clinical trials knowledge with no effect on consent rates was reported by Strevel *et al.* (2007) in the cancer phase I trial setting. Despite the fact that more than half the patients in their study felt that it helped them with their decision about participation, there was no effect on consent rates (Strevel *et al.* 2007).

In this study, arguably, the theoretical basis for the intervention was not sufficiently developed in terms of the relationship between knowledge/understanding, attitudes and behaviour. The rational approach to decision making was implicit in the study, with *informed* consent the major theoretical focus because of the need for any intervention targeted at consent rates to take into account the ethical requirements of the *process*, and to avoid the dangers of coercion (McDaid *et al.* 2006). In light of the questionable assumptions concerning an association between knowledge and decisions/behaviour, previous research and the results of this study, it is argued that it is uncertain whether any intervention focussing on increasing patient understanding will result in an increase in clinical trial recruitment, and that time and future research may be better spent studying other aspects of the communication process.

9.2.3 Interaction

It is possible that, in terms of influencing the clinical trial participation decision, the interaction aspect of communication between the patient and the clinician is more important than patient understanding of the information. A focus on increasing understanding to effect a rational decision making approach, as was the case in this study, may not be effective in reducing rates of patient refusal, since other factors such as the context, trust in the clinician, patient-clinician relationship, etc., may be more important in this setting. The importance of the interaction between patient and clinician in the communication process for informed consent has been highlighted by Manson and O'Neill (2007), and is also consistent with ideas from a number of decision analysis perspectives

(e.g. when the decision tree is applied to the individual patient using his/her own valuations of the outcomes (Hopkins 1993, p21)).

There are several examples in the literature where it has been suggested that components of the interaction that takes place in the communication process for clinical trials are influential in terms of patient recruitment. These include some of the reported barriers to recruitment, such as attitudes of individual health professionals and mistrust of the clinician (Abraham *et al.* 2006; Fayter *et al.* 2006; Mills *et al.* 2006), and motivators to recruitment, such as good communication with the clinician, trust and rapport (Cox and Avis 1996; Jenkins and Fallowfield 2000; Featherstone and Donovan 2002; Eng *et al.* 2005). The results of the AVPI study would suggest that further research is needed to determine the effects of individual communication factors on consent.

9.2.4 Information content

A generic approach to randomised clinical trials was adopted in this study in terms of the information contained in the AVPI, with a focus on the concept of randomisation. In an attempt to make a generic approach more relevant to the individual patient, the AVPI was customised to tumour type with input from local medical consultants, and with a local geographical focus in terms of filming locations, and also a local approach to the supporting music. This appeared to be effective in improving patient understanding of the research, but it did not improve recruitment rates. It may be that a more specific approach is required and that the intervention was not tailored enough. This is consistent with the findings of the study by Du *et al.* (2008), who used an even more generic approach than was used in the AVPI study, with an off-the-shelf video about clinical trials which had been previously produced by the National Cancer Institute, aimed at the general American population. Du *et al.* (2008) tested this with lung cancer patients in a wide variety of trials, and found that there was no difference in knowledge and attitudes as a result of the intervention, and no statistically significant difference in enrolment rates. It may be that, in

both Du *et al.'s* (2008) study and the AVPI study, by making the production specific to the clinical trial that the patient was considering (rather than just the cancer type as in the AVPI study), the video/DVD would have been more effective, since the benefits for decision making of tailoring the information, particularly in health behaviour change studies, have been widely reported (Lusk *et al.* 2003; Petty *et al.* 2006; Noar *et al.* 2007).

To develop AVPI specific to an individual trial would have substantial practical and financial challenges, particularly if introduced into standard practice, in view of the large volume of trials running at any one time within a cancer centre. Trade-offs may need to be made in terms of local tailoring, as it may not be practical to do both (local to the cancer centre and also specific to the trial) in a multicentre study, since this could potentially result in large numbers of different productions being made for each individual study. Despite this, a tailored approach specific to an individual trial is worthy of further research. Work by Wallace *et al.* (2006) has shown that, in a 'difficult' randomised trial with very different treatment options, a multi-professional education session with patients, which included viewing a customised video, did increase consent rates. However, it is unclear how much of a role the video itself played in increasing rates as there were a variety of other factors involved in the multi-professional education session, and this issue would need to be taken into account when designing a study with a customised AVPI.

9.2.5 Summary of possible reasons why refusal rates were not reduced in this study

Due to the lack of evidence in the literature in relation to the effect of AVPI on clinical trial recruitment, it is not possible to identify with any certainty the reasons why the intervention in this study was not effective in increasing recruitment (reducing refusal rates) by increasing patient knowledge/understanding. However, as discussed, it is likely to be due to one or more of the following four reasons: knowledge/understanding is not sufficient to influence patient choice about clinical trial participation; the interaction is more important;

the study intervention was not tailored enough; or the study, in retrospect, was not sufficiently powered.

Despite the finding that the intervention did not reduce rates of refusal as hoped, it is essential not to underplay the fact that improving patient understanding is fundamental to informed consent, independent of the decision to consent or refuse. As demonstrated in this study, effective interventions such as AVPI are valuable in this area and will be further discussed in the next section.

9.3 Knowledge and anxiety

Although refusal rates were not reduced, the study hypothesis was partially confirmed in that the AVPI did increase knowledge (understanding) without increasing anxiety.

9.3.1 Knowledge/understanding

In addition to the main role of knowledge/understanding as a potential way of reducing clinical trial refusal rates, knowledge/understanding was of independent interest since it is fundamental to informed consent theory and the ethical framework for informed consent (Faden and Beauchamp 1986; Beauchamp and Childress 2001). As previously discussed, from an ethical viewpoint, understanding can be considered key to an informed consent, which can be viewed as the authorisation of an autonomous action (Faden and Beauchamp 1986). This also requires competence and voluntariness. Improving patient understanding, and hence the informed consent process, is integral to good clinical practice in clinical trials.

By improving patient understanding in this study, the fundamental ethical conditions for informed consent were met. This is an important outcome, in such a challenging specialist area of practice: patients with cancer and randomised trials. This outcome is consistent with previous work, predominantly from other specialities involving AVPI, where

understanding was increased without increasing anxiety (e.g. Luck *et al.* 1999; Mason *et al.* 2003). The AVPI study adds to the small body of evidence in the cancer and non-cancer clinical trial setting, where audiovisual patient information has been shown to improve patient knowledge/understanding as part of the consent process (Diabetes Control and Complications Trial Research Group 1989; Norris and Philips 1990; Agre *et al.* 2003; Curbow *et al*. 2004; Wirshing *et al*. 2005; Joseph *et al.* 2006; Strevel *et al.* 2007). It was encouraging to find that in both the intervention and the no-intervention arms of the study, patients were more knowledgeable following the information-giving process, although this was more marked in the intervention group. This would suggest that patient understanding was also improved with the written information and/or the verbal process/interaction with the clinician.

Randomisation and equipoise were identified in the literature as being important in terms of study design (scientifically and ethically), but were also identified to be problematic in terms of patient understanding and acceptance. In this study, these issues were explicitly addressed in the AVPI with visual examples. Five questions in the questionnaire were designed to assess understanding in terms of randomisation and equipoise. These questions were concerned with how treatment is allocated (two questions), the main aim of a randomised trial (RCT), justification for doing an RCT (equipoise), and an example assessing understanding of the principles of RCTs. For all five questions, the patients receiving the AVPI had increased understanding from pre to post assessment. In four out of five questions, there was an increase in understanding in the no-intervention arm, showing that the existing process for informing patients at the cancer centre are also relatively effective in improving patient understanding about randomised trials.

The literature suggests that many patients still believe that, in an RCT, the doctor chooses the treatment for them (Ellis *et al.* 1999b; Hietanen *et al.* 2000). This was supported by the AVPI study, where at baseline 44% in the intervention group and 43% in the no-

intervention group incorrectly answered the question about how the treatment is allocated, with the majority believing that the doctor chose it. However, at the decision-making visit (post intervention), only 19% of patients in both groups got this question wrong. Although this is an improvement from baseline, it still means that one fifth of patients did not understand how treatment was allocated.

Previous studies have shown both a poor and a good understanding of the terms randomisation and equipoise. Authors of studies showing a good understanding suggest that the issue for patients is more about acceptance of the concepts (Fallowfield *et al.* 1998a; Featherstone and Donovan 1998, 2002; Robinson *et al.* 2005; Mills *et al.* 2006; Madsen *et al.* 2007). The AVPI study focussed mainly on understanding of the concepts, however, and the majority of patients appeared to understand the concepts (according to the knowledge questionnaire); there is also evidence from the decision questionnaire suggesting that acceptance of both randomisation and equipoise is important for consent. Statements concerned with acceptance of equipoise were more important to patients who agreed to consent to a trial, compared with those who refused. Interestingly, significantly more patients who refused a trial wanted the doctor to choose their treatment, in preference to it being selected by the randomisation process. These findings support the idea that acceptance of both randomisation and equipoise is important for clinical trial acceptance (Fallowfield *et al.* 1998a; Featherstone and Donovan 1998, 2002; Robinson *et al.* 2005; Mills *et al.* 2006; Madsen *et al.* 2007).

It must be acknowledged, however, that it is not known in any detail how patients felt about the concepts due to the quantitative approach taken in this study, which did not allow for any exploration of the issues. It is recognised that acceptance of randomisation and equipoise would be best assessed via interview, where a deeper understanding of patients' views could be ascertained. Following this, it would appear that optimising acceptance of the concepts would be best addressed by effective clinician-patient

interaction, where discussion and explanation has been shown to change patients' views about randomisation (Fallowfield *et al.* 1998a).

Patients' understanding of voluntariness was assessed in the questionnaire, in terms of voluntariness of the participation decision, freedom to withdraw from the trial, and what would happen if they refused to participate in the trial. Patients in the intervention group had high levels of understanding in all three areas. Issues around voluntariness were also identified as major factors affecting patients' decisions to accept or decline the trial. It was encouraging that the intervention increased understanding of voluntariness, and that this understanding was high, since voluntariness was shown to be an important component within the ethical framework of informed consent, linked to patient understanding (Faden and Beauchamp 1986).

The issue of 'substantial understanding' was discussed in the literature review as an important target to aim for in terms of informed consent (Faden and Beauchamp 1986), despite the difficulty of defining it. This study accepted the principles of substantial understanding as being core information, in additional to specific information as desired by the patient (discussed in Chapter 3, Section 3.7.1), and attempted to include the information required for 'substantial understanding' in the intervention arm of the study (via the combination of the AVPI and the standard written information sheet). The information was then discussed on an individual basis during the clinical consultation. Faden and Beachamp's (1986, p308) definition of understanding - understanding *that* you are being asked to decide about taking part in a trial, and understanding *what* is communicated about the trial - was also integral to the AVPI. It must be acknowledged, however, that although the knowledge questionnaire was designed to assess the key issues, understanding was not measured in terms of whether or not it was substantial; no attempt was made to specify how much understanding is necessary for it to be considered 'substantial' since no absolute level was defined. This study focussed on the *comparisons*

from baseline measures and across the two groups (intervention and no intervention), rather than absolute values.

9.3.2 Assessment of understanding

The new knowledge questionnaire which was developed for this study was shown to be valid and reliable for assessing patient understanding of randomised trials, and acceptable for use in the cancer setting. It helps to address the lack of assessment tools for objectively assessing patient understanding in the randomised cancer trial setting, although it is accepted that the questionnaire would benefit from further work, as will be discussed in terms of the implications for further research.

Although the focus in this study was very much on objective understanding, as assessed via the knowledge questionnaire, patients' own perceptions were also determined when they were asked one question about their understanding of the information received. Both the patients who said 'yes' to a clinical trial, and those who said 'no', reported high levels of understanding of the information they received. As reported in the literature, patients often perceive their understanding to be high, despite obvious misconceptions and low measures of objective understanding, and this was the reason why the knowledge test was adopted as the main measure of understanding in this study (Sutherland *et al*. 1990; Miller *et al*. 1996; Hietanen *et al.* 2000). However, it was encouraging that there was an association between the patients' perceptions and the objective measures. From the subjective assessments, what was particularly interesting was the finding that the patients who consented to a trial *felt* more informed as compared with those who refused a trial. The AVPI did not make them feel more informed; there was no difference in terms of whether or not they received the intervention. The question must then be asked: if the AVPI did not make people feel more informed, what did? Could this be due to factors associated with communication and the patient-clinician interaction?

9.3.3 Influence of demographics and patient characteristics

Education qualifications and stage of cancer were independently associated with higher baseline knowledge in this study. This is consistent with the existing literature, in which less education was associated with lower levels of knowledge in a review of consent for clinical trials (Sugarman *et al*. 1998), and knowledge of clinical trial information was poorer in patients with more advanced disease (Schaeffer *et al*. 1996; Cox *et al.* 2006). By supporting previous research, the AVPI findings in this area help to emphasise the importance of spending additional time and support, as necessary, for patients with lower educational backgrounds and/or with advanced disease, in order to help them with understanding clinical trial information.

9.3.4 Relation between knowledge and anxiety

By increasing knowledge, the intervention did not increase anxiety, which is a finding consistent with much of the literature investigating knowledge and anxiety levels with AVPI (e.g. Hewison *et al.* 2001; Mason *et al.* 2003; Danino *et al.* 2005). Anxiety was most commonly assessed by the same tool used in this study, the Spielberger State-Trait Anxiety Inventory, which allowed comparisons to be made. It was encouraging that, as well as not increasing anxiety as a result of increasing knowledge, anxiety was actually reduced, which has been found by other work investigating AVPI within and outwith the cancer clinical trial setting (e.g. Thomas *et al.* 2000; Orringer *et al.* 2005). It is acknowledged that the higher baseline anxiety in the intervention group cannot be explained. For one thing, patients did not know their randomisation result before completing the questionnaire. For another, there were similar numbers of consultant and registrars involved in the initial patient consultation in both the intervention and no-intervention groups. The higher baseline patient anxiety level in the intervention group cannot therefore be explained by the seniority or experience of the medical staff involved in the consultation. However, the distribution of medical oncology and clinical oncology

staff is unknown, and this may be important in terms of clinicians' attitudes, as demonstrated by Fallowfield *et al.* (1997).

9.4 Non-rational, social and process factors that affect decision making

If knowledge/understanding does not affect behaviour in the clinical trial decision situation, then what does? What influences a patient's decision about consenting or not consenting to a clinical trial? Reasons for patient refusal and acceptance were investigated in this study, in an attempt to add to the literature in this area which focuses on the patient's perspective (Cox and McGarry 2003), and the real-life clinical trial decision making situation (as opposed to the hypothetical trial situation). Both rational and non-rational reasons were identified by patients. However, patients will not always be aware of the factors influencing their decisions. Patients make decisions in a number of ways, depending on the individual and the situation. In terms of clinical trial participation, patients need to make an *informed decision* about whether or not to take part. An informed decision is one where "a reasoned choice is made by a reasonable individual, using relevant information about the advantages and disadvantages of all the possible courses of action, in accord with the individual's own beliefs" (Bekker *et al.* 1999, p1). For the patient considering whether to participate in a clinical trial, it would appear that the processes implicated in rational models of decision making are not followed (Tabak 1995) and this may be due to non-cognitive factors such as emotions and those involved in the clinician/patient interaction, such as trust. Over the years there has been a gradual shift away from full acceptance of rational models of decision making in healthcare, in recognition of the wider context and factors involved. This wider context was reflected in the AVPI study results, with non-rational, social and process factors being found to be important to the decision - specifically social relationships and the influence of others such as the doctor and the family.

9.4.1 Social relationships/influence of others

It is unknown how much of an impact patients' discussions with their families actually have on their decision about clinical trial participation, although it is potentially substantial. In this study, family members were the main people that patients discussed their decision with; more patients who accepted the trial had discussion with their families compared with those who refused (84% v 70%). The importance of family and friends in clinical trial decision making has been highlighted in the literature (Verheggen *et al.* 1998), with several cancer trials showing that family members influenced the patient against participation (Paskett *et al*. 1996; Camerini *et al.* 1999; Spiro *et al.* 2000; Wilt *et al*. 2003). This highlights the importance of social relationships in clinical trial decision making, and lends supports to models incorporating this element, such as the communication model proposed by Albrecht *et al.* (2003), where the family is an integral component.

In view of the large proportion of patients discussing the clinical trial participation decision with their family, there is an important responsibility on health care professionals to ensure that patients' 'significant others' are involved in the information-giving and support process for clinical trials, and that they have an accurate understanding of what this involves. This finding supports education of the general public about clinical trials to promote a positive attitude towards, and an improved background community knowledge of, clinical trials (Edwards *et al.* 1998; Trauth *et al.* 2000; Apolone and Mosconi 2003; Comis *et al.* 2003; Fisher 2006). Individuals would then be better placed to support their loved ones in terms of clinical trial decision making, should the situation arise.

A large number of patients who consented to a clinical trial, compared with those who refused (47.2% v 17.4%), reported discussing the decision with their doctor. This would suggest that the doctor is also influential in the patients' decision, particularly in light of the difference in the two groups. Only one patient who did not discuss his/her decision with anyone, accepted the trial (0.8%), whereas 8.7% of patients who reported not discussing

their decision with anyone refused to take part, which would suggest that these patients had already made up their minds, as discussed in Section 9.5.1. This will probably always be a difficult group to influence, in terms of improving both the consent process and consent rates.

It is also interesting to note that, of the 45 eligible patients seeing the same doctor at the initial trial consultation visit and the decision making visit, the large majority (91%) then went on to consent to the clinical trial offered to them. This is a higher number than the overall consent rate in this study, and would suggest that the relationship may have been an influencing factor.

In terms of nursing staff, both the specialist nurse (CNS) and the research nurse were identified by substantial numbers of patients as personnel they discussed their participation decision with. CNSs are nurses who are educated to degree level and above, with specific expertise and/or experience in their respective specialities (Roberts-Davis and Read 2001; Cameron and Masterson 2003). They are an integral member of the multi-disciplinary healthcare team (Fischer 2007), working across a range of specialities - for example, diabetes, stroke, cancer, from diagnosis to discharge or death. That patients identified CNSs as people they discussed their clinical trial participation decision with, is consistent with the important communicator-carer role of the CNS (McCreaddie 2001). Patients value the support of the CNS and it is not surprising that they discussed such an important decision with them. The majority of patients (if not all) in this study would have been seeing a CNS with expertise specific to their cancer type throughout their diagnostic and treatment journey. Similar to the doctors, discussion with CNSs was mainly by patients who agreed to a clinical trial, compared with those who refused (40% v 8.7%).

On the other hand, research nurses (who would be expected to be more expert than other nurses, including the CNS, in terms of clinical trials), were identified by a relatively large proportion of patients who refused a clinical trial (30%), as people that they discussed their decision with. One quarter of patients who accepted a trial had had discussion with the research nurse. Because of the way that clinical trials are organised at the cancer centre, all patients considering participation in a phase I trial will see a research nurse as part of the clinical consultation, but this is not the case for randomised clinical trials, the focus of this study. Patients in randomised clinical trials are seen in the wards and clinics, along with patients receiving conventional cancer care, and will only see a research nurse if the trial is particularly complex. This would explain why only a quarter of patients who consented to a trial had discussed it with a research nurse. This makes it even more encouraging that 30% of patients who refused the trial had discussed it with the research nurse. Due to nature of the research nurse role, as well as their substantial expertise in clinical trials, they are in a good position to inform patients. In this study, after having a discussion with the research nurse, patients were comfortable in making the decision to refuse the trial. It may be that the research nurse helped to confirm the decision for the patient, although it is acknowledged that factors involved in the interaction are unknown.

9.4.2 Most important reasons to patients

Various reasons have been offered in the literature as benefits to clinical trial participation in terms of improved patient outcomes, such as increased survival and improved quality of life, although it is acknowledged that the research is limited in this area (ECRI 2002). However, reasons for participation must be considered with reasons against participation to provide a balanced analysis (ECRI 2002). Patient refusal, and therefore selection of the standard treatment, can be the better decision for the individual patient in terms of their personal balance account of the risks and benefits of clinical trial participation.

In addition to scoping the reasons, this study aimed to assess the relative importance of reasons why patients agreed or refused to take part in a trial, in the same way that Jenkins and Fallowfield (2000) did in their study, by asking patients to select their most important reason in terms of the trial participation decision. Results are consistent with other research identifying hope and expectation for personal benefit, and altruism, as important motivating factors for patients who agree to participate in a clinical trial. Trust in the doctor was an important factor in patients' decisions to consent to the AVPI study, which is consistent with findings from other studies (Tabak 1995; Cox and Avis 1996; Albrecht *et al.* 1999; Jenkins and Fallowfield 2000; Featherstone and Donovan 2002; Eng *et al.* 2005). Interestingly, trust was not as important in this study for patients who refused a trial, suggesting that it is a motivator for participation.

The fact that reasons for refusal were less clear in the AVPI study highlights the difficulties in understanding why patients refuse clinical trials, as previously identified in the literature, as well as the individual nature of the decision, where context is important. It may be that the content of informed consent is not important in the decision, and that the role of information is to make people feel more involved, or to help manage expectations, and that it is not used in the decision itself. As already highlighted, the importance of an informed patients' refusal must also be acknowledged as this will sometimes be the appropriate decision for an individual patient. This was the reason that informed consent played such a prominent role in the study. The individual nature of the decision is fundamental to a good patient decision and has been acknowledged by the ECRI (2002) by their Health Technology Assessment review which was carried out to review studies which investigate reasons for the clinical trial participation decision. The rationale behind this review was to prepare an evidence-based supplement for patients to help with their decision about whether or not to take part in a clinical trial (ECRI 2002). They also found that there was little agreement across studies, in terms of the reasons why patients refused a clinical trial.

9.5 Parameters of the informed consent process

9.5.1 Timing

A particular challenge for informed consent in clinical trials is to access the patients who make their decision about whether or not to take part in the trial prior to receiving any information about it (or before discussing it), or soon after. They are often unwilling to even consider the information, an issue which is difficult in any research study. This would perhaps be easier if audiovisual patient information was standard practice in the consent process for clinical trials, and if it were presented to the patient as part of their routine care – although it is recognised that there would still be some patients who would choose not to view it. This approach to standard practice can be justified in light of the benefits shown by the AVPI in improving the informed consent process, and may help with the issues identified by Huizinga *et al.* (1999) and Tabak (1995), who question the quality of consent when patients make their decision soon after receiving information about the trial, and do not take time to consider their decision. This is referred to by Sutherland *et al.* (1998) as a 'gut response' to making the clinical trial decision, soon after hearing information about the trial. If AVPI can increase patient understanding at the initial information-giving session, when patients are first made aware about the clinical trial, it may assist them to make a more informed decision. This may mean the need to include video viewing as part of the initial consultation, +/- taking it home, to enable influencing of the decision at an early point in time, before patients' minds are made up, thus challenging the 'gut response'.

At the other end of the scale, in this study some patients felt that they did not have enough time to make the decision about clinical trial entry, although this was not an issue for the majority of patients. Again this is consistent with the literature, and highlights the challenges of allowing patients enough time for decision making, whilst at the same time not compromising the need to promptly initiate anticancer treatment. For this reason, the period of one week is often a clinically acceptable time period. However, the individuality

of patients, and their needs in terms of decision making, must be recognised. A useful way of addressing this would be to assess, at the proposed decision making time point, their satisfaction with the time given for decision making. Wherever possible, the decision making time should then be extended, if this is desired by the patient, in order to avoid the potential for coercion and decisional regret.

9.5.2 Acceptability of the intervention

The AVPI was well received by patients, and this study supports the view that audiovisual approaches to patient information are becoming more and more acceptable to patients (Thomas *et al.* 2000; Agre *et al.* 2002). Only two patients were excluded from the study because they did not have a computer, video or DVD player, showing that the technology is widely available in patients' homes. This supports previous research in the oncology setting, where 89% of patients had access to a video player at home (Thomas *et al.* 1999), and shows that the technology is even more available in patients' homes now.

Almost all patients reported watching the AVPI, and a large majority reported finding it useful. However, in terms of influence on decision making, 61% reported that the AVPI had had no effect on their decision (this was 90% of those who refused a trial and 57% of those who accepted). Despite this, 42% of patients who consented to a clinical trial reported that the AVPI had made them want to take part in the trial. This was an interesting finding: although patients liked the AVPI and found it useful, they did not feel that it had a major role in their decision making. This is consistent with the benefits of the intervention having more to do with the consent process (increasing understanding and reducing anxiety), than with decision making (refusal rates). It is also consistent with the findings of other studies (Norris and Philips 1990; Agre *et al.* 2003; Wirshing *et al.* 2005; Joseph *et al.* 2006; Strevel *et al.* 2007).

Patients were asked about the role of written information in terms of their decision, since this is a regulatory requirement of informed consent, and because written information was used in both arms of the AVPI study. Although almost all patients read the trial-specific written information sheet and reportedly found it useful, one third reported that, like the AVPI, it had had no effect on their decision to participate in the trial (or not). For the two thirds of patients who reported an influence on their decision, this appeared to be more so in patients who agreed to take part in the trial, compared with those who refused (69% v 48%). This was an interesting finding, since other authors have reported that, in decision-making situations, patients relied more on the consultation and the influence/advice of the clinician, and less on the supporting tools (for example, Penman *et al.* 1984). However, the literature is inconsistent, and Garcea *et al.* (2005) found in their study of patients with colorectal cancer that over 90% claimed to have made their decision after reading the patient information leaflet. AVPI does appear to be a useful decision aid for the process, but it is questionable how much of a role, if any, it has on the decision itself.

9.6 Implications and recommendations

There are several implications for practice and recommendations for further research, which will now be discussed.

9.6.1 Implications for practice

On the basis of the results of this study, an AVPI intervention that focuses on increasing understanding of clinical trials in general cannot be recommended as a way of reducing refusal rates to clinical trials.

AVPI could be used to inform patients about randomised cancer trials prior to their decision about participation, in light of its effective role in increasing patient knowledge/understanding. The AVPI could be viewed as part of the initial consultation, +/- taking it home, with a view to influencing of the decision at an early time point, before

patients' minds are made up, thus promoting an *informed* decision. The AVPI study highlighted the importance of assessing individual needs in terms of the time given for decision making, and extending this time as required, in order to avoid the potential for coercion and decisional regret. If the AVPI were to be used outwith the study site, there would be cost implications, and local aspects of the production would need to be addressed. The pharmaceutical industry, and other cancer centres, have shown interest in taking this forward. Another consideration which would need to be addressed, if the AVPI is to be used in future, is the opening scene of the production, which involved the use of music which is only covered by licence for a five-year period, and limited to use in the UK.

The knowledge questionnaire could be used as a routine assessment of patient understanding, to provide the opportunity for clinicians to correct misconceptions prior to consent (via the 'correct answers' information sheet, supported by further personal discussion). A model similar to that evaluated by Joseph *et al.* (2006) (discussed in Chapter 4, Section 4.6.1) could be adopted, where the AVPI and questionnaire were used as part of a two-step education approach. Patients were not allowed to enrol in the trial until they met a certain standard in relation to understanding. If this approach were to be adopted, it would have to be properly evaluated.

The AVPI has the potential to be further developed for use in teaching heath care professionals about clinical trials, although it was not originally designed for this purpose. Following a request from the academic sector, the DVD has been used as a teaching tool for cancer nurses to enable them to learn more about cancer clinical trials. However, no evaluation has yet been undertaken, and this would be necessary for any further development in this setting.

9.6.2 Recommendations for further research

Several implications for further research were identified as a result of this study. These concern four main areas. Firstly, in relation to assessing patient understanding of clinical trials; secondly, further tailoring of AVPI in the cancer trial setting; thirdly, in considering other aspects of the consent process as a means to increasing clinical trial recruitment; and, fourthly, using behaviour decision theory to better understand the factors involved.

Firstly, the knowledge questionnaire would benefit from further testing in the randomised clinical trial setting in order to further establish reliability and validity. It would also be useful to test the tool in relation to randomised cancer trials outwith the cancer centre and in other countries, to determine its generalisability. Following publication of an article on the development and testing of the questionnaire, a cancer unit in Belgium has requested permission to have the questionnaire professionally translated for use in a research study there. Another UK cancer centre has also made contact, and is keen to use the tool in a local research setting.

Secondly, as previously discussed in Section 9.2.4 earlier in this chapter, it may be that in this study, the AVPI was not tailored enough for it to have an impact on recruitment rates. This is an area worth further investigation, employing research using a trial-specific tailored AVPI as part of a large multicentre study, where it would be possible to attain meaningful patient numbers. However language issues would need to be considered, and it may be best limited to English-speaking countries initially to determine if the approach is useful.

Thirdly, factors related to the communication process (as discussed in Section 9.2.3), in particular the clinician-patient interaction, may be influential in terms of clinical trial recruitment rates, and is an area where research is much needed. Albrecht *et al.* (1999) found that patients were more likely to take part in research when their physician verbally

presented items that were normally included in the consent form, and when they behaved in a 'reflective, patient-centred, supportive and responsive manner'. Albrecht *et al.* (2003) have developed a model to explain patient decision making in the context of clinical trials and hypothesise that 1) the characteristics of the physician, 2) the nature of the trial protocol itself, 3) predisposing factors of the patient, and of the patient's family member or significant other, affect a patient's decision to enrol in a clinical trial; they also suggest that the impact of all of these variables on the actual participation decision is mediated by the kind of communication that occurs between the individuals. Including the family in this approach is valuable in light of the substantial influence that family often have in terms of patient decision making in the clinical trial context, as identified in the AVPI study, as well as in previous research. Albrecht's model is currently being evaluated to determine the extent to which all the components, as incorporated in a more elaborated structural equation model, independently and collectively explain patient perceptions of the physician, and patient decisions regarding treatment (Albrecht *et al.* 2003). This is an example of the type of research that would identify the effect of the interaction on clinical trial consent rates. Another approach would be to focus on specific aspects of the process, such as clinicians' communication skills, and assess the effect of enhanced communication on recruitment rates, in addition to assessing improvements in the communication process itself, the approach most commonly employed to date.

The fourth potential area for further research identified by this study is the exploration of individual clinical trial participation decisions in depth, based on behaviour decision theory and a fully elaborated theoretical framework, with the aim of understanding more about the processes and factors that influence the actual decision. Adopting an approach to decision making which goes beyond rational choice models would take due account of the socio-cultural and affective factors, such as information gained from sources other than health care professionals, cultural norms and emotion (Holmes-Rovner and Wills 2002). A potentially useful approach would be to investigate the role of newer models of health

behaviour theory, with clinical trial consent as the behaviour under study - for example Leventhal's Common Sense Model (CSM). The CSM is based on rational choice theory, but also considers emotional/affective responses, and could potentially help to explain the broad range of factors involved in the clinical trial decision. Understanding the factors involved is the first step in targeting effective interventions to increase consent rates.

9.7 Study limitations

Although the study provides useful information for practice, its limitations must be acknowledged. It was carried out at a regional cancer centre, where there is great interest in, and experience with, clinical trials, and findings may not therefore generalise to patients being seen in different settings. The sample consisted of a particularly high number of patients with breast cancer, and patients were recruited from a total of 18 different clinical trials. As a result of this, there was a high number of female patients as compared with males. This number of trials could be considered an advantage in terms of generalisability, but could also be seen as a limitation, as it was not possible to say with any confidence if there were differences between trials, in terms of patients' decisions, as a result of factors within the trials themselves. Some of the trials had very different arms (e.g. chemotherapy v hormone therapy, chemotherapy v best supportive care) where patients may have a preference for one treatment over the other.

The knowledge questionnaire was not re-piloted after changes were made following the initial testing with patients and research nurses. Although most of the changes were relatively minor, one question was removed as a result of the initial testing, and following this it would have been useful to have undertaken further testing. The reason why this was not done is that time had not been built into the study timetable to allow this, and it would have been difficult to have then extended the study to accommodate further testing.

It is acknowledged that a deeper understanding could have been achieved by using a qualitative approach to explore factors affecting patient decision making, to add to the small research base in this area (Paskett *et al.* 1996; Featherstone and Donovan 2002). Interviews could have been used in addition to the questionnaires, as suggested by Jenkins and Fallowfield (2000), to allow a more in-depth interpretation and understanding of the data. In addition, physician interpersonal skills and the quality of interaction have not been addressed in this study, and it may be that these factors were influential in patients' decisions.

9.8 Conclusions

Despite the limitations, findings from this study support the use of AVPI as a useful addition to the consent process for randomised cancer trials, in terms of improving patient understanding prior to decision making. AVPI addresses the fundamental ethical challenges of informed consent by improving patient understanding. It appears to reduce anxiety, and has been shown to be an acceptable medium for patients. In this study, AVPI was not shown to have any effect on refusal rates to randomised cancer trials.

The main study conclusions can be summarised as follows:

- AVPI has been shown to be a useful and acceptable addition to the consent process in cancer clinical trials.
- AVPI can increase patient understanding of randomised cancer clinical trials and reduce patient anxiety. By improving patient understanding, the AVPI supports the fundamental ethical framework necessary for informed consent (Faden and Beauchamp 1986).
- AVPI focussing on general clinical trials information cannot be recommended as a way of reducing refusal rates to clinical trials. In this study, AVPI did not increase clinical trial recruitment rates and did not influence decision making outcomes.

- The knowledge questionnaire 'Questionnaire: Patient Understanding of Research' was shown to be a sensitive and effective instrument for measuring understanding of randomised clinical trials in the cancer setting, although further work is necessary.
- This study confirms existing findings from studies assessing factors affecting decision making, with personal benefit and altruism being key motivating factors, and reasons for refusal less clear. The need for qualitative work in this area is highlighted to gain a deeper understanding of what is important to patients, and the reasons why they refuse clinical trial participation.

Several implications for practice have been identified, which include using AVPI as part of the standard information package for patients considering randomised cancer trials, and focussing more on patients and staff education in this area. The knowledge questionnaire could be introduced to routine practice as a tool to determine patient understanding prior to decision making, allowing clinicians the opportunity to correct any misconceptions prior to consent. Further research focussing on AVPI specific to individual trials would be helpful, to determine if a more customised approach would increase clinical trial recruitment. The importance of studying other aspects of the consent process, such as the interaction between the clinician and the patient, in addition to more detailed exploration of the factors affecting patients' decisions, were highlighted.

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APPENDICES

APPENDIX 1.1

Publications Written as a Result of the Study

Hutchison, C. and McCreaddie, M. (2007) The process of developing audiovisual patient information: opportunities and challenges. *Journal of Clinical Nursing,* 16 (11), pp. 2047-2055.

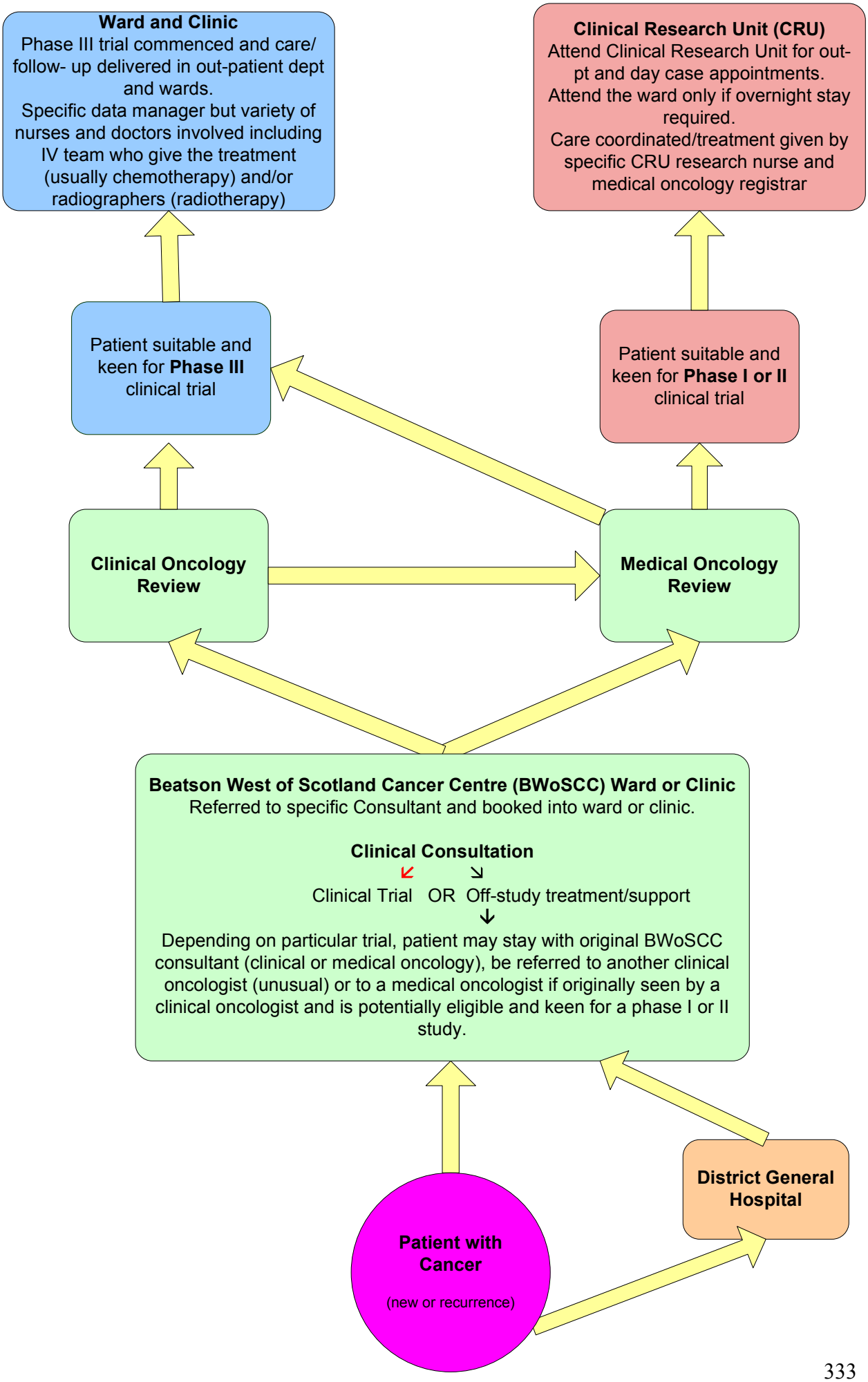
Hutchison, C., Cowan, C. and Paul, J. (2007) Patient understanding of research: developing and testing of a new questionnaire. *European Journal of Cancer Care,* 16 (2), pp. 187-196.

Hutchison, C., Cowan, C., McMahon, T. and Paul, J. (2007) A randomised controlled study of an audiovisual patient information intervention on informed consent and recruitment to cancer clinical trials. *British Journal of Cancer*, 97 (6), pp. 705-711.

Hutchison, C. (2008) Trial recruitment and audiovisual patient information. *Cancer Nursing Practice*, 7 (1), pp. 19-20.

APPENDIX 1.2

Clinical Trial Patient Pathway at The Beatson West of Scotland Cancer Centre



APPENDIX 2.1

Literature Search – Recruitment to Clinical Trials

A) Recruitment to Cancer Clinical Trials: Influencing Factors, Barriers and Willingness/Refusal

Databases searched: Ovid MEDLINE(R) (mesz), Ovid MEDLINE(R) In-Process and Other Non-Indexed Citations (prem), CDSR (coch), ACP Journal Club (acp), DARE, CCTR, British Nursing Index (brni), CINAHL (nursing), EMBASE (emez), PsycINFO (psyf).

Search Strategy

1 exp clinical trials/ or controlled clinical trials/ or randomized controlled trials/ or multicenter studies/ or "research and development"/ or exp clinical trial/ (1309928)
2 ((controll$ or clinical or randomiz$ or randomis$) adj (trial$ or study or studies or research$)).ti,ab. (742221)
3 1 or 2 (1747925)
4 patient selection/ or research subjects/ or "consent (research)"/ or research subject recruitment/ or research subject/ or refusal to participate/ or experimental subjects/ (74953)
5 ((accru$ or enrol$ or recruit$ or participat$ or enlist$ or consent$ or enter$ or join$ or volunteer$) adj3 (trial$ or study or studies or research$)).ti,ab. (177276)
6 4 or 5 (247643)
7 exp social class/ or socioeconomic factors/ or exp poverty/ or exp age factors/ or exp sex factors/ or exp Marital Status/ or Educational Status/ or gender issues/ or health inequalities/ or literacy/ or family characteristics/ or exp socioeconomics/ or exp social status/ or exp academic achievement/ or exp socioeconomic class attitudes/ or exp educational background/ or exp demographic characteristics/ or exp socioeconomic status/ (1121858)
8 ((gender$ or sex or class or depriv$ or poverty or income$ or age or socioeconomic$ or sociodemograph$ or socio?demograph$ or socio?economic$ or poor$ or wealth$ or status$ or social$ or education$ or literat$ or illiterat$ or single or married or divorced or spous$ or partner$ or marital) adj3 (reason$ or factor$ or caus$ or result$ or decision$ or attitude$ or influenc$)).ti,ab. (379530)
9 7 or 8 (1417012)
10 exp neoplasms/ or medical oncology/ or oncology service, hospital/ or exp cancer/ or cancer services/ or exp oncology care units/ or exp oncology/ or exp cancer care facilities/ or exp neoplasm/ or cancer center/ (3300877)
11 (cancer$ or carcin$ or malign$ or neoplas$ or oncol$ or tumo?r$).ti,ab. (2753633)
12 10 or 11 (3884393)
13 ((willing$ or ready or able or agree$ or choose or chose or accept$ or involve$ or assent$ or commit$ or benef$ or increas$ or comply or complian$) adj3 (accru$ or enrol$ or recruit$ or participat$ or enlist$ or consent$ or enter$ or join$ or volunteer$)).ti,ab. (57886)
14 ((dropout$ or failure$ or refus$ or difficult$ or barrier$ or obstacle$ or imped$ or problem$ or deter$ or discourage$ or unwilling$ or adverse$ or declin$ or reluct$) adj3 (accru$ or enrol$ or recruit$ or participat$ or enlist$ or consent$ or enter$ or join$ or volunteer$)).ti,ab. (28363)
15 13 or 14 (84074)
16 3 and 6 and 12 and (9 or 15) (2384)
17 limit 16 to english (2317)
18 limit 17 to english language (2317)
19 limit 18 to yr="1987 - 2007" (2245)
20 remove duplicates from 19 (1579)
21 from 20 keep (293)

B) Clinical Trial Recruitment (Non Cancer): Influencing Factors and Willingness/Refusal, Limited to “Review”

Databases searched: Ovid MEDLINE(R) (mesz), Ovid MEDLINE(R) In-Process and Other Non-Indexed Citations (prem), CDSR (coch), ACP Journal Club (acp), DARE, CCTR, British Nursing Index (brni), CINAHL (nursing), EMBASE (emez), PsycINFO (psyf).

Search Strategy

1 exp clinical trials/ or controlled clinical trials/ or randomized controlled trials/ or multicenter studies/ or "research and development"/ or exp clinical trial/ (1309928)
2 ((controll$ or clinical or randomiz$ or randomis$) adj (trial$ or study or studies or research$)).ti,ab. (742221)
3 1 or 2 (1747925)
4 patient selection/ or research subjects/ or "consent (research)"/ or research subject recruitment/ or research subject/ or refusal to participate/ or experimental subjects/ (74953)
5 ((accru$ or enrol$ or recruit$ or participat$ or enlist$ or consent$ or enter$ or join$ or volunteer$) adj3 (trial$ or study or studies or research$)).ti,ab. (177276)
6 4 or 5 (247643)
7 exp social class/ or socioeconomic factors/ or exp poverty/ or exp age factors/ or exp sex factors/ or exp Marital Status/ or Educational Status/ or gender issues/ or health inequalities/ or literacy/ or family characteristics/ or exp socioeconomics/ or exp social status/ or exp academic achievement/ or exp socioeconomic class attitudes/ or exp educational background/ or exp demographic characteristics/ or exp socioeconomic status/ (1121858)
8 ((gender$ or sex or class or depriv$ or poverty or income$ or age or socioeconomic$ or sociodemograph$ or socio?demograph$ or socio?economic$ or poor$ or wealth$ or status$ or social$ or education$ or literat$ or illiterat$ or single or married or divorced or spous$ or partner$ or marital) adj3 (reason$ or factor$ or caus$ or result$ or decision$ or attitude$ or influenc$)).ti,ab. (379530)
9 7 or 8 (1417012)
10 exp neoplasms/ or medical oncology/ or oncology service, hospital/ or exp cancer/ or cancer services/ or exp oncology care units/ or exp oncology/ or exp cancer care facilities/ or exp neoplasm/ or cancer center/ (3300877)
11 (cancer$ or carcin$ or malign$ or neoplas$ or oncol$ or tumo?r$).ti,ab. (2753633)
12 10 or 11 (3884393)
13 ((willing$ or ready or able or agree$ or choose or chose or accept$ or involve$ or assent$ or commit$ or benef$ or increas$ or comply or complian$) adj3 (accru$ or enrol$ or recruit$ or participat$ or enlist$ or consent$ or enter$ or join$ or volunteer$)).ti,ab. (57886)
14 ((dropout$ or failure$ or refus$ or difficult$ or barrier$ or obstacle$ or imped$ or problem$ or deter$ or discourage$ or unwilling$ or adverse$ or declin$ or reluct$) adj3 (accru$ or enrol$ or recruit$ or participat$ or enlist$ or consent$ or enter$ or join$ or volunteer$)).ti,ab. (28363)
15 13 or 14 (84074)
16 3 and 6 and 12 and (9 or 15) (2384)
17 limit 16 to english (2317)
18 limit 17 to english language (2317)
19 limit 18 to yr="1987 - 2007" (2245)
20 remove duplicates from 19 (1579)
21 3 and 6 and 9 (5843)
22 limit 21 to english (5600)
23 limit 22 to english language (5600)
24 limit 23 to yr="1997 - 2007" (4502)
25 remove duplicates from 24 (3600)
26 3 and 6 and 15 (4398)
27 limit 26 to english (4228)
28 limit 27 to english language (4228)
29 limit 28 to yr="1997 - 2007" (3277)
30 remove duplicates from 29 (1986)
31 26 or 30 (4398)
32 remove duplicates from 31 (2760)
33 32 not 20 (2190)
34 review.mp. (2771947)
35 33 and 34 (336)
36 from 35 keep (86)

APPENDIX 3.1

Literature Search – Informed Consent

Measures of Informed Consent in Cancer (and Non Cancer) Clinical Trials

Databases searched: Ovid MEDLINE(R) (mesz), Ovid MEDLINE(R) In-Process and Other Non-Indexed Citations (prem), CDSR (coch), ACP Journal Club (acp), DARE, CCTR, British Nursing Index (brni), British Nursing Index Archive (bnib), CINAHL (nursing), EMBASE (emed), PsycINFO (psyf).

Search Strategy

1 exp clinical trials/ or controlled clinical trials/ or randomized controlled trials/ or multicenter studies/ or "research and development"/ or exp clinical trial/ (1334208)
2 ((controll$ or clinical or randomis$ or randomiz$) adj (trial$ or research$ or study or studies)).ti,ab. (721846)
3 1 or 2 (1746030)
4 exp neoplasms/ or medical oncology/ or oncology service, hospital/ or exp cancer/ or cancer services/ or exp oncology care units/ or exp oncology/ or exp cancer care facilities/ or exp neoplasm/ or cancer center/ (3131691)
5 (cancer$ or carcin$ or malign$ or neoplas$ or oncol$ or tumo?r$).ti,ab. (2617175)
6 4 or 5 (3682358)
7 exp Informed Consent/ or decision making/ or choice behavior/ or judgment/ or patient decision making/ or exp patients rights/ or exp decision making process/ or exp "consent (research)"/ or exp decision making, patient/ (194546)
8 ((inform$ or share$ or participat$ or involve$ or explicit$) adj3 (choice$ or consent$ or choose or decide or decision)).ti,ab. (52978)
9 7 or 8 (225216)
10 exp uncertainty/ or exp Anxiety/ or exp knowledge/ or exp comprehension/ (176518)
11 (equipoise$ or uncertain$ or unsure$ or know$ or comprehen$ or understan$ or understood or anxious$ or worr$ or anxiety).ti,ab. (2652918)
12 10 or 11 (2715290)
13 exp health surveys/ or health care surveys/ or exp interviews/ or questionnaires/ or Evaluation Studies/ or exp "Outcome and Process Assessment (Health Care)"/ or outcome assessment/ or outcomes research/ (1697873)
14 (scale$ or measur$ or instrument$ or assess$ or evaluat$).ti,ab. (6486465)
15 13 or 14 (7388987)
16 15 and 3 and 9 and 12 (3612)
17 15 and 3 and 6 and 9 and 12 (819)
18 16 or 17 (3612)
19 limit 18 to english (3388)
20 limit 19 to english language (3388)
21 remove duplicates from 20 (2415)
22 limit 21 to yr="1996 - 2007" (2093)
23 results from AVPI search (1064)
24 results from recruitment search (2802)
25 22 not (23 or 24) (1888)
26 3 and 6 and 9 and 12 (1152)
27 26 not (22 or 23 or 24) (640)
28 remove duplicates from 27 (483)
29 limit 28 to english (433)
30 limit 29 to yr="1996 - 2007" (342)
31 25 or 30 (380)
32 remove duplicates from 31 (337)

APPENDIX 4.1

Literature Search – Audiovisual Patient Information

Audiovisual Patient Information with Reference to Clinical Trials and/or Cancer

Databases searched: Ovid MEDLINE(R) (mesz), Ovid MEDLINE(R) In-Process and Other Non-Indexed Citations (prem), CDSR (coch), ACP Journal Club (acp), DARE, CCTR, British Nursing Index (brni), British Nursing Index Archive (bnib), CINAHL (nursing), EMBASE (emez), PsycINFO (psyf).

Search Strategy

1 exp neoplasms/ or exp medical oncology/ or exp oncology service, hospital/ or exp neoplasm/ or oncology/ or cancer center/ or oncology care units/ or cancer care facilities/ or exp cancer/ or cancer services/ (3300546)
2 (cancer$ or carcin$ or malign$ or tumo?r$ or neoplas$ or oncolog$).ti,ab. (2752616)
3 1 or 2 (3883813)
4 audiovisual aids/ or motion pictures/ or multimedia/ or videodisc recording/ or compact disks/ or videotape recording/ or audiovisual equipment/ or videorecording/ or audiovisuals/ or audiovisual production/ or cd rom/ or digital versatile disc/ or videodiscs/ or audio visual aids/ or educational audiovisual aids/ or audiovisual communications media/ or instructional media/ or audiovisual instruction/ or educational television/ or televised instruction/ or videotape instruction/ or films/ (60347)
5 (video or dvd or cdrom or audio?visual or audiovisual).ti,ab. (67264)
6 4 or 5 (109138)
7 exp clinical trials/ or randomized controlled trials/ or exp clinical trial/ or randomized controlled trial/ or "research and development"/ (1307543)
8 ((randomis$ or randomiz$ or controll$ or clinical$ or phase$) adj (research$ or study$ or studies or trial$)).ti,ab. (744244)
9 7 or 8 (1747863)
10 patient selection/ or research subjects/ or exp informed consent/ or patient participation/ or consumer participation/ or research subject/ or refusal to participate/ or patient decision making/ or "consent (research)"/ or research subject recruitment/ or patients empowerment/ or patients rights/ or "patients attitudes and perceptions"/ or experimental subjects/ or client participation/ (168031)
11 ((patient$ or user$ or consumer$ or subject$ or participant$) adj (recruit$ or volunteer$ or accru$ or enrol$ or enlist$ or commit$ or join$ or enter$ or accept$ or involve$ or consent$ or choose or chose or select$ or participat$)).ti,ab. (112589)
12 10 or 11 (268950)
13 patient education/ or health education/ or health knowledge, attitudes, practice/ or patient acceptance of health care/ or consumer health information/ or patient information/ or health information/ or health knowledge/ or patient attitudes/ or patients education/ or client education/ (333619)
14 ((patient$ or user$ or subject$ or consumer$ or participant$) adj3 (inform$ or educat$ or develop$ or consent$ or knowledge$ or understand$ or accept$ or attitude$ or decision$ or teach$)).ti,ab. (377738)
15 13 or 14 (665602)
16 6 and 9 and 15 (1415)
17 3 and 6 and 9 and 15 (301)
18 6 and 9 and 12 (439)
19 3 and 6 and 9 and 12 (114)
20 16 or 17 or 18 or 19 (1617)
21 limit 20 to english (1569)
22 limit 21 to english language (1569)
23 limit 22 to yr="1987 - 2007" (1529)
24 remove duplicates from 23 (1049)
25 from 24 kept 325

APPENDIX 5.1

Study Team

NAME	POSITION
Cathy Hutchison	**Cancer Consultant Nurse** NHS Greater Glasgow and Clyde/The Beatson West of Scotland Cancer Centre
Professor Jim Cassidy	**Professor of Clinical Oncology/Clinical Trials Lead/Colorectal Cancer Lead** The Beatson West of Scotland Cancer Centre
Chloe Cowan	**Research Practitioner** The Beatson West of Scotland Cancer Centre
Tracey McMahon	**Data Manager** CRUK Clinical Trials Office, The Beatson West of Scotland Cancer Centre
Jim Paul	**Head of Biostatistics** CRUK Clinical Trials Office, The Beatson West of Scotland Cancer Centre
Dr Noelle O'Rourke	**Consultant Clinical Oncologist/Lung Cancer Clinical Lead/Clinical Lead for West of Scotland Lung Cancer Managed Clinical Network** The Beatson West of Scotland Cancer Centre
Dr Peter Canney	**Consultant Medical Oncologist/Breast Cancer Clinical Lead** The Beatson West of Scotland Cancer Centre
Dr Helen Mackay	**Consultant Clinical Oncologist (Breast Cancer)** Formerly The Beatson West of Scotland Cancer Centre
Iona Brisbane	**Lung Cancer Clinical Nurse Specialist** The Beatson West of Scotland Cancer Centre
Pauline McIlroy	**Breast Cancer Clinical Nurse Specialist** The Beatson West of Scotland Cancer Centre
Lynne Stirling	**Breast Cancer Clinical Nurse Specialist** The Beatson West of Scotland Cancer Centre
Alice MacLeod	**Colorectal Cancer Clinical Nurse Specialist** The Beatson West of Scotland Cancer Centre
Dr Lesley McNair	**Head of Clinical Psychology** The Beatson West of Scotland Cancer Centre
T.H.	**Patient** The Beatson West of Scotland Cancer Centre
C.G.	**Patient** The Beatson West of Scotland Cancer Centre

APPENDIX 5.2

Randomised Clinical Trials Open in Lung, Breast and Colorectal Cancer During the Period of AVPI Study Recruitment

Breast			
B91	Advanced disease (A)	A randomised phase II study of loading dose Ibandronate schedules in patients with bone metastates from breast cancer	Open throughout
B78	Limited disease (L)	A prospective randomised comparison of G-CSF secondary prophylaxis vs. conservative management of chemotherapy induced neutropenia to maintain dose intensity in adjuvant chemotherapy for breast cancer	Open throughout
B87	(A)	A randomised 2 arm multicentre open label phase III trial comparing the activity and safety of a weekly vs. a 3 weekly Paclitaxel treatment schedule in patients with advanced or metastatic breast cancer	Open throughout
B90	(L)	Post operative radiotherapy in minimum risk elderly breast cancer	Open throughout
B88	(L)	A phase III randomised controlled trial to determine whether adjuvant Zoledronic acid reduced recurrence in patients with high risk localised breast cancer	Closed Jan 06
B92	(A)	A phase III trial of novel Epothilone BMS-247550 plus Capecitabine vs. Capecitabine alone in patients with advanced breast cancer previously treated with an anthracycline or a taxane	Open throughout
B93	(L)	Ovarian protection trial in oestrogen non-responsive premenopausal breast cancer patients receiving adjuvant or neoadjuvant chemotherapy	Open throughout
B94	(L)	Neoadjuvant study of sequential Epirubicin/ Cyclophosphamide and Paclitaxel +/- Gemcitabine in the treatment of high risk early breast cancer with molecular profiling	Opened Jan 06
B99	(L)	Fast prospective randomised clinical trial testing 5.0 GY and 6GY fractions of whole breast radiotherapy in terms of late normal tissue responses and tumour control	Opened Oct 05
B102	(A)	Study of Faslodex with or without concomitant Arimidex vs. Exemestane following progression on non-steroidal aromatase inhibitors	Opened June 05
B104	(L)	Trial of accelerated adjuvant chemotherapy with Capecitabine in early breast cancer	Opened Mar 06
B110	(A)	A phase III randomised open label comparative study of standard whole brain radiation with or without concurrent RSR13 in women with brain metastases from breast cancer	Opened Jul 05
B126	(L)	Randomised trial testing observation (no radiotherapy) against radiotherapy in women with low risk completely excised ER positive ductal carcinoma in situ (DCIS) of the breast on adjuvant endocrine therapy	Opened Jun06
Lung			
L75	(A)	A randomised controlled trial of active symptom control with or without chemotherapy in the treatment of mesothelioma	Open throughout
L59	(A)	A multicentre randomised trial of high vs. standard doses of prophylactic cranial irradiation in limited small cell lung cancer (SCLC) complete responders	Closed Dec 05
L73	(A)	A phase III randomised double blind placebo controlled trial of Carboplatin and Etoposide with or without Thalidomide in SCLC	Closed Mar 06
L76	(A)	Phase III randomised study of TLK286 vs. Gefitinib as third line therapy in locally advanced or metastatic non small cell lung cancer (NSCLC)	Closed May 05

L84	(A)	A BTOG phase III trial of Gemcitabine plus Cisplatin at 80mg/m2 vs. Gemcitabine plus Cisplatin 50mg/m2 vs. Gemcitabine plus Carboplatin AUC6 in stage IIIB/IV NSCLC	Opened Oct 05
L67	(A)	Prophylactic cranial radiation in extensive disease SCLC	Closed Mar 06
L78	(A)	A randomised phase III study of two doses of Alimta with locally advanced or metastatic NSCLC who have failed prior platinum containing chemotherapy	Opened May 05 Closed Oct 05

Colorectal

GI95	(A)	A phase III randomised open label multi-centre study of Irinotecan and Cetuximab vs. Irinotecan as second line treatment in patients with metastatic EGFR positive colorectal carcinoma	Open throughout
GI101	(A)	Open randomised controlled multi-centre phase III study comparing 5FU/FA plus Irinotecan plus Cetuximab vs. 5FU/FA plus Irinotecan as first line treatment for epidermal growth factor receptor-expressing metastatic colorectal cancer	Opened April 05 Closed Feb 06
GI103	(A)	A phase III trial comparing either continuous chemotherapy plus Cetuximab or intermittent chemotherapy with standard continuous palliative combination chemotherapy with Oxaliplatin and a fluoropyrimidine in first line treatment of metastatic colorectal cancer	Opened June 05
GI104	(L)	A randomised three arm multinational phase III study to investigate Bevacizumab in combination with either intermittent Capecitabine plus Oxaliplatin or a 5 FU/FA with Oxaliplatin vs. folfox 4 regimen alone as adjuvant chemotherapy in colon cancer	Opened Apr 05
GI108	(L)	Chemotherapy or no chemotherapy in clear margins after neoadjuvant chemoradiation in locally advanced rectal cancer. A randomised phase III trial of control vs. Capecitabine plus Oxaliplatin	Opened May 05
GI117	(A)	A multi-centre open label parallel group randomised phase IIB clinical trial to evaluate the safety and efficacy of co-factor and 5FU vs. Leucovorin and 5FU in subjects with metastatic colorectal carcinoma	Opened Dec 05
GI119	(A)	A multi-centre randomised double blind placebo controlled phase III study of the efficacy of Xaliproden in preventing the neurotoxicity of Oxaliplatin in first line treatment of patients with metastatic colorectal cancer treated with Oxaliplatin/5FU/FA	Opened May 06

APPENDIX 5.3

Patient Information Sheet

INFORMATION SHEET FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Study title
A Randomised, Controlled Study Into the Effect of an Audiovisual Intervention on Patient Recruitment to Cancer Clinical Trials.

Introduction
You have been invited to participate in a research study. Before making a decision it is important that you understand why the study is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with relatives, friends or your nurse or doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?
Research into cancer treatments is important but patients are asked to consider complex information about research at stressful times. We are looking at ways of improving information and making it easier for patients to decide whether or not to take part in research trials for 3 common cancers – breast, lung and bowel. The aim of this study is to see if information in video / CD-ROM / DVD format improves peoples' knowledge about clinical trials. Also, the aim is to see if it makes any difference to their decision about whether or not to take part in a clinical trial. To take part in the study, you need to have access to either a video recorder, DVD player or a computer to play CD-ROMs. The study is being carried out as part of a Clinical Doctorate course through Stirling University and will run for approximately 2 years.

Why have I been chosen?
You have been chosen because you have been diagnosed with either lung, breast or bowel cancer and your doctor has spoken to you about a research trial. It is planned to involve about 184 patients in the study.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide that you do wish to take part, you will be asked to sign a consent form to say that you have read and understood this Patient Information Sheet, that all your questions have been answered completely and that you wish to continue with the study. You will be given a copy of the information sheet and consent form to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?
Half of the patients in this study (Group 1) will receive a video (or DVD or CD-ROM) that lasts 10-15 minutes as well as written information and discussion about the trial with your nurse or doctor. This will be given to you following your consent to this study, to take home and watch before your next hospital visit.

If you are allocated to the other group (Group 2), you will be given written information and discussion about the trial with your nurse or doctor. We do not know if people will find the video useful and comparisons need to be made. Whether you will be in the group allocated to receive the video or not, will be decided randomly by computer, like by the toss of a coin. You will have a one in two chance of receiving the video.

What do I have to do?
If you are in Group 1, you will be asked to view the video and read written information before your next visit. If you are in Group 2 you will be asked to read written information and discuss it. Regardless of which group you are in, you will be asked to complete 2 questionnaires (about knowledge and anxiety) at your first visit and 3 questionnaires (about knowledge, anxiety and your decision about the treatment trial) at your second visit. These should take between 15-20 minutes in total to complete at each visit. You will be given these questionnaires by the research nurse when you first discuss the treatment trial with the doctor and when you come back to see your doctor to discuss your decision about the treatment trial. This is usually about a week from the time of your first visit to discuss the trial.

What is the procedure being tested?
The procedure being tested is an information video / CD-ROM / DVD about clinical research trials, which has been developed by the researcher with patients and staff in the department. It contains general information about clinical research trials and information about cancer research in your specific cancer type. It is intended to supplement the written information you will receive, to allow a more informed decision to be made.

What are the possible disadvantages and risks of taking part?
Taking part in this study will not cause you any additional hospital visits than choosing not to take part in the study. The total time commitment will be about 1 hour 20 minutes. This includes time for viewing the video, completing the questionnaires and 2 meetings with the research nurse when you are at the hospital to see the doctor.

What are the possible benefits of taking part?
Taking part in the study may not be of direct benefit to you, but could help in the development of information and treatment for the benefit of future patients.

Will my taking part in the study be kept confidential?
All of the information that is collected about you during the course of the study will be kept strictly confidential. No information will be fed back to your oncologist. The Data Protection Act (1998) and the NHS Scotland Code of Practice on Protecting Patient Confidentiality (July 2003) will be adhered to. We will collect some personal information from your hospital notes including demographic details like age, diagnosis and sex. This log will be kept in a locked drawer in the researcher's office. All other study information, including returned questionnaires will be kept in a separate locked cupboard. All data will be entered into a computer and anonymised. You will be allocated a Study Identification (ID) number which will be used on all questionnaires to enable them to be linked to the personal data which will be entered onto the computer without your name or hospital number. Electronic information will be password protected. Following completion of the study, the data will be stored and destroyed in accordance with Standard Operating Procedures in the Beatson Oncology Centre Clinical Trials Unit (specifically No 002, Filing and Archiving of Clinical Documentation). Your General Practitioner will be advised of your participation.

What will happen to the results of the research study?
At the end of the study, the results will be published in a health care journal. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. You will not be identified in any report/publication.

Who has reviewed the study?
The West Ethics Committee at North Glasgow University Hospitals Division and Stirling University Department of Nursing Research Ethics Committee have both reviewed the study.

Contact for further information
Please ask if there is anything that is not clear or if you would like more information. The doctor treating you will be pleased to answer any further questions or discuss any issues that arise as a result of this study. In case of any questions specific to this study, please telephone: Cathy Hutchison, Cancer Consultant Nurse on 0141 211 2344.

Thank you for taking the time to read this information sheet.

Version 2: 7/06/04

APPENDIX 5.4

Consent Form

Study Code:

Patient Identification Number for this trial:

CONSENT FORM

Title of Project:

A Randomised, Controlled Study into the Effect of an Audiovisual Intervention on Patient Recruitment to Cancer Clinical Trials.

Name of Researcher: Cathy Hutchison, Cancer Consultant Nurse.

Please initial box

1. I confirm that I have read and understand the information sheet dated 7th June 2004 (version 2) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of my medical notes may be looked at by responsible individuals from North Glasgow University Hospitals Division or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Name of Patient	**Date**	**Signature**
Name of Person Taking Consent (if different from researcher)	**Date**	**Signature**
Researcher	**Date**	**Signature**

1 for patient; 1 for researcher; 1 to be kept with hospital notes.

APPENDIX 5.5 – Registration Form

A RANDOMISED, CONTROLLED STUDY INTO THE EFFECT OF AN AUDIOVISUAL INTERVENTION ON PATIENT RECRUITMENT TO CANCER CLINICAL TRIALS

INITIALS: Forename ____ Surname ____ **DATE OF BIRTH*(dd/mm/yyyy)*: ___/___/____**

GENDER (M/F): ____ **REFERRING BOC CLINICIAN:**

REGISTRATION FORM

Any answer in a shaded box means the patient is ineligible unless a waiver is provided, in which case details must be provided below

		Yes	No
1.	Does the patient have a diagnosis of colorectal, breast or lung cancer? Specify which: _____	☐	☐
		☐	☐
2.	Is the patient clinically eligible for entry into a cancer treatment trial, randomised against control/standard treatment running at the BOC?	☐	☐
	Please give BOC study identifier _____		
3.	Is the patient aged ≥ 18 years?	☐	☐
4.	Does the patient have access to a video recorder, CD-ROM or DVD player?	☐	☐
5.	Is the patient able to understand English?	☐	☐
6.	Has the patient given written informed consent? *Date of consent* ___/___/___	☐	☐

If a waiver has been obtained from the Chief Investigator to register a patient who is otherwise strictly ineligible please tick ☐ and provide details below:-

Please sign below to confirm that all of the data given above is correct:-

INVESTIGATOR'S NAME _____

INVESTIGATOR'S SIGNATURE _____ **DATE *(dd/mm/yy)*** ____/____/____

When all the details above are completed contact the CRUK Trials Unit, Glasgow to obtain a patient trial identifier and treatment allocation:-
Tel: 0141 211 8544 (58544 internally)
Fax: 0141 211 1880 (51880 internally)

Allocated patient trial number _____

Allocated intervention ☐ **A = Audiovisual**
B = None

Registration date *(dd/mm/yy)* ____/____/____

Please return completed form to: CRUK Trials Unit, Beatson Oncology Centre, Western Infirmary, Glasgow G11 6NT, UK
Version 1 16/12/2004

APPENDIX 5.6 - Recruitment Log Sheets

A Randomised Controlled Trial into the Effect of an Audiovisual Intervention on Patient Recruitment to Cancer Clinical Trials.

PATIENTS ENTERED INTO AVPI STUDY (Study opened _____) BREAST/LUNG/COLORECTAL

Date	**Treat-ment Trial Code**	**Patient Name**	**AVPI Study Number**	**Hospital Number**	**Sex M/F**	**Age**	**Post code**	**Diagnosis**	**Stage of Cancer**	**Consul-tant**	**Clinician discussion trial**	**Randomisation**	**Entered into treatment trial?**	
								Site of primary cancer	Limited (**L**) or Advanced (**A**)	Initials	Visit 1 / Visit 2	Video **(V)** or no Video **(N)** (Write **CD or DVD if** pt chooses CD or DVD)	Yes (**Y**) No (**N**)	**Reasons not** Pt refused (**R**) Not eligible (**N**) Other (**O**) -specify

A Randomised Controlled Trial into the Effect of an Audiovisual Intervention on Patient Recruitment to Cancer Clinical Trials.

PATIENTS NOT ENTERED INTO AVPI STUDY (Study opened _____) BREAST/LUNG/COLORECTAL

Date	**Treat-ment Trial Code**	**Patient Name**	**Hospital Number**	**Sex M/F**	**Age**	**Post code**	**Diagnosis**	**Stage of Cancer**	**Consul -tant**	**Clinician discussion trial**	**Reason not entered into AVPI study**	**Entered into treatment trial?**
							Site of primary cancer	Limited (**L**) or Advanced (**A**)	Initials		Not eligible for AVPI study **(NV)** Not eligible for treatment trial (**NT**) Pt refused AVPI study (**R**) - give reason Other reason (**O**) - specify	Yes (**Y**) No (**N**)

APPENDIX 5.7

Letter to GP

Divisional Offices (West)
Administration Building
Western Infirmary
Dumbarton Road
Glasgow
G11 6NT
Telephone: 0141 211 2283
Email: cathy.hutchison@northglasgow.scot.nhs.uk

(Insert date)

(GP Address)

Dear (*Insert GP name)*

RE: *Attach addressograph label with patient details*

I write to inform you that your patient, as detailed above, has agreed to take part in a study looking at the effect of an audiovisual intervention on informed consent and consent rates to cancer clinical trials. This is in addition to the treatment trial that is being discussed with them by their hospital Medical Consultant.

This study involves randomising patients to receive a video/DVD/CD-ROM about clinical trials (patients choose which) + standard written information about the specific trial (Group 1) **OR** standard written information alone (Group 2). Both groups will then be compared in terms of knowledge, anxiety and consent rates.

Please find enclosed copy of the patient information sheet that the patient received.
Your patient has been randomised to Group *(Insert 1 or 2).*

Should you wish any further information, please do not hesitate to get in touch.

Yours sincerely

Cathy Hutchison
Cancer Consultant Nurse

Version 1: 29/04/04

APPENDIX 5.8

Knowledge Questionnaire (Questionnaire: Patient Understanding of Research)

CONFIDENTIAL Pre/Post Pt Inits: __ __ ID_____

QUESTIONNAIRE – PATIENT UNDERSTANDING OF RESEARCH

We are interested in what people know and understand about clinical research trials/studies and how this affects whether they take part. It would be very helpful if you could complete this questionnaire. It will not be shown to your doctor or any of the staff at the hospital. A prepaid envelope is provided for you to return it.

Please read the statements below and circle a), b), c) or d) – whichever one best describes your understanding of the statement. Please circle ONE answer only.

1. The main reason for carrying out research with patients is …

a) to improve current treatments.
b) to find treatments with no side-effects.
c) to help pay for cancer treatments.
d) don't know.

2. Research with patients is carried out…

a) only when a new treatment has no harmful side-effects.
b) only when a new treatment is more expensive.
c) when a new treatment is potentially better than the best available, standard one.
d) don't know.

3. In a *randomised* clinical research trial/study…

a) the treatment of the individual patient is decided by chance.
b) the doctor chooses the treatment for you, depending on your symptoms.
c) you choose the treatment, from the ones available in the trial.
d) don't know.

4. The main aim of a randomised trial is to….

a) find out if a new treatment is better than the best available standard treatment
b) to compare the costs of 2 treatments.
c) to compare treatments across different countries.
d) don't know.

5. When a trial is "randomised"…

a) the process selects the *best* treatment for you.
b) you have exactly the same chance of receiving the new treatment (or not receiving it), as any other patient taking part.
c) the doctor decides which treatment is the right one for you.
d) don't know.

6. It is justified for doctors to carry out a randomised trial...

a) when the new treatment has already been proven to be better than the standard treatment.
b) when they expect the old treatment to be better and want to prove this.
c) when there is genuine uncertainty from expert cancer doctors about which treatment is best.
d) don't know.

7. If "best supportive care" is one of the randomisation options in the trial, it means that…

a) supportive care is the standard usual treatment for that type and stage of cancer.
b) only patients who need their symptoms treated can take part in the trial.
c) patients will not receive drug treatments in this trial.
d) don't know.

8. Patients are chosen for a trial…

a) only if they live close to the hospital.
b) after the doctors and nurses together decide which patients would benefit most.
c) if they fit the guidelines for selecting patients (developed from previous research work).
d) don't know.

9. Taking part in the trial…

a) is not compulsory as long as a refusal form is signed after getting information about the trial.
b) is voluntary - there are no conditions.
c) is expected if your doctor thinks it is best for you.
d) don't know.

10. You can leave a trial…

a) only if you experience side-effects.
b) at any time without giving a reason.
c) with good cause.
d) don't know.

11. If you do not want to take part in a trial…

a) you can choose between the new and the standard treatment.
b) you will be offered the new treatment.
c) you will be offered the treatment which is currently considered the standard treatment for your cancer.
d) don't know.

12. Doctors involved in clinical research trials/studies...

a) do not receive any personal payment from drug companies.
b) receive a personal fee for every patient enrolled in the trial.
c) receive a personal fee for every trial they are involved in.
d) don't know.

ABOUT YOU

A. **Have you previously taken part in a research study (often known as a clinical trial)?**

Yes ☐ No ☐

B. **Has someone you know well or a member of your family been in a research study/clinical trial?** Yes ☐ No ☐

C. **Please tell us about your educational qualifications**
TICK each box that applies to you

No educational or vocational qualifications. ☐ 1

Qualification below degree level.
(e.g. diploma, standard and higher grades, A level, vocational qualification) ☐ 2

Degree, degree-level vocational qualification, or higher. ☐ 3

D. **Please tell us your Post Code**: ☐

Date completing questionnaire ☐

Thank you very much for taking the time to complete this questionnaire.

Please can you return it in the enclosed envelope as addressed to:

Cathy Hutchison, Cancer Nurse Consultant
2nd Floor, Administration Building
Western Infirmary, Dumbarton Road
Glasgow, G11 6NT.

Version 4: 2/11/04

APPENDIX 5.9

Spielberger's State-Trait Anxiety Inventory – State Scale

a) Permission letter from Mind Garden, Inc.

Date: **February 13, 2008**

To whom it may concern,

This letter is to grant permission for: **Catherine Hutchison**
to use the following copyright material;

Instrument: *State Trait Anxiety Inventory for Adults*

Author: *Charles D. Spielberger*

Copyright: *1983 by Charles D. Spielberger*

for her/his thesis or dissertation research.

In addition, five (5) sample items from the instrument may be reproduced for inclusion in a proposal or thesis.

The entire measure may not at any time be included or reproduced in other published material.

Sincerely,

Electronically signed by

Valorie Keller
Mind Garden, Inc.
855 Oak Grove Ave. Suite 215
Menlo Park, CA. 94025

RE: Inv #1253, April 11, 2004

b) 5 sample questions from State-Trait Anxiety Inventory – State Scale

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

1. I feel calm…….. 1 2 3 4

7. I am presently worrying over possible misfortunes…….. 1 2 3 4

9. I feel frightened…….. 1 2 3 4

16. I feel content……..1 2 3 4

18. I feel confused…….. 1 2 3 4

1 = Not at all
2 = Somewhat
3 = Moderately so
4 = Very much so

APPENDIX 5.10

Clinical Trial Decision Questionnaire

We are interested in the reasons why patients **accept** or **decline** to take part in clinical trials/studies. We would be grateful if you would fill in this questionnaire. It will not be shown to your doctor or any of the staff at the hospital. A prepaid envelope is provided for the return of the form.

First we would like to know if you have agreed to take part in a clinical trial/study?
Yes ☐ No ☐ Don't Know ☐

Below are some reasons that may have influenced your decision to **accept** or **decline** to take part in a clinical trial/study. Please answer each question and tick the box that shows most clearly how you feel.

		Strongly agree	Agree to some extent	Unsure	Disagree to some extent	Strongly disagree
1	I thought the trial/study offered the best treatment available.	☐	☐	☐	☐	☐
2	I believed the benefits of treatment in the trial/study would outweigh any side-effects.	☐	☐	☐	☐	☐
3	I was satisfied that either treatment in the trial/study would have been suitable for me.	☐	☐	☐	☐	☐
4	I was worried that my illness would get worse unless I joined the trial/study.	☐	☐	☐	☐	☐
5	The idea of randomisation worried me.	☐	☐	☐	☐	☐
6	I wanted the doctor to choose my treatment rather than be randomised by computer.	☐	☐	☐	☐	☐
7	The doctor told me what I needed to know about the trial.	☐	☐	☐	☐	☐
8	I trusted the doctor treating me.	☐	☐	☐	☐	☐
9	I was given too much information about the trial.	☐	☐	☐	☐	☐
10	I was given enough information about the trial.	☐	☐	☐	☐	☐
11	I knew that I could leave the trial/study at any time and still be treated.	☐	☐	☐	☐	☐
12	I did not feel able to say no.	☐	☐	☐	☐	☐
13	I wanted to help with the doctor's research.	☐	☐	☐	☐	☐
14	I feel that others with my illness will benefit from the results of the trial/study.	☐	☐	☐	☐	☐
15	The doctor wanted me to join the trial/study.	☐	☐	☐	☐	☐
16	Others, e.g. family and friends wanted me to join the trial/study.	☐	☐	☐	☐	☐

17. Which was the most important reason for you out of the list? (Please give number)____

18. How much of the total information you received, did you understand?

None of it	A little	Some of it	Most of it	All of it
☐	☐	☐	☐	☐

19. Did you have enough time to make your decision?

Yes ☐ No ☐ Not sure ☐

20. Who did you discuss taking part in the research study (clinical trial) trial with? (please tick all that apply)

Family ☐
Doctor ☐
GP ☐
Other ☐ Please say who_____

Specialist nurse ☐
Nurse in ward/clinic ☐
Research nurse ☐
No one ☐

21. Did you read the written information sheet? Yes ☐ No ☐

22. Did you find it useful? Yes ☐ No ☐

23. What effect, if any, did it have on your decision about whether or not to take part in the research study (clinical trial)?

Made me want to take part	Made me not want to take part	Had no effect on my decision
☐	☐	☐

If you received the video/CD-ROM/DVD, please complete the following questions by ticking the most appropriate box.

24. Did you watch the video/CD-ROM/DVD Yes ☐ No ☐

25. Did you find it useful? Yes ☐ No ☐

26. What effect, if any, did it have on your decision about whether or not to take part in the treatment trial?

Made me want to take part	Made me not want to take part	Had no effect on my decision
☐	☐	☐

Thank you very much for taking the time to complete this questionnaire

Please can you return it in the enclosed envelope as addressed to:
Cathy Hutchison, Consultant Nurse
Administration Building - 2nd Floor, Western Infirmary, Dumbarton Road, Glasgow, G11 6NT.

APPENDIX 5.11

Record of Returned Questionnaires

A Randomised Controlled Trial into the Effect of an Audiovisual Intervention on Patient Recruitment to Cancer Clinical Trials.

PATIENT NAME	STUDY NO.	Video(V), CD (CD) DVD (DVD) or Nothing (N)	(1) CTDQ, (2) Knowledge & (3) Anxiety questionnaires		VISIT	COMMENTS
			Date given to patient	**Date back**		

APPENDIX 5.12

Correct Answers to Knowledge Questionnaire

QUESTIONNAIRE: PATIENT UNDERSTANDING OF RESEARCH

Thank you for taking the time to complete the above questionnaire. Please find below for your information, a list of the correct answers.

Correct Answers

1. **The main reason for carrying out research with patients** ….is to improve current treatments.

2. **Research with patients is carried out** ….when a new treatment is potentially better than the usual, standard one.

3. **In a *randomised* clinical research trial/study**…the treatment of the individual patient is decided by chance.

4. **The main aim of a randomised trial is to….** find out if a new treatment is better than the commonly used treatment.

5. **When a trial is "randomised" …** you have exactly the same chance of receiving the new treatment (or not receiving it), as any other patient taking part.

6. **"Drawing a blank" in a randomised trial…**is not possible because it is not known which option is best.

7. **It is justified for doctors to carry out a randomised trial...** when there is genuine uncertainty from expert cancer doctors about which treatment is best.

8. **If “best supportive care” or “symptom control” is one of the randomisation options in the trial, it means that…**supportive care or symptom control is the standard usual treatment for that type and stage of cancer.

9. **Patients are chosen for a trial…**if they fit the guidelines for selecting patients (developed from previous research work).

10. **Taking part in the trial…**is voluntary - there are no conditions.

11. **You can leave a trial…**at any time without giving a reason

12. **If you do not want to take part in a trial…**you will be offered the treatment which is currently considered the standard treatment for your cancer.

13. **Doctors involved in clinical research trials/studies...**do not receive any financial incentives from drug companies.

APPENDIX 6.1 – Video-script Used in Filming

Cancer clinical trials video script [draft 6-Final-November 2004]

Action	Dialogue
<u>Exterior</u> George Square **ML Shot** (face) of City Chambers, **pan out** and round to Queen St Station, hold Top of Byres Road ? Safeway car park **ELS to MLS (high)** looking down Byres Rd to Dumbarton Rd **ML shot** of Hillhead U taken from other side of road WIG entrance – Dumbarton road Stand facing Kelvin Hall (at an angle) **Low level long shot** of oncoming traffic (buses) **ML Shot** of drive, round to **MLS to MCU** shot of entrance to Beatson Oncology Centre (**High shot from balcony)** **<u>Interior</u>** **RECEPTION** **MLS** of LG coming in the main entrance towards Reception and by. **2 shots: track & pan from reception**	**<u>Opening sequence with soundtrack "King of the Road" (Proclaimers)</u>** **SCENE 1** **SCENE 2**

Interior **CRU-Consulting room/Office** Office computer, x-ray boxes, white coat on peg, books, in tray etc **ML Shot** LG walking into "office", swings round to follow, **(?pan or track)** LG sits.	**SCENE 3**
Cut to **MS** (slight R angle)	**SCENE 4** Hello. Welcome to our Clinical Trials video. My name's Louise and I'm presenting this video on behalf of the Clinical Trials Unit at the Beatson Oncology Centre. This video has been made to give you more information about clinical trials, specifically… randomised clinical trials…. It will focus generally on research in [lung/breast/bowel] cancer and address some important issues. This should help you to understand your written information sheet. So, - first things first. - 'What are Clinical Trials?
MCU shot **LS** (face on, eye level) from outside office LG walking through waiting area towards camera **MCU** (left angle)	Well.., Clinical trials are research studies that are carried out with patients to improve current treatments. Results from previous research studies have already improved the way we treat people with [lung/breast/bowel] cancer. **(Stop)** **(Look to Left)** …But we still need to learn more and improve the treatments available.
CRU – Out-Pt Treatment Area - Clinician with a patient	**SCENE 5** **(LG walks over to Clinician (Right) and introduces him/her)**

2 shot **MCU** (face on) LG and Clinician	This is [Dr Mackay/Dr O'Rourke/Professor Cassidy] who is going to tell us a bit more about clinical trials in [breast/lung/bowel] cancer. **CLINICIAN** **(Looks to LG):** Thanks Louise
MCU Clinician	**(Turns to camera):** All of the medicines or drugs that you and other patients have been given during the course of your treatment will have been subject to clinical trials with patients, in the past. **SCENE 6**
CU Head and shoulders – clinician only Direct to camera	Without Clinical trials, the current treatments available for [lung/breast/bowel] cancer would never have been developed. Clinical trials are the only safe and effective way to improve cancer care. And the results of earlier clinical trials are used to advise you now. **SCENE 7**
MCU of LG head & shoulders	**LG: nod to Clinician, then straight to camera:** Clinical trials in cancer are carried out when a new treatment is potentially better than the currently best available standard treatment **SCENE 8**
Interior **CRU**	
MCU of LG leaning against glass window, side on	A lot of people are frightened by the idea of being part of an "experiment" … but the clinical trials that we do are informed and controlled. **LG unseen (voice only):**
Pan out & round to take in day ward with patients and staff	If you do decide to take part, you will be one of hundreds, sometimes thousands of people taking part world-wide in the same trial.
Back to **MS** of LG side on	Now for the technical bit.. -
CU LG	What exactly is a randomised clinical trial? **SCENE 9**
Interior **Pharmacy** Pharmacy making up chemotherapy.	**(Voice only)** A randomised clinical trial is a research study with patients which tests out the currently available best treatment against a new treatment. Treatments are compared to find out which is better.

Interior **CRU Consulting Room/Office** **MS** (straight on) of LG sitting at desk 2 x A4 mini Flip charts. One "new" (closed) one "current standard" (open) both pictured and titled. Chemo bags	**SCENE 10**
LG indicates appropriately. "new" "standard"	An important point to note here is that we expect the new treatment to be <u>at least as good</u> as the currently available standard treatment.
LG indicates again "new", "standard"	If the new treatment wasn't expected to be at least as good as the currently best available treatment….
LG flicks/closes flip chart over new treatment.	Then the clinical trial wouldn't be allowed to go ahead.
LG re-opens "new"	We are really hoping that the new treatment <u>will be better</u> than the currently best available treatment, but…
Puts "new" and "standard" flip charts side by side.	there is <u>no evidence</u> at this stage that either treatment is better. That is the purpose of the trial – to find this out…….
CU shot	And… Randomised trials are only done when there is genuine uncertainty from expert cancer doctors about which treatment is best.
(Set up "new V standard" using the 2 flipcharts).	**SCENE 11**
MCU	So a randomised clinical trial is basically a controlled competition between 2 or more treatments.
Shots of treatments in progress: 1) Patient receiving chemotherapy in out-pt clinic 2) Patient receiving radiotherapy	**SCENE 12** **Voiceover:** Treatment can mean a single method of treating cancer such as drug therapy (sometimes called chemotherapy) or therapy using x-rays (called radiotherapy) or when we talk about treatment it can mean using a combination of methods. The type of treatment you are offered depends on your disease.

	SCENE 13
Interior **CRU**	
MLS of LG walking and talking side on along corridor outside day ward/**track**	Often a trial will involve 2 groups of patients. One group will usually have the best available standard treatment (or at least an equivalent treatment), for a particular type of cancer. The other group will have the new treatment being tested. **(Stop)**
CU of LG	I'll give you a couple of examples to try and explain how it works
	SCENE 14
For first 2 examples: LG full length shot, plain background – "Example 1" text comes in from bottom R	
CU then pan out to MCU Following text flies in on screen (ppt style)	
	Voiceover:
"Drug A *(standard treatment/ present best practice)*	Here, Drug A is the present best practice or standard treatment for a particular cancer.
versus	
Drug B *(new treatment)"*	Drug B is the new treatment being tested. The trial compares both drugs to see which is best. You have an equal chance of getting either drug A or drug B.
(Pictures of tablets in bottles as background)	
"Example 2" text comes in from bottom R	
Face on then pan out	
"Radiotherapy still shot" flies in to one side of screen	Here, the current best practice or standard treatment for this particular cancer is radiotherapy
"V" to middle	
"Radiotherapy still shot" to other side, followed by	The new "treatment" involves the same radiotherapy plus

"Chemo still shot"	chemotherapy.
<u>Interior</u> **CRU Consulting Room/Office**	
MCU of LG sitting at desk	We don't know if giving chemotherapy as well as the standard radiotherapy will make the overall treatment better. The trial will find this out. You would have an equal chance of getting the radiotherapy on its own or getting it with chemotherapy.
	SCENE 15
<u>Interior</u> **CRU Consulting Room/Office**	
MS of LG	In some cases cancer treatments are used to "hold the line" and to try and stop the cancer from getting worse. Also, sometimes treatment to help symptoms (for example pain or breathlessness), is the current best available practice for a particular type and stage of cancer.
CU of LG	This can be called "best supportive care" or symptom control".
Cut to LG **MLS**, plain background – "Example 3" text comes in from bottom R	
Face on then pan out to CRU	**Voiceover:** An example of a randomised trial in this case may be….
	SCENE 16
Nurse/patient with nurse giving "patient tablets still" flies in to one side of screen	…..comparing the standard current best practice called <u>Best Supportive Care</u> which could include something like giving steroid tablets to help relieve breathlessness …
Same "nurse/patient still " to other side	with the new treatment, which involves the <u>same Supportive Care</u> plus
+ "chemo still shot"	<u>Chemotherapy, Drug X</u> .
<u>Interior</u> **CRU Consulting Room/Office**	

MLS of LG/ CRU background shot	The hope is that the chemotherapy will be even more effective in relieving breathlessness and fighting the cancer than the current best practice – supportive care. I hope these examples make things a bit clearer. So, to recap……. A randomised clinical trial is a research study with patients which tests out the currently best available treatment against a new treatment. Treatments are compared to find out which is better. Remember…the main aim of a randomised trial is to find out if a new treatment is better than the commonly used treatment. The word "randomised" really just refers to the way in which the trial is run. It's a scientific way to make sure that the results are correct and not biased. I'll tell you a wee bit more later about how it is done.
Interior **CRU Waiting Area**	**SCENE 17**
MCU (top down track, L to R) on LG (?standing) 10 extras, move into shot, **MCU** pans out to **MLS**	So, you are one of hundreds, possibly thousands of similar patients from the UK, Europe and even America. You've been picked because you meet certain criteria which are developed from previous research work. For example, you've got a certain type or stage of cancer, age and general health.
	SCENE 18
Cut to MLS, LG direct to camera **(eye level)**	If you agree to take part in the randomised clinical trial, the question is, - what treatment do you get?
LG walks through extras to camera	Do you get the standard treatment which is currently the best available practice, or do you get the new treatment? Remember that we expect the new treatment to be <u>at least as good</u> as the standard treatment. **(stops)**
MCU (face on)	The new treatment may be better than the standard treatment, or it may not, - that's the purpose of doing the clinical trial.
MCU (from L)	If you take part in the clinical trial, whichever treatment you get - the standard treatment or the new treatment, - we already know that both are effective and appropriate to your condition. In other words, either way, you will receive a treatment that is effective for your condition.
MCU (from R)	So, who decides whether you get the standard treatment or the new treatment? Well, it's all down to chance, or to give it its technical name – randomisation.

	SCENE 19
Interior **CTU**	
Shots of Data Managers at computers	**Voiceover** Which group you go into 'standard or new' is usually done by a computer who allocates you randomly to one of the two groups.
MCU (face on)/**Split screen with Data Manager Shot**	The Doctor does not decide who goes into which group.
Interior **CRU Waiting Area**	
Cut to MLS of LG in waiting room with extras seated in background. Pan into **MS**	You therefore have an equal chance of being in either group. In other words…., you have exactly the same chance of receiving the new treatment, or not receiving it as any other patient taking part in the trial.
	SCENE 20
CU of LG (face on)	So, … do you have to take part in a clinical trial? – No –
L to R track	Taking part in the trial is completely voluntary. You decide whether or not you want to take part.
MCU (face on)	If you don't want to take part, you'll be offered the standard treatment currently available for your cancer and your current and future care will not be compromised in any way. The new treatment is not available outside a clinical trial.
CU	If you do decide to take part, you are free to leave the trial at any time – and you don't have to explain yourself. Your care will continue as before. It really is up to you.
	SCENE 21
Text only on screen Fly in text 1, 2 & 3	**Voiceover** Remember… 1) Taking part is voluntary 2) You can leave at any time without giving a reason 3) If you don't take part you'll be offered the treatment that is considered the standard best practice.
MCU of LG	But before you decide, what are the benefits and disadvantages of taking part?

	SCENE 22
Interior **CRU waiting room with "extras"** **MLS** (from R) of LG with extras in background. LG walks from extras across to computer and sits down	Well, one of the possible disadvantages in taking part in a clinical trial, is that you might have to come to the hospital more often to have more blood tests, scans or other involvement, although this is not always the case.
MCU (face on) / Split screen "still" of doctors/nurse team	On the plus side, you will be closely monitored and see the same small team of doctors and nurses.
MCU (face on moving round to LG's left) ? background (extras)	There may be side-effects with the new treatment, should you be randomised to this group. Everyone has fears of side-effects, however they are often no worse than with the standard treatment, and remember you may be randomised to this group.
CU (face on)	The benefits of taking part… well Sometimes the only way to access new treatments is by taking part in clinical trials.
	SCENE 23
Text only on screen "Funding for Clinical trials" Fly in "drug companies" "charities" "various government organisations" "the NHS".	**Voiceover** Clinical trials are expensive and are funded by drug companies, charities, various government organisations and the NHS. Any payment that is made goes directly to the hospital to be set against the costs of running the trial. Doctors are not given any personal payments by drug companies for running clinical trials.
	SCENE 24
MS (slight angle) of LG sitting on desk	That's about it… Thank you for taking the time to view this video. We do hope that you have found it helpful. **(pick up and show patient information sheet)** It will now be useful for you to read the information sheet the doctor gave you about your specific trial. It will also give you some additional information about the specific treatments themselves and what is involved.

Interior **OP Clinic/Reception** **MLS to MCU** (face on) of clinician walking out of clinic corridor towards reception desk **Track** LG **Start music** **Text only** **For further information contact: names and numbers** **Credits**	**SCENE 25** **CLINICIAN:** Please take time to consider your decision about whether or not to take part in the trial and phone us if you have any questions. We are always willing to discuss the trial at any stage with you and your family on a 1:1 basis. **SCENE 26** **(stop)** Be reassured that whichever decision you take it will be fully supported by the clinical team. We look forward to seeing you at your next outpatient appointment. **Slight nod and turn to R cue LG to walk by and out** **SCENE 27**

APPENDIX 7.1

Initial Knowledge Questionnaire (Prior to Testing)

CONFIDENTIAL Pre/Post Pt Inits: __ __ ID_____

QUESTIONNAIRE – PATIENT UNDERSTANDING OF RESEARCH

We are interested in what people know and understand about clinical research trials/studies and how this affects whether they take part. It would be very helpful if you could complete this questionnaire. It will not be shown to your doctor or any of the staff at the hospital. A prepaid envelope is provided for you to return it.

Please read the statements below and circle a), b), c) or d) – whichever one best describes your understanding of the statement. Please circle ONE answer only.

1. The main reason for carrying out research with patients is …

a) to improve current treatments.
b) to find treatments with no side-effects.
c) to help pay for cancer treatments.
d) don't know.

2. Research with patients is carried out…

a) only when a new treatment has no harmful side-effects.
b) only when a new treatment is more expensive.
c) when a new treatment is potentially better than the usual, standard one.
d) don't know.

3. In a *randomised* clinical research trial/study…

a) the treatment of the individual patient is decided by chance.
b) the doctor chooses the treatment for you, depending on your symptoms.
c) you choose the treatment, from the ones available in the trial.
d) don't know.

4. The main aim of a randomised trial is to….

a) find out if a new treatment is better than the commonly used treatment
b) to compare the costs of 2 treatments.
c) to compare treatments across different countries.
d) don't know.

5. When a trial is "randomised"…

a) the process selects the *best* treatment for you.
b) you have exactly the same chance of receiving the new treatment (or not receiving it), as any other patient taking part.
c) the doctor decides which treatment is the right one for you.
d) don't know.

6. 'Drawing a blank' in a randomised trial…

a) is not possible because it is not known which option is best.
b) is not possible because you can always demand the new treatment.
c) can happen if allocated to a non-drug option or "supportive care/symptom control" (You are then worse off than if allocated to treatment).
d) don't know.

7. It is justified for doctors to carry out a randomised trial...

a) when they expect the *new* treatment to be better and want to prove this.
b) when they expect the *old* treatment to be better and want to prove this.
c) when there is genuine uncertainty from expert cancer doctors about which treatment is best.
d) don't know.

8. If "best supportive care" or "symptom control" is one of the randomisation options in the trial, it means that…

a) supportive care or symptom control is the standard usual treatment for that type and stage of cancer.
b) only patients who need their symptoms treated can take part in the trial.
c) patients will not receive drug treatments in this trial.
d) don't know.

9. Patients are chosen for a trial…

a) only if they live close to the hospital.
b) after the doctors and nurses together decide which patients would benefit most.
c) if they fit the guidelines for selecting patients (developed from previous research work).
d) don't know.

10. Taking part in the trial…

a) is not compulsory as long as a refusal form is signed after getting information about the trial.
b) is voluntary - there are no conditions.
c) is expected if your doctor thinks it is best for you.
d) don't know.

11. You can leave a trial…

a) only if you experience side-effects.
b) at any time without giving a reason.
c) with good cause.
d) don't know.

12. If you do not want to take part in a trial…

a) you can choose between the new and the standard treatment.
b) you will be offered the new treatment.
c) you will be offered the treatment which is currently considered the standard treatment for your cancer.
d) don't know.

13. Doctors involved in clinical research trials/studies...

a) do not receive any financial incentives from drug companies.
b) receive a personal fee for every patient enrolled in the trial.
c) receive a personal fee for every trial they are involved in.
d) don't know.

ABOUT YOU

A. **Have you previously taken part in a research study (often known as a clinical trial)?**

Yes ☐ No ☐

B. **Has someone you know well or a member of your family been in a research study/clinical trial?** Yes ☐ No ☐

C. **Please tell us about your educational qualifications**
TICK each box that applies to you

No educational or vocational qualifications. ☐ 1

Qualification below degree level. ☐ 2
(e.g. diploma, standard and higher grades, A level)

Degree, degree-level vocational qualification or above. ☐ 3

D. **Please tell us your Post Code**: ☐

Date completing questionnaire ☐

Thank you very much for taking the time to complete this questionnaire.

Please can you return it in the enclosed envelope as addressed to:

Cathy Hutchison, Cancer Consultant Nurse, Administration Building,
Western Infirmary, Dumbarton Rd, Glasgow, G11 6NT.

APPENDIX 7.2

Questionnaire to Assess Acceptability of Knowledge Questionnaire:

CONFIDENTIAL Pt Inits: __ __ ID_____

Please can you answer the following questions in relation to the **Questionnaire: Patient Understanding of Research**, that you have just completed.

Please tick (√) appropriate box.

1. How long did the questionnaire take you to complete?

5 minutes	10 minutes	15 minutes	20 minutes	More than 20 minutes

2. Was it clear what the questions were asking?

Yes ☐ No ☐ Not sure ☐

3. Did you like the format of the questionnaire?

Yes ☐ No ☐ Not sure ☐

4. Please give any comments below

_____

_____

Please complete the following for yourself

5. Male ☐ Female ☐ *(tick appropriate box)*

6. Age ☐ yrs

7. Diagnosis ☐

Thank you for your help.
Please return this form with the questionnaire in the envelope provided.

APPENDIX 7.3

Patient Information Sheet for Exploratory Testing of Knowledge Questionnaire

INFORMATION SHEET FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Study title
Exploratory Testing of Knowledge Questionnaire (to be used in main study: randomised, controlled study into the effect of an audiovisual intervention on patient recruitment to cancer clinical trials).

Introduction
You have been invited to participate in a research study. Before making a decision it is important that you understand why the study is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with relatives, friends or your nurse or doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?
The aim of this study is to develop a questionnaire to be used in a future study of informed consent and patient recruitment to cancer clinical trials for lung, breast or bowel cancer. The study is being carried out as part of a Clinical Doctorate course through Stirling University.

Why have I been chosen?
You have been chosen because you have either:

(1) been diagnosed with lung, breast or bowel cancer
(2) been diagnosed with lung, breast or bowel cancer and have previously participated in a randomised cancer trial
OR
(3) you are a research nurse involved in randomised clinical trials

It is planned to involve 78 people in total in the study. Your hospital consultant is aware of the project.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide that you do wish to take part, you will be asked to sign a consent form to say that you have read and understood this Information Sheet, that all your questions have been answered completely and that you wish to continue with the study. You will be given a copy of the information sheet and consent form to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?
If you agree to take part you will be given a questionnaire to complete about knowledge and understanding of clinical trials. This should take no longer than 15 minutes to complete.

What do I have to do?
You will be asked to complete the questionnaire at the clinic or if you prefer, you can take it home and will be given a stamped addressed envelope to post back.

What is the procedure being tested?
The procedure being tested is a questionnaire to assess peoples' general knowledge about cancer clinical trials.

What are the possible disadvantages and risks of taking part?
Taking part in this study will not cause you any additional hospital visits than choosing not to take part in the study.

What are the possible benefits of taking part?
Your participation in this study is not expected to be of direct benefit to you, but will help in the development of information and treatment for the benefit of future patients.

Will my taking part in the study be kept confidential?
All of the information that is collected about you during the study will be kept strictly confidential. No information will be fed back to your oncologist. The Data Protection Act (1998) and the NHS Scotland Code of Practice on Protecting Patient Confidentiality (July 2003) will be adhered to. We will collect some personal information from your hospital notes including demographic details like age, diagnosis and sex. This log will be kept in a locked drawer in the researcher's office. Returned questionnaires will be kept in a separate locked cupboard. All data will be entered into a computer and anonymised. You will be allocated a Study Identification (ID) number which will be used on both questionnaires to allow them to be linked to the personal data which will be entered onto computer without your name or hospital number. Electronic information will be password protected. Following completion of the study, the data will be stored and destroyed in accordance with Standard Operating Procedures in the Beatson Oncology Centre Clinical Trials Unit (specifically No 002, Filing and Archiving of Clinical Documentation).

What will happen to the results of the research study?
At the end of the study, the questionnaire will be amended as appropriate and used in future work as already discussed. Results will be published in a health care journal. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. You will not be identified in any report/publication.

Who has reviewed the study?
The West Ethics Committee at North Glasgow University Hospitals Division and Stirling University Department of Nursing Research Ethics Committee have both reviewed the study.

Contact for further information
Please ask if there is anything that is not clear or if you would like more information.
Contact: Cathy Hutchison, Cancer Consultant Nurse on 0141 211 2344.

Thank you for taking the time to read this information sheet.

APPENDIX 7.4

Consent Form for Exploratory Testing of Knowledge Questionnaire

Study Code:

Patient Identification Number for this trial:

CONSENT FORM

Title of Project:

Exploratory Testing of Knowledge Questionnaire (to be used in main study: randomised, controlled study into the effect of an audiovisual intervention on patient recruitment to cancer clinical trials).

Name of Researcher: Cathy Hutchison, Cancer Consultant Nurse.

Please initial box

1. I confirm that I have read and understand the information sheet dated 14 th June 2004 (version 2) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from North Glasgow University Hospitals Division or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Name of Patient	**Date**	**Signature**
Name of Person Taking Consent (if different from researcher)	**Date**	**Signature**
Researcher	**Date**	**Signature**

1 for patient; 1 for researcher; 1 to be kept with hospital notes.

APPENDIX 8.1 Monthly Numbers of Patients Recruited to AVPI study in Relation to Each Clinical Trial

	Jan 05	Feb 05	Mar 05	Apr 05	May 05	Jun 05	Jul 05	Aug 05	Sep 05	Oct 05	Nov 05	Dec 05	Jan 06	Feb 06	Mar 06	Apr 06	May 06	Jun 06	Jul 06	Aug 06
B78																				
B87																				
B88	3	1	3	1	1	8	3	7	2	4	8	6								
B90							1	1	1						1					
B91		1		1		2							1						1	
B92																				
B93																				
B94																				
B99										5		1		1	1	5	7	3	2	5
B102																				
B104														2	3	2	5	3	3	7
B110																				
B126																			1	
L59																				
L67																				
L73					1															
L75					1															
L76	1		1																	
L78									1											
L84																		1		
GI95					1															
GI101					5	4	1	2	2											
GI103						1				2			5	4	2	2	1			
GI104				1	3	1		1		3	1		1							
GI108																1				
GI117																2	1			2
GI119																	1		4	

Breast Cancer: Limited Disease

Breast Cancer: Advanced Disease

Lung Cancer: Advanced Disease

Colorectal Cancer: Limited Disease

Colorectal Cancer: Advanced Disease