Attitudes to randomized clinical trials amongst out-patients attending a medical oncology clinic

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Abstract

Objective To assess the understanding of and attitudes towards randomized clinical trials amongst patients attending oncology out-patient clinics.

Design Cross-sectional survey.

Subjects Patients attending medical oncology out-patient clinics at a Sydney teaching hospital.

Main outcome Patients' willingness to participate in a randomized clinical trial.

Results Sixty consecutive patients were surveyed. The mean age was 55.2 (SD 14) years. Eighty-eight per cent of respondents thought that patients should be asked to participate in trials testing new treatments, however, only a third would consider participating in a randomized trial themselves. If a trial was endorsed by an independent cancer information service such as the NSW Cancer Council, 72% of respondents would be more likely to participate. Knowledge about randomized trials was not high. Respondents scored a median of 3 out of 7 (interquartile range, 2–4) correct answers to a series of questions about randomized trials. Patients willing to participate in a randomized trial were more likely to perceive the doctor favourably ($P = 0.05$), less likely to perceive trials as experimental ($P = 0.05$) and less likely to perceive trials as representing an inconvenience or loss of control ($P = 0.09$).

Conclusions Understanding amongst patients of the need for and mechanisms of randomized clinical trials is not good. This may contribute to the difficulties investigators face in seeking consent for clinical trials. Evaluation of new strategies to educate the public and patients about randomized trials is needed. Involvement of consumers in the design and conduct of clinical trials and evaluation of strategies to improve doctors' communication of clinical trial information is also required.

Introduction

Randomized clinical trials (RCTs), or overviews of randomized clinical trials, are considered the gold standard for the evaluation of therapeutic interventions[1] and provide the highest levels of evidence on which to base decisions about individual patient treatment.[2] There are numerous examples in recent medical history where treatments for which there was strong prima facie evidence based on biological hypotheses, were shown to be ineffective or even harmful when evaluated in randomized trials.[3–5] A societal need exists, therefore, to include people in clinical trials testing the efficacy of new or existing therapies. Currently only a minority of cancer patients receive treatment as part of a clinical trial.[6,7]

The failure of doctors to recommend trial participation is a major issue affecting the recruitment of eligible patients onto randomized clinical trials.[7–10] Many doctors experience difficulty initiating clinical trial discussions. Fallowfield noted that doctors included clinical trials amongst a list of the five most difficult areas of discussion during patient consultations.[11] Clinical trials are perceived by some doctors to conflict with the ethical principles of beneficence and individual patient autonomy.[12] Discussion of clinical trials may be perceived to interfere with the physician-patient relationship, compromising the doctors' duty of care.[13] Some doctors are uncomfortable with the dual role of clinician and researcher.[14] Others express concern that the admission of uncertainty, the stringency of trial design and the random allocation of treatment may undermine the patients' need at a time of great vulnerability, to place faith in a caring doctor to navigate the route to an optimal outcome. However, these concerns may also reflect inadequate doctor-patient communication about clinical trials and highlight a need for the development of ethical communication strategies.[15] Doctors may also be constrained by logistical problems (including lack of available time and resources), or the doctor may not be in a state of equipoise about the trial question, believing instead that there is sufficient evidence to recommend one treatment or approach over another.[16]

Surveys conducted in the last decade amongst members of the community and cancer and cardiac patients, found a high level of support for the general concept of patient participation in medical research.[17,18] However, a lesser proportion of patients are willing to be randomized onto trials.[8,10] Patients report a number of reasons for choosing to participate in clinical trials. These include the doctor's desire for the patient to participate, the chance to obtain new treatments and the opportunity to contribute to research knowledge and benefit humanity.[19–21] Reasons for declining an invitation to join a clinical trial include a preference for the doctor to make the decision about treatment, concerns about receiving the new treatment, or a preference to choose their own treatment. Additional inconvenience (extra visits to the clinic, staff changes) has also been cited as a major negative aspect of participation in clinical trials.[21]

Previous research has examined the association between demographic characteristics, framing effects and patient preferences for involvement in clinical decision making, on patients' decision to enter a randomized trial.[20,22] Younger patients, women, patients with a higher education or socio-economic background and patients wishing to adopt a more active role in clinical decision making are less likely to agree to participate in a randomized trial. Additionally, patients with higher needs for information about their illness, have a preference for greater involvement in treatment decisions in general.[23]

Trial specific issues, particularly the choice of therapies under evaluation, will also impact on patient acceptance of a clinical trial. Patients may be less willing to consider trials with a no treatment arm, significant differences in the expected toxicity (chemotherapy versus hormone therapy; standard dose versus high dose chemotherapy), or trials evaluating different treatment approaches (surgery versus radiotherapy).

Review of the literature examining informed consent for clinical trials highlights a number of misunderstandings amongst informed participants about important aspects of randomized clinical trials. Amongst parents consenting to enrolment of critically ill babies in a randomized trial, random allocation of treatment and its rationale was not well understood.[24] In another study of parents consenting to a randomized trial on behalf of their children, neither the need to assess safety as well as efficacy, or the right to withdraw from the study were widely appreciated and many parents expressed the opinion that informed consent was unnecessary, as they would trust the advice of the doctor.[25] There has been little research amongst adults considering trial participation themselves, examining understanding of the manner in which randomized trials are conducted, or the impact of patients' attitudes towards randomized trials on willingness to participate. These issues are important in order to improve doctor-patient communication about clinical trials.

Focus groups are a useful means of examining the range of opinions or experience amongst participants[26] and use group process to explore and clarify participants' views.[27] This study used focus group interviews to supplement a review of the literature, to explore patient and community understanding and attitudes towards randomized trials. The information was used to inform a subsequent survey of cancer patients attending medical oncology out-patient clinics, assessing the association of knowledge of and attitudes towards randomized clinical trials on willingness to participate in such trials.

Methods

Focus groups

Focus group interviews were conducted with women in the community and women previously diagnosed with breast cancer. Women previously diagnosed with breast cancer were chosen because protocols exist for a wide range of clinical situations and many of these women would have been previously invited to participate in a clinical trial. Women in the community were identified via a local primary school. Invitations to mothers and grandmothers of children at the school were sent out with a weekly newsletter. A list of women diagnosed with localized breast cancer during 1995 was generated from the database of the Medical Oncology Department, Royal Prince Alfred Hospital (RPAH). This list was reviewed by the attending clinicians, who gave permission to invite their patients to participate in a focus group. Women were contacted by telephone and invited to participate in a focus group. This project was conducted with the approval of the Central Sydney Area Health Service Ethics Committee.

Daytime and evening focus groups of between four and eight women were organized using methods previously described.[26,28] A facilitator and an observer were present in all groups. Four focus groups with women in the community and four focus groups with women previously treated for breast cancer were planned. Written informed consent was obtained from all participants on the day of their discussion group. Participants were asked to complete a brief demographic sheet prior to the focus group. The discussion explored women's understanding of clinical decision making; their knowledge about the clinical trial process; their willingness to consider participation in a clinical trial and their perceptions of the advantages and disadvantages of receiving treatment on a clinical trial. All focus groups were audiotaped with the consent of the participants. Audiotapes were transcribed in full. The analysis of transcribed material was informed by grounded theory.[29] Transcripts were read and individual points identified. These were organized into mutually exclusive themes by two authors (PE and PB). Responses were then summarized according to the original questions posed. As no new or additional information was discussed during the last two groups, both raters met and decided that no additional focus groups were required. The final list of issues was discussed to ensure consistency of interpretation between the two raters.

Survey

Information obtained from the literature and the focus group interviews was used to develop a questionnaire assessing knowledge and attitudes to clinical trials. During mid-1996 a cross-sectional survey of 60 patients attending medical oncology out-patient clinics at the Royal Prince Alfred Hospital, Sydney was undertaken. Whilst the initial qualitative work had been conducted in women, it was decided to extend the survey to include men in order to explore the generalizability of the views expressed. In addition much of the content of the questionnaire was based on previous literature which had included men in their samples. All patients attending medical oncology out-patient clinics were eligible to be surveyed other than non-English speaking patients and patients attending for their first consultation (these patients were being enrolled in a separate study examining doctor-patient communication). Patients were approached by one of two research assistants prior to a scheduled out-patient appointment. The purpose of the project was explained, a plain English statement outlining the study was given to the patient to read and written consent was obtained from those agreeing to participate.

Demographic data including age, sex, marital status, educational background, type and stage of cancer and any previous invitation to join a formal clinical trial (randomized or other) were collected. Respondents' informational needs (3-point scale previously used by Cassileth[30]) and preference for involvement in clinical decision making (5-point scale previously described by Degner[31]) were assessed, as it was hypothesized these factors would be associated with the outcome. Knowledge of and attitudes towards randomized clinical trials were measured using a 5-point Likert scale. Finally respondents were asked to indicate their willingness to participate in a hypothetical randomized clinical trial.

Data analysis was undertaken using the Statistical Package for Social Scientists (SPSS).[32] The major outcome assessed was respondents' willingness to participate in a randomized clinical trial. Answers to knowledge questions were summed and the total score (range 0–7) used as an indicator of existing knowledge about the randomized clinical trial process. Analysis of variance was used to explore the relationship between knowledge scores and trial participation. A principal components analysis[33] was undertaken on the items assessing attitudes to clinical trials and scores calculated for the resulting factors. A multivariate logistic regression analysis was undertaken to examine the relative influence of these factors on patients' decision to join a clinical trial in order to inform further research into communication of clinical trial information. There was little published information examining the association between knowledge of randomized trials and willingness to participate. A sample of 60 patients had a power of 0.80 at a significance level of 0.05 to detect a difference of 1.5 (approximately 1 standard deviation) or greater, in mean knowledge scores amongst patients willing to participate in a clinical trial, compared with patients who were not.

Results

Thirty women responded to the invitations to attend a focus group interview distributed via the primary school, however, only 21 were able to attend on days when focus groups were planned. One hundred and four women previously treated for breast cancer were contacted. Forty-three women were interested in attending a focus group, however, only 20 women were able to attend on days when focus groups were organized. These results have been reported in more detail elsewhere.[34] Women in the community were somewhat younger (median age group 30–39 years) than women previously treated for breast cancer (median age group 50–59 years), although they were similar in other characteristics. The majority of women in both groups were married or in a *de facto* relationship. Approximately 40% were educated beyond high school and some 85% reported a family history of cancer.

Many of these women had significant reservations about personal involvement in clinical

research. The majority of women did not understand the need for clinical trials to establish the worth of new and existing treatment approaches, or the manner in which this would happen. Very few women considered that the doctor would use the results of previous clinical trials, in making a treatment recommendation. The reason why treatment in a randomized trial would be allocated at random was not understood. Many women felt that clinical trials would only be offered as a last resort, when other options had failed. Random allocation of treatment and the uncertainty/experimental nature of clinical trials were considered major negative aspects about clinical trials. In contrast to suggestions in the literature,[35,36] a number of women attending these focus groups indicated that they would be more willing to consider participating in a clinical trial once they were better informed. Information obtained from the focus groups in conjunction with that from the literature was used to inform the development of a questionnaire for the subsequent part of the study.

The baseline characteristics of the 60 respondents included in the cross-sectional survey are summarized in Table 1. No person declined to complete a questionnaire. The mean age of respondents was 55.2 years (SD 14 years) and respondents were a median of 1.7 years (interquartile range 0.7–4.4 years) following the diagnosis of their cancer. There were a high proportion of women in this sample (77%) and over 50% of patients had a diagnosis of breast cancer. The remaining respondents had a wide variety of diagnoses. Over half the patients surveyed were receiving potentially curative treatment. Eight respondents (14%) in this survey were receiving treatment as part of formal drug therapy clinical trials.

Table 2 shows respondents' preferences for the amount of information they would like to

Table 1 Baseline characteristics of respondents completing the attitudes to clinical trials questionnaire (n = 60)

Variable		Value (%)
Age (mean)		55.2 years (SD 14 years)
Time since diagnosis (median)		1.7 years (iqr* 0.7–4.4 years)
Sex	Male	14 (23%)
	Female	46 (77%)
Education	School certificate	30 (51%)
	Higher school certificate	6 (10%)
	Tertiary (non university)	9 (15%)
	Tertiary (university)	14 (24%)
Marital status	Single	4 (7%)
	Married/*de facto*	40 (66%)
	Widowed/divorced/Separated	16 (27%)
Cancer type	Breast	32 (53%)
	Gastrointestinal	8 (14%)
	Lymphoproliferative	6 (10%)
	Gynaecological	4 (7%)
	Testicular	3 (5%)
	Lung	2 (3%)
	Other	5 (8%)
Treatment intent	Adjuvant/curative	26 (52%)
	Palliative	24 (48%)
Enrolled in clinical trial		8 (14%)

*iqr – interquartile range

Table 2 Respondents' preferences for information and involvement in clinical decision making

	Number (%)
Amount of information desired by patient	
I want all information whether good or bad	55 (93%)
I want only good information	3 (5%)
I want very little information	1 (2%)
Preference for involvement in clinical decision making	
I prefer to make the final selection about treatment	2 (4%)
I prefer to make the final selection about treatment after seriously considering my doctors opinion	21 (36%)
I prefer that my doctor and I share decision making	13 (22%)
I prefer my doctor makes the final decision about treatment but considers my opinion	14 (24%)
I prefer to leave all decisions regarding treatment to my Doctor	8 (14%)

receive from their doctor and their desired level of involvement in clinical decision making. Over 90% of respondents indicated a desire to receive as much information as possible from their doctor regarding their cancer and its treatment, whether the news was good or bad. More variation was observed in respondents' preferences for involvement in decision making. Approximately 40% of respondents chose an active role in decision making, preferring to make their own decisions; 22% chose a collaborative role, preferring shared decision making; and 38% chose a passive role, preferring to leave treatment decisions to the doctor.

Twenty-four respondents stated that they had been invited to participate in a clinical trial. Of these respondents, 17 indicated that they believed they were currently participating in a clinical trial. On review of their medical records however, only six of these 17 patients were enrolled into formal clinical trials. One further respondent who was enrolled in a clinical trial did not indicate this on their questionnaire. It is not known if this was an error by the respondent, or if they were unaware of their trial involvement, even though enrolment procedures for recruitment require both receipt of a patient information sheet and a signed consent form.

Respondents' knowledge of the randomized trial process was assessed using seven statements about randomized trials. Respondents were asked to indicate whether or not they agreed that the statements were true (see Table 3). Fifty-one per cent of respondents agreed that randomized trials were the best way of finding out whether one treatment was better than another, yet 31% were unaware that treatment

Table 3 Summary of respondents knowledge of the randomized trial process (n = 58)

Statement	Agree	Don't know	Disagree
Clinical trials are only offered when the doctor thinks the situation is hopeless	10 (18%)	6 (10%)	42 (72%)
Clinical trials test treatments which nobody knows anything about	11 (19%)	12 (21%)	35 (60%)
In a randomized trial the treatment you get is decided by chance	25 (43%)	15 (26%)	18 (31%)
In a clinical trial the doctor would make sure I got the best of the treatments	43 (74%)	8 (14%)	7 (12%)
Clinical trials are more helpful for the doctor or the drug company than for patients	11 (19%)	19 (34%)	27 (47%)
Randomized trials are the best way of finding out whether one treatment is better than another	30 (51%)	23 (40%)	5 (9%)
The doctor really knows that one of the treatments in the trial is better than the other	14 (24%)	23 (40%)	21 (36%)

is allocated by chance in a randomized trial. Nearly one in four respondents thought that the doctor would know that one of the treatments offered in a randomized trial was better than the other, and 74% of respondents thought that the doctor would ensure that they received the best of the treatments offered on a randomized trial. Nearly one in five respondents thought that clinical trials are offered only when the doctor considers the situation hopeless and that clinical trials test treatment which nobody knows anything about. Respondents received a score out of 7, representing the number of correct responses. The median score was 3 (interquartile range 2–4) and only 11 (19%) respondents knew the correct responses to five or more of the seven statements.

The majority of respondents (88%) believed that patients should be asked to take part in trials testing new treatments. However, only 33% of respondents would consider taking part in a trial comparing different treatments, where treatment was selected at random by a computer, i.e. a randomized trial. If such a trial was endorsed by an independent cancer information service, such as the NSW Cancer Council, 72% of respondents stated that they would be more likely to take part.

Despite reluctance by many patients to consider participation in a randomized trial, it is apparent that respondents wished to be made aware of uncertainty about treatment options when it exists. Fifty-seven of the 60 respondents would prefer their doctor to tell them when it is not really known what the best treatment is, and when there is no evidence to suggest that one treatment is better than another (Table 4).

There was no evidence of any difference in mean knowledge scores between respondents who would consider joining a trial (3.2, SD 1.4) and those who would not (3.2, SD 1.7, mean difference 0, 95% CI −0.9 to 0.9, $P = 0.65$), or between respondents receiving treatment as part of a clinical trial (3.4, SD 1.3) and those not (3.0, SD 1.5, mean difference 0.4, 95% CI −0.7 to 1.5, $P = 0.48$). In addition, there was no evidence of any association between decision making preferences and willingness to join a clinical trial ($P = 0.77$).

Respondents were given a list of 20 items purported to influence participation in clinical trials. They were asked to indicate on a 5-point Likert scale the extent to which these items would influence their decision to participate in a clinical trial. Three patients (5%) did not complete this section. One item was omitted because it lowered the overall internal reliability. The Cronbach alpha of the remaining 19 items was 0.75. A principal components factor analysis with varimax rotation was undertaken on these 19 items (see Appendix 1). A six factor solution explaining 66.5% of the variance in respondents' willingness to join a trial, suggested the following factors: (i) perception of the doctor (trust in the doctor, expert opinion); (ii) personal benefit; (iii) perception of inconvenience/loss of control on a clinical trial; (iv) sense of obligation to the doctor; and (v) attitudes towards experimentation and uncertainty. The items contributing to the remaining factor (the treatment given in the study will cure me, other sufferers will benefit from the trial results and it may be the only way to get access to a new drug) were not easily categorized. This factor explained only 7% of

Table 4 Patient preferences' for acknowledging medical uncertainty

If there is no evidence to suggest that one treatment is better than another for patients like you, would you prefer your doctor to	Number (%)
Pretend there is no uncertainty and recommend a treatment	1 (2%)
Tell you he/she does not really know the best treatment and invite you to join a clinical trial which will find out (so the doctor will know for future patients)	18 (30%)
Tell you he/she does not really know the best treatment but give you his opinion	37 (63%)
Tell you he does not really know the best treatment and let you choose the one you want	2 (3%)
Other	1 (2%)

the variance and was not associated with respondents' decision to join a clinical trial ($P = 0.42$).

A logistic regression analysis was undertaken to examine the relative importance of these six factors in determining patients' willingness to join a clinical trial (Table 5). Willingness to participate in a clinical trial was most strongly influenced by patients' perception of the doctor (OR 1.8, $P = 0.05$) and their attitudes to experimentation and uncertainty in treatment allocation (OR 0.58, $P = 0.05$). There was a trend for decisions to be influenced by patients' perception of inconvenience/loss of control on a clinical trial (OR 0.77, $P = 0.09$). There was no evidence that the remaining factors influenced patients' willingness to participate in a clinical trial.

Discussion

Recruitment of patients to randomized trials is essential if we are to continue to achieve therapeutic gains in cancer care. Randomized trials are only ethical when there is a genuine uncertainty (equipoise), as to whether one treatment or approach is superior to another for a particular condition.[37] Well designed trials offer patients current best therapy, or an alternative considered as good or potentially better. However, these results suggest that patients neither understand, nor agree with the need for and manner in which randomized trials are conducted. This is likely to be a significant impediment to effective doctor-patient communication about clinical trials.

Patient misunderstanding is evident in a number of areas. Nearly one in five patients in this survey thought that clinical trials tested treatments which nobody knows anything about, or that they were only offered when the doctor thought the situation was hopeless. It is important that doctors are aware of these beliefs and offer reassurance, as an invitation to participate in a clinical trial may alter patients' perception of either their treatment options or overall situation. Amongst respondents in this survey, dislike of being part of an experiment and the uncertainty of treatment allocation were negatively associated with patients' willingness to join a clinical trial.

Respondents in this survey were either unfamiliar with, or uncomfortable in acknowledging uncertainty about treatment options. Approximately one in four people thought that the doctor would really know which treatment was better on a clinical trial and nearly three quarters of respondents thought that the doctor would ensure that they got the better of the treatments. These findings are in agreement with Cassileth, who also found that a high proportion of patients believed that the doctor really knew which of the treatments was best.[17] This may partly explain why only 43% of respondents believed that treatment is allocated by chance on a randomized trial.

It would appear that the strongest reason to consider participation in a clinical trial in this study was a favourable perception of the doctor. This finding raises a number of ethical concerns. Such patients may adopt a more passive role in the consultation and seek less information. These views are consistent with observations by Llewellyn-Thomas *et al.* that cancer patients declining an invitation to participate in a clinical trial were more likely to want an active role in treatment decision making.[20] It is important to

Table 5 Results of multivariate logistic regression examining the importance of patient attitudes to clinical trials on patient willingness to join a clinical trial

Factor	Odds ratio	*P*-value
Perception of the doctor	1.8	0.05
Personal benefit	1.1	0.33
Perception of inconvenience/loss of control on a clinical trial	0.77	0.09
Sense of obligation to the doctor	1.5	0.42
Attitudes towards experimentation and uncertainty	0.58	0.05
Other variables	0.75	0.17

recognize that patients may be subject to subtle coercion regarding clinical trial participation and reinforces the doctor's need to provide a balanced view of all treatment alternatives, in addition to the option of a clinical trial.[38]

The communication of information about clinical trials is an important and often overlooked area. Even amongst informed participants, fulfilment of the legalistic requirements of informed consent is often insufficient to address the ethical aspects of the consent process for clinical trials. Gert *et al.* argue that there are moralistic ideals which the doctor should strive to achieve in addition to the legalistic obligations.[39] These include the provision of adequate information about treatment alternatives which does not over emphasize the attractiveness of one or belittle another, re-opening the consent process when new information or issues arise, and choosing a range of statistics to present, rather than selecting those which put a favourable slant on the doctors preferred option. We are currently undertaking further research examining doctor-patient communication of clinical trial information. Content analysis of audiotapes of consultations in which recruitment to randomized clinical trials is discussed, is being undertaken to examine the manner in which patients are invited to participate in trials.

Education of patients and the community about the role of clinical trials in establishing the effectiveness of therapeutic approaches and the manner in which trials are conducted is an important goal.[40] This may improve patients' understanding of clinical trials, which appears ethically desirable, but it is uncertain what effect this will have on trial recruitment. Published data suggest that providing more detailed information about the treatments may improve peoples' understanding about their treatment, but does not lead to increased willingness to participate in trials.[35,36] A number of women in our earlier focus groups commented that they would be more willing to consider participating in a clinical trial, having learnt more about the way in which they are conducted. However, this was not evident amongst respondents in the survey. There was no evidence that respondents either participating in clinical trials, or who would consider participation, had any greater knowledge about the clinical trial process.

An interesting finding to emerge from this survey is that nearly three quarters of the respondents would be more willing to consider participating in a clinical trial if it was endorsed by an independent patient information service such as the New South Wales Cancer Council. Such a process would require the development of mechanisms to review trial protocols and assess their relative merits. The notion that these organizations might be asked to participate in the appraisal of trials coming to ethics committees warrants investigation. There has been a recent move to involve consumers in the development of trial protocols, patient information and public education on clinical trials. Organizations such as the Consumers Advisory Group for Clinical trials (CAG-CT) in the United Kingdom and the National Breast Cancer Centre in Australia are looking at ways to incorporate consumer input into clinical research. It is hoped that such strategies will raise the patient focus of randomized clinical trials and may help improve recruitment.

There are several limitations to this study. Focus groups data were derived from women in the community and breast cancer patients. This information was used to supplement data from the literature. However, it is possible that issues more pertinent to men may have been less strongly emphasized. Respondents' willingness to participate in a randomized trial reflects a hypothetical decision. Contextual factors are also likely to be important, therefore these results require validation amongst a sample of people considering entry into a real clinical trial.

The findings of this survey indicate that patient misunderstanding about randomized clinical trials is widespread. The results suggest that the manner in which patients evaluate the positive and negative aspects of clinical trials has implications both for doctors' communication of clinical trial information and patients' willingness to consider trial participation. However, these findings require validation in a larger sample. Prospective research is needed to exam-

ine factors influencing the decisions of patients who have been invited to participate in a randomized trial. Consideration should be given to evaluation of strategies, such as education of patients or the community about randomized trials, or involvement of consumer groups in the design and/or recruitment to clinical trials, so as to raise the awareness of and potentially participation in randomized clinical trials.

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Appendix 1 Factor analysis grouping of items assessing attitudes towards randomized clinical trials

Factor 1: perception of the doctor-patient relationship (trust in the doctor, expert opinion)
- I trust the doctor treating me
- The doctor is an expert in the field
- I have been given good information to read about the treatment

Factor 2: personal benefit
- I think the study offers the best treatment available
- I believe the treatment given in the study will cure me
- I believe the benefits will outweigh any side-effects
- It might help my children if they fall ill in the future

Factor 3: perception of inconvenience/loss of control on a clinical trial
- I would no longer have any say in what happened to me
- The trial would involve extra inconvenience
- The doctor may not be able to tell me as much about my progress
- I would be monitored more closely if I was in a trial

Factor 4: sense of obligation to the doctor
- The doctor wants me to join the study
- I would not want to say no

Factor 5: attitudes towards experimentation and uncertainty
- I do not want to be a guinea-pig
- I do not like the idea of randomization
- I want to help with the doctors research

Factor 6: other variables
- I feel that other sufferers will benefit from the trial results
- The doctor has told me everything I need to know about the study
- It may be the only way to get access to a new drug