Original Article

Barriers to Clinical Trial Participation as Perceived by Oncologists and Patients

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Key Words

Barriers to clinical trials, health services research, psychology, psychosocial factors, doctor–patient communication, cancer

Abstract

Although clinical trial research is required for the development of improved treatment strategies, very few cancer patients participate in these studies. The purpose of this study was to describe psychosocial barriers to clinical trial participation among oncologists and their cancer patients. A survey was distributed to all medical oncologists in Pennsylvania and a subset of their patients. Relevant background information and assessment of practical and psychosocial barriers to clinical trial participation were assessed. Among 137 oncologists and 170 patients who completed the surveys, 84% of patients were aware of clinical trials, and oncologists and patients generally agreed that clinical trials are important to improving cancer treatment. However, oncologists and patients were more likely to consider clinical trials in advanced or refractory disease. When considering 7 potential barriers to clinical trials, random assignment and fear of receiving a placebo were ranked highly by both patients and oncologists. Patients identified fear of side effects as the greatest barrier to clinical trial participation, whereas oncologists ranked this psychosocial barrier as least important to their patients. Overall, the study found that although oncologists and patients are aware of clinical trials and have favorable attitudes toward them, psychosocial barriers exist for patients that may impact participation in clinical trials. Furthermore, important discrepancies exist between the perceptions of oncologists and those of patients regarding what the psychosocial barriers are. We concluded that characterizing oncologist and patient perceived barriers can help improve communication and decision making about clinical trials, such that participation may be optimized. (*JNCCN* 2007;5:753–762)

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The National Comprehensive Cancer Network (NCCN) believes that, "the best management for any cancer patient is in a clinical trial."[1] Although clinical trial research is required for the development of improved cancer treatment strategies, only 2% to 7% of cancer patients participate in these studies.[2–4] Research into barriers to participation in clinical trials has largely focused on practical deterrents for both physicians and patients, including costs, administrative and staffing insufficiencies, limited access to clinical trials, restrictive inclusion criteria, and logistical issues, such as distance to the treatment site and time away from home and work.[2,5–9] Lack of awareness has also been identified as a significant barrier to clinical trial participation.[10,11] Studies of health-protective behavior and information processing of health risks have shown that patients react both cognitively and affectively to health information, especially when the information is emotionally threatening and includes significant risks.[12–17] Patients' cognitive and emotional reactions to health information can play an influential role in treatment decision making and adaptation to cancer threat.[18–20] However, little systematic research has been performed on psychosocial barriers to clinical trial participation.[8,21,22] To fill this empiric gap, the primary objective of this study was to characterize cognitive, affective, and practical barriers to participation in clinical treatment trials among oncologists and their cancer patients across Pennsylvania.

Methods

Participants

Eligible physician participants were practicing medical oncologists in Pennsylvania. Eligible patients were adults (at least 18 years old) with cancer undergoing follow-up by medical oncologists in Pennsylvania. All patients were able to communicate in English. Four hundred seventy-eight medical oncologists were identified through the membership lists of the American Board of Internal Medicine and American Society of Clinical Oncology, and each oncologist was mailed a package containing 1 physician survey and 10 patient surveys for doctors to distribute to their patients. Participating oncologists received $50. Oncologists who did not return their survey within 4 weeks of the initial mailing were called or e-mailed with a reminder to complete the questionnaire. Patient participants were provided with a postage-paid return envelope for the completed survey and received $25 for participation. All patient surveys were linked to their treating oncologists' practice through an identification code number. All participants provided written informed consent, and the study was approved by the Institutional Review Board at the coordinating center (Fox Chase Cancer Center).

Measures

To inform and guide the development of oncologist and patient surveys, the authors conducted 6 focus groups. Two groups (1 oncologist and 1 patient) were conducted at each of 3 sites, representing a comprehensive cancer center (Fox Chase Cancer Center), an urban medical center with a largely minority population (Temple University Cancer Center), and a hospital-based community practice (Delaware County Memorial Hospital) to identify relevant practical and psychosocial barriers to clinical trial participation. Guided by the Cognitive-Social Health Information Processing (C-SHIP) framework,[19,23] available literature, and focus-group feedback, study-specific surveys were developed for oncologists and patients. They were designed to explore 3 major areas: 1) background information (e.g., sociodemographic information, medical practice characteristics, medical history); 2) cognitive–affective barriers to clinical trial participation; and 3) practical barriers to clinical trial participation.

The oncologist survey assessed sociodemographic information, including gender, age, ethnicity, and racial group; professional setting (e.g., private practice, academic medical center, community/other hospital-based); board certifications; number of individual patients seen in the past 12 months; number of new patients entered into practice in the past 12 months; number of treatment clinical trials currently active at a site; and number of patients enrolled in treatment clinical trials in the past 12 months. Interest in participating in treatment clinical trials was assessed by Likert-style questions: "Not at all," "A little," "Some," "Moderate," and "A lot" (e.g., "It is important to keep my patients informed about investigational treatments that are available," "I am interested in offering cancer treatment clinical trials in my practice"). Perceived cognitive–affective and practical barriers were assessed using 20 Likert-style questions ranging from "Not at all" to "A lot" (e.g., "I believe that clinical trials are important to improving cancer treatment," "The availability of support staff influences my ability to offer patients clinical trials"). In addition, physicians completed a ranking section: "why patients do not participate in cancer treatment clinical trials" (7 items, with "1" indicating the most important reason and "7" indicating the least important reason).

The patient survey assessed sociodemographic information, including gender, age, ethnicity, racial group, education level, and marital, employment, and health insurance status. Patients were asked to list their cancer diagnosis, age at diagnosis, and disease status. Awareness of clinical trials was assessed according to whether they had ever heard of clinical trials or participated in a clinical trial to treat cancer. Additionally, patients' interest and willingness to participate in clinical treatment trials were assessed by Likert-style questions: "Not at all," "A little," "Some," "Moderate," and "A lot" (e.g., "I am interested in learning about cancer treatment clinical trials;" "I would participate in a cancer treatment clinical trial if it was offered to me"). Perceived cognitive–affective and practical barriers to participation in cancer treatment clinical trials among patients were assessed using 48 Likert-style questions ranging from "Not at all" to "A lot" (e.g., "It is my responsibility to learn about ways to treat cancer;" "I believe that I would get good care if I participated in a clinical trial;" "I would be willing to travel for treatment"). In addition, patients completed a ranking section: "why patients may not want to participate in cancer treatment clinical trials" (7 items, correlates with 7-item ranking section in physician survey, with "1" indicating

the most important reason and "7" indicating the least important reason).

Statistical Analysis

Descriptive statistics were used to characterize the demographics and background variables of patients and oncologists. Background variables were collapsed when appropriate to accommodate categories with low representation. Descriptive statistics also were used to characterize responses to measures of 1) oncologists' interest in participating in clinical trials; 2) patients' awareness of, interest in, and willingness to participate in clinical trials; 3) both patients' and oncologists' perceived cognitive–affective and practical barriers to clinical trial participation; and 4) patients' and oncologists' ranking sections.

Spearman correlations were conducted to assess the magnitude and significance of association between continuous variables within each population (e.g., age, interest in participating in clinical trials, cognitive–affective and practical barriers). Kruskal-Wallis tests were used to detect differences between oncologists' background variables (e.g., race, gender) and perceived barriers for Likert-style questions. The same methods were used for patient analysis. To characterize patient categorical background variables with binary measures (e.g., "have you heard of clinical trials"), a Fisher's exact test was used. Wilcoxon tests were used to evaluate the differences between oncologists' and patients' distribution of ranking items. Analyses were repeated on a subset of the sample for patient participants that could be matched to an oncologist office and for oncologist participants that could be matched to at least 1 patient participant; data were analyzed using SASv9.1 (SAS Institute, Inc., Cary, NC).

Results

Participant Characteristics

A total of 478 physicians were mailed survey packets and 137 oncologist surveys were completed (29% participation rate). The sample was primarily white (86%). Of respondents, 63% indicated that they practice in a private practice or community hospital setting and 38% in an academic setting. Physician demographics are summarized in Table 1.

Oncologists' practice characteristics are shown in Table 2. The median number of individual patients seen in the past 12 months was 700, with a median of 200 new patients per physician. As expected, oncologists at academic medical centers were more likely to enroll patients in clinical trials ($P < .0003$), and a correlation was seen between number of active trials and enrollment ($P < .0001$).

A total of 170 patients completed surveys (47% men; 53% women), 14% of whom were non-white. Approximately two thirds (65%) of patient participants were married/partnered, and approximately half

Table 1 Oncologist Background and Demographic Characteristics ($N = 137$)

Demographic	Median	Min	Max
Age (y)	49	32	71
Demographic	**Frequency**	**Percentage**	
Sex			
Male	111	81	
Female	26	19	
Ethnicity			
Hispanic or Latino	1	1	
Non-Hispanic or Latino	134	99	
Race			
White	118	86	
Asian	14	10	
African American or Black	2	1.5	
Native American/ Pacific Islander	2	1.5	
Unknown	1	1	
Professional setting			
Private practice or community/other hospital-based	85	62	
Academic medical center	52	38	
Board certified physician			
Medical oncology	124	91	
Hematology	80	59	

Table 2 Oncologist Practice Characteristics ($N = 137$)

	Median	Quartiles
Patients seen in the past year	700	400, 2000
New patients in the past year	200	100, 300
Patients enrolled in treatment clinical trials in the past year	12	4, 29
Active treatment clinical trials	34	20, 100

(52%) were educated beyond high school. Fifty-five percent were treated in a community setting, and nearly all (95%) had health insurance. These data are summarized in Table 3.

Table 3 Patient Background and Demographic Characteristics (*N* = 170)

Demographic	Median	Minimum	Maximum
Age (y)	56	22	85
Age at diagnosis (y)	53	5	85
		N	**Percentage (%)**
Sex			
Male		80	47
Female		90	53
Race			
White		145	85
African American		21	13
Black (not of African descent)		1	0.5
Native American/ Pacific Islander		1	0.5
Haitian-West Indian		1	0.5
Missing		1	0.5
Marital status			
Married/partnered		111	65
Other		59	35
Education			
High school or below		81	48
Above high school		89	52
Health insurance			
Yes		162	95
No		8	5
Practice setting (derived from oncologists self-report)			
Community/hospital-based		87	51
Academic medical center		71	42
Unable to determine		12	7
Cancer diagnosis (primary sites)			
Breast		37	22
Lung		27	16
Leukemia		20	12
Colorectal		17	10
Prostate		13	8
Lymphoma		11	7
Other		43	26
Patients listing a second primary site		11	6

Oncologist and Patient Barriers

Oncologists generally had a favorable attitude about the value and importance of clinical trials. Nearly all oncologists (98%) agreed "moderately" (28%) or "a lot" (70%) that it is important to inform their patients about available clinical trials. Fifty-seven percent of oncologists reported that they were more likely to turn to investigational treatments for patients with advanced stage cancer. Seventy-nine percent agreed that their patients would benefit from participating in a clinical trial. Although both academic and community oncologists agree about the importance of clinical trials, community-based oncologists are less likely to agree that their patients will benefit from participating (Table 4). Physician age, race, and gender were not associated with number of patients enrolled in treatment clinical trials, interest in participating in a clinical trial, or interest in offering treatment clinical trials.

The most significant practical barriers for oncologists were staffing (65% agreed "moderately" or "a lot") and strict eligibility requirements (50% agreed "moderately" or "a lot"). Only a small minority of physicians reported financial constraints (11%) or time constraints (12%) as major barriers to participating in clinical trials.

Most patients (84%) had heard of clinical trials; 85% agreed that clinical trials are important to improving cancer treatments and 80% agreed that they would

Table 4 Oncologist Interest in Clinical Trials

Statement	% Agree Moderately or A Lot	Academic vs. Community	*P* Value
Important to keep patients informed about investigational treatments.	98	100 vs. 97	NS
Clinical trials are important to improving cancer treatment.	98	100 vs. 97	NS
Interested in offering clinical trials.	96	98 vs. 94	NS
Patients will benefit from participating.	79	90 vs. 72	0.01
I'm more likely to turn to investigational treatments with patients with advanced stage cancer.	57	65 vs. 52	NS

Abbreviation: NS, not significant.

receive good care if they participated. However, only 65% were interested in learning about clinical trials and only 57% believed that they would benefit from participation. Non-white patients were less likely than white patients to have heard of clinical trials (64% vs. 87%; $P = .0019$). Higher education (beyond high school) was also associated with having heard of clinical trials (94% vs. 72%; $P < .0001$) and interest in learning about clinical trials (76% vs. 52%; $P < .0012$), whereas 20% of patients reported that they had no way of learning about cancer treatment clinical trials. Willingness to participate in a clinical trial was not associated with education, race, age, or gender. Twenty-six percent of patients were concerned that they would be more likely to experience side effects on a clinical trial than with standard therapy. Similar to oncologists, patients (75%) were more likely to consider clinical trials if standard therapies were failing (Table 5). Approximately half of the patients (52%) had significant concerns about the financial cost of participating in a treatment trial. Only 37% of patients agreed that they would be willing to travel for treatment on a clinical trial.

Oncologists and patients were asked to rank the same 7 patient barriers (2 practical and 5 psychosocial; Table 6). Among patients, completion of this section of the questionnaire (7 numbers assigned) was associated with younger age ($P < .0001$), white race ($P = .03$), and higher education (P = .03). Regarding psychosocial barriers, both oncologists and patients ranked randomization and potential for receiving a placebo highly. Non-white oncologists ranked fear of randomization as less of a barrier than white oncolo-

Table 5 Patient Psychosocial Barriers

Statement	% Agree Moderately or A Lot
Participating in CTs is important to improving cancer treatment.	85
I would get good care if I participated in a CT.	80
I would more likely to join a CT if standard treatments weren't helping.	75
I would be interested in participating in a CT that my doctor told me about.	72
I am interested in learning about CTs	65
Participating in a cancer treatment CT would benefit me.	57
The thought of participating in a CT makes me hopeful.	50
I would be more likely to experience side effects on a CT than with standard therapy.	26

Abbreviation: CT, clinical trial.

Table 6 Ranking of Barriers by Oncologists and Patients

Barrier (Statement)	Oncologists *N* = 130 Average Rank (Most Frequent Rank)	Patients *N* = 86 Average Rank (Most Frequent Rank)	*P* Value
Psychosocial Barriers			
Patients are (I am) uncomfortable with being randomly assigned (for example, a coin toss) to a treatment.	1 (1)	2 (2)	.001
Patients (I) don't trust the medical establishment and fear being (I will be used as) a "guinea pig" for research.	2 (1)	6 (7)	<.0001
Patients (I) fear receiving a placebo (for example, a sugar pill) on a clinical trial.	3 (2)	3 (1)	NS
Patients (I) don't understand what clinical trials are.	4 (4)	7 (7)	<.0001
Patients (I) fear side effects that might come with treatment on a clinical trial.	5 (5)	1 (1)	<.0001
Practical Barriers			
Patients (I) are (would be) unable to fulfill trial requirements due to logistical barriers such as transportation.	6 (5)	4 (4)	.03
Patients (I) don't have access to clinical trials.	7 (7)	5 (6)	<.0001

Abbreviation: NS, not significant.

gists (mean rank, 3.5 vs. 2.5; $P = .004$). Male patients ranked fear of placebos as less of a barrier than female patients (mean rank, 3.8 vs. 3.0; $P = .04$). Significant discordance was seen, however, on how oncologists and patients ranked other psychosocial barriers. Patients ranked fear of side effects as the most important barrier, whereas oncologists ranked this last among psychosocial barriers ($P < .0001$; Figure 1). Compared with oncologists in academic centers, those from a community setting ranked fear of side effects as a less important barrier (mean rank, 3.6 vs. 4.5; $P = .01$). Other psychosocial barriers with significant discordance were lack of trust in medical establishment (oncologists' rank 2, patients' rank 6; $P < .0001$; Figure 2), and patients' lack of understanding of clinical trials (oncologists' rank 4, patients' rank 7; $P < .0001$; Figure 3). In general, oncologists and patients ranked practical barriers, including logistical issues and access to clinical trials, lower in importance. Compared with white oncologists, non-whites viewed patient inability to fulfill requirements as a more significant barrier (mean rank, 3.7 vs. 4.9; $P = .008$).

Ninety-two percent of patients came from offices with at least 1 physician survey participant. Eighty-nine percent of oncologist respondents had at least 1 patient participant. No significant demographic or outcome differences were seen between the 2 datasets (i.e., total sample, subset of patient/oncologist participants that could be matched to an oncology office).

Discussion

Decisions about participating in clinical trials are not simply based on the empiric evidence, but rely heavily on the individual's cognitive-emotional state and their health-related values and goals. Through a comprehensive assessment approach, we were able to delineate the psychosocial and practical factors that impact participation in cancer treatment clinical trials among patients and physicians.

Nearly all (> 95%) oncologists acknowledged the importance of clinical trials and were interested in offering them to patients. Likewise, awareness of clinical trials was high (84%) and 85% of patients agreed that participation is important to improving cancer treatment. Previous research has shown that awareness ("understanding") of and positive attitudes toward clinical trials are associated with the general public's willingness to participate in a cancer clinical trial.[10,11] However, although 79% of physicians agreed that

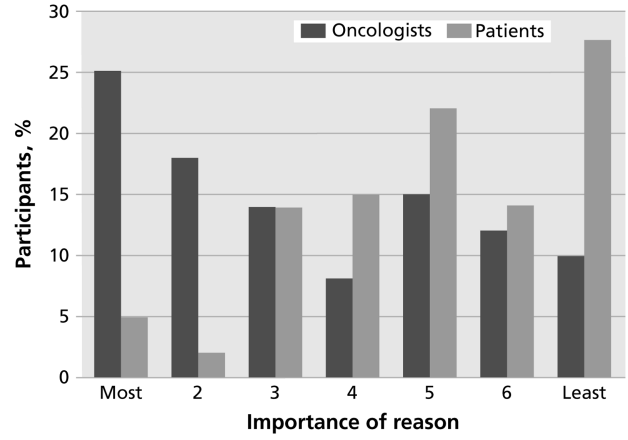

Figure 2 Reason why patients do not participate in clinical treatment trials: "I don't trust the medical establishment and fear I will be used as a 'guinea pig' for research" ($P < .0001$).

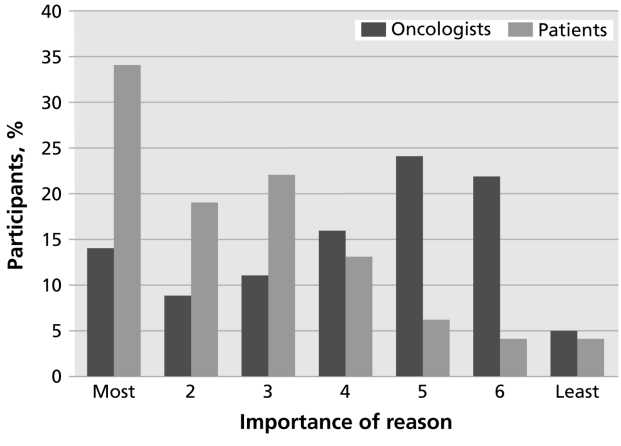

Figure 1 Reason why patients do not participate in clinical treatment trial: "I fear side effects that might come with treatment on a clinical trial" ($P < .0001$).

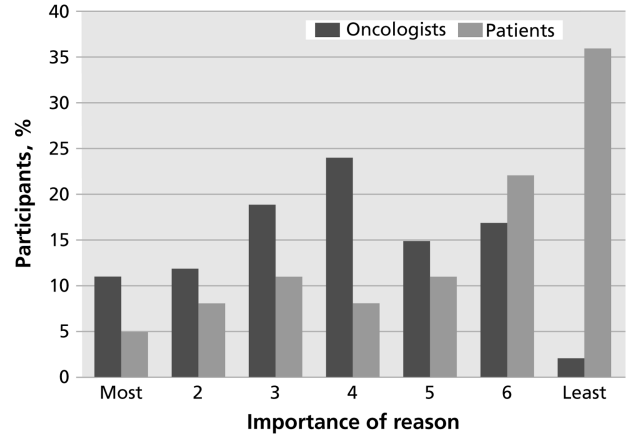

Figure 3 Reason why patients do not participate in clinical treatment trials: "Patients (I) don't understand what clinical trials are" ($P < .0001$).

patients would benefit from participation, only 57% of patients believed they would personally benefit ($P < .0001$). On the one hand, this level of optimism among patients is encouraging, particularly in conjunction with the finding that 65% of patients were interested in learning about clinical trials. On the other hand, one may interpret this finding as concerning, given our previous research[24] and that of others[25] demonstrating that high expectation of personal benefit drives clinical trial participation. Both oncologists (57%) and patients (75%) tend to favor clinical trials for patients with late-stage or refractory disease, situations in which the potential for benefit may be small. Therefore, participation may be a particular problem for patients with early-stage disease, situations in which there is relatively greater potential for benefit.

Patients ranked side effects as the most important barrier to clinical trial participation; approximately one fourth of patients believed they would be more likely to experience side effects on a clinical trial than with standard therapy. In contrast, oncologists ranked fear of side effects lowest among 5 potential psychosocial barriers for patients. Given the discordance between patients' expectations of toxicity and the expectations of their physicians,[24,26] and empiric data regarding relatively infrequent severe toxicity of phase I trials,[27] fear of side effects as a barrier may be addressed through education targeted to both physicians (i.e., patient concerns) and patients (i.e., information regarding side effects).

Oncologists identified "lack of trust in the medical establishment and fear of being used as a 'guinea pig' for research" as a major patient barrier to clinical trial participation (Figure 2), whereas patients ranked this barrier of lesser importance. Similarly, physicians ranked lack of patient understanding higher than their patients. These differences in perception may reflect study participant selection biases, but they highlight the importance of improving doctor–patient communication when discussing potential psychosocial barriers about participation. Our exploratory analyses also suggest that patient demographic characteristics, such as sex, race, and education, should be considered when tailoring physician–patient communication about clinical trials.[28–32] Further study is warranted to fully define the physician characteristics (e.g., sex, race, practice setting) that may influence perceptions about patient barriers. In particular, these data suggest that the psychosocial barriers existing in academic and non-academic clinical settings may differ, and therefore approaches to optimizing clinical trial participation should be tailored to specific practice environments.

Practical barriers were also identified by physicians and patients. Physicians reported inadequate staffing as a barrier, but did not consider financial or time constraints as major issues. This indicates that improvements in reimbursement have been made since previous reports that highlighted financial considerations.[2,5,33,34] Strict eligibility requirements remain a major impediment to clinical trial recruitment for physicians. Recent studies show that approximately 60% to 80% of patients presenting to community academic practices are not eligible for otherwise relevant studies.[4,35] Approximately half of the patients in this study raised concerns about the cost of participating in a clinical trial, and only 37% would be willing to travel for a clinical trial. Given that most cancer patients are not treated at academic medical centers, these data suggest a clear need for improving access to clinical trials in community settings.[2,8,10] That the Pennsylvania patients and physicians responding to the surveys ranked access to clinical trials as less important than other barriers is encouraging.

Although this study was conducted statewide in Pennsylvania, caution in interpreting these results is warranted because of potential biases related to nonresponse and the possibility of incorrect completion of the ranking items by a substantial proportion of patient participants. Nevertheless, the final study population involved patients and physicians from rural, urban, and suburban locations, and academic and nonacademic practice settings. Another potential bias is that 95% of the patients reported having health insurance, whereas only 84% to 86% of Pennsylvanians are insured.[36,37] Oncologist and patient demographics in this study, including sex and race, are similar to those in the general statewide populations,[38] although non-white cancer incidence in Pennsylvania is 9.5%, which is slightly lower than the study's sample of 14%.[39,40] In addition, the authors' findings are consistent with those of other studies regarding barriers to clinical trials.[11,41–45] Whether these data can be extrapolated nationwide or to other countries requires further study.

Participation in a clinical trial must be decided by patients and their oncologists. This decision is heavily influenced by the communication that occurs between them, and also is impacted by other sources of

information for patients, individual beliefs and expectations, and each patient's decision-making calculus.[46] Because most patients rely on their physicians as a primary source of health information,[47,48] communication is critical to quality decision-making, particularly for clinical trial participation.[49–51] Much of the research into ways to enhance medical communication about clinical trials has focused on physicians' communication skills.[49,52–55] However, although patients may have some experience communicating with physicians, most cancer patients have limited experience discussing treatment options in general, and clinical trial participation in particular, with physicians. Thus, patients may not have a repertoire of communication skills for engaging in these discussions. Several studies have shown that, with relatively modest effort, communication skills interventions significantly enhance patients' question-asking, provision of detailed information, and elicitation of information from physicians.[56–60] Patient communication skills training can promote adherence to treatment regimens[59,61] and improvement in health outcomes.[62–64] We are currently conducting a study to assess the impact of Internet-based cancer patient communication skills training on the content of doctor–patient consultations and decision making (NIH R01 82085; available at: http://www.clinicaltrials.gov, registration number NCT00244868. Accessed August 16, 2007).

Conclusions

This study represents an initial step in delineating psychosocial barriers to clinical trial participation. Further characterization of nonpractical psychosocial barriers could lead to tailored interventions addressing the specific concerns of the involved parties and discordant perceptions to optimize patient–provider communication and decision making about clinical trial participation.

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