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ORIGINAL REPORT

Randomized Trial of a Web-Based Intervention to Address Barriers to Clinical Trials

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See accompanying article on page 479; listen to the podcast by Dr Warner at www.jco.org/podcasts

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ABSTRACT

Purpose

Lack of knowledge and negative attitudes have been identified as barriers to participation in clinical trials by patients with cancer. We developed Preparatory Education About Clinical Trials (PRE-ACT), a theory-guided, Web-based, interactive computer program, to deliver tailored video educational content to patients in an effort to overcome barriers to considering clinical trials as a treatment option.

Patients and Methods

A prospective, randomized clinical trial compared PRE-ACT with a control condition that provided general clinical trials information produced by the National Cancer Institute (NCI) in text format. One thousand two hundred fifty-five patients with cancer were randomly allocated before their initial visit with an oncologist to PRE-ACT (n = 623) or control (n = 632). PRE-ACT had three main components: assessment of clinical trials knowledge and attitudinal barriers, values assessment with clarification back to patients, and provision of a video library tailored to address each patient's barriers. Outcomes included knowledge and attitudes and preparation for decision making about clinical trials.

Results

Both PRE-ACT and control interventions improved knowledge and attitudes (all $P < .001$) compared with baseline. Patients randomly allocated to PRE-ACT showed a significantly greater increase in knowledge ($P < .001$) and a significantly greater decrease in attitudinal barriers ($P < .001$) than did their control (text-only) counterparts. Participants in both arms significantly increased their preparedness to consider clinical trials ($P < .001$), and there was a trend favoring the PRE-ACT group ($P < .09$). PRE-ACT was also associated with greater patient satisfaction than was NCI text alone.

Conclusion

These data show that patient education before the first oncologist visit improves knowledge, attitudes, and preparation for decision making about clinical trials. Both text and tailored video were effective. The PRE-ACT interactive video program was more effective than NCI text in improving knowledge and reducing attitudinal barriers.

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INTRODUCTION

Cancer clinical trials establish the evidence base for clinical practice. However, few patients participate.[1-3] Barriers to clinical trial participation are multifactorial, and include practical impediments that limit access, as well as knowledge gaps and negative attitudes among both patients and their providers.[4-11] Although public awareness of clinical trials is improving,[12] there is little indication that patient participation has increased over several decades, suggesting that other fundamental barriers exist.

Patient impediments to consideration of clinical trials may be practical, such as lack of access,[1] insurance constraints,[13] inconvenience,[14] and cost.[15] In addition, we have cataloged the nonpractical psychosocial barriers for patients. These include knowledge gaps and attitudes that influence a patient's willingness or ability to consider a clinical trial as a therapeutic option.[6,7] Other influences on patient decision making about clinical trials derive from family members,[4]

communities, institutions,[16] and health-care providers.[10,17] Numerous studies have also characterized populations that are underrepresented in clinical trials, such as racial and ethnic minorities,[18-22] older patients,[4,23] and those of lower socioeconomic status,[24] supporting the development of tailored approaches to overcome barriers to participation.

A recent National Cancer Institute (NCI)–American Society of Clinical Oncology workshop sought to catalog evidence-based best practices to address low participation rates in clinical trials.[25] The proceedings summary suggested that patient decision aids should be explored to improve decision making about clinical trials and that tailored interventions should be pursued. Research involving decision aids has shown that both videos and written text are effective means of conveying information and increasing knowledge,[26-28] with video messages more effective in eliciting behavior change compared with text.[29,30] We developed Preparatory Education About Clinical Trials (PRE-ACT), a Web-based, tailored, interactive computer program, in an effort to optimize patient decision making about clinical trials by improving preparation for their consideration as a treatment option. The PRE-ACT program has three main components: an assessment of clinical trials barriers, values assessment with clarification back to patients, and provision of a video library tailored to address the knowledge and attitudinal barriers of each patient. We conducted a prospective, randomized clinical trial to compare PRE-ACT with a control condition that provided general clinical trials information in text format to patients.

The underlying theoretical model and development of the PRE-ACT program have been described previously.[31-33] We hypothesized, on the basis of the Cognitive-Social Health Information-Processing (C-SHIP) cognitive-affective behavioral theory[34] and the Ottawa Decision Support Framework,[35-37] that by addressing each individual patient's barriers to consideration of clinical trials before the initial oncologist consultation, and providing clarification of patient preferences and values, patients would be better prepared to consider participation in a clinical trial, if presented as a treatment option. We also hypothesized that improved preparation would be associated with higher clinical trial participation rates among patients taking part in PRE-ACT (Fig 1).

PATIENTS AND METHODS

Study Design

We conducted a phase III randomized trial comparing PRE-ACT with a control condition consisting of text about clinical trials. Patients were identified before their initial oncologist visit at one of four NCI-designated comprehensive cancer centers. Research team members contacted patients by phone and offered them the opportunity to participate. Interested patients were provided access to a secure study Web site. Patients who provided electronic consent were then randomly allocated. Allocation was stratified by study site, with permuted blocks of eight and 10. All patients then received an online baseline survey followed by the educational intervention, and then a postintervention survey. These were completed at home, or in the office before the physician appointment. After the visit, patients completed a postconsultation survey online, by mail, or phone according to preference. Treating physicians were not informed that their patients had enrolled until after the consultation.

Institutional review boards at the study sites (Case Comprehensive Cancer Center, which includes University Hospitals Seidman Cancer Center and Cleveland Clinic Taussig Cancer Institute, Cleveland, OH; Fox Chase Cancer Center, Philadelphia, PA; Barbara Ann Karmanos Cancer Institute, Wayne State University, Detroit, MI; and Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL) approved this study.

Eligibility Criteria

Eligibility criteria included advanced or early-stage cancer, first outpatient consultation with a medical oncologist at the study center, 18 years of age or older, ability to read and communicate verbally in English, ability to provide electronic informed consent, and access to high-speed Internet or willingness to complete the study in the clinic before the oncologist visit.

Measures

Participants completed three surveys: baseline (completion time approximately 25 minutes), postintervention (delivered after the educational intervention, completion time approximately 15 minutes), and postconsultation (delivered 2 weeks after the oncologist visit, completion time approximately 15 minutes). The baseline survey included demographics and preference assessments regarding the importance of length and quality of life[38-40] and shared decision making.[41] The baseline survey also included assessments of clinical trials knowledge (19 items: agree, disagree, unsure), attitudinal barriers (28 items: five-point Likert scale), and preparation for decision making (10 items: four-point Likert scale). The barriers assessments were based on literature review, our prior work, focus groups, and pilot testing.[6,7,33,42,43] The preparation measure was adapted from the Ottawa Decision Support Framework.[44,45] The postintervention survey assessed satisfaction with the intervention (12 items) and reassessed knowledge, attitudinal barriers, and preparation. The postconsultation survey assessed decisional conflict (16 items: five-point Likert Scale)[35] and satisfaction with treatment decision (six items).[46] Previously unpublished survey items are in the Data Supplement.

Interventions

PRE-ACT was designed to provide approximately 10 minutes of video content from a library of 28 potential videos lasting less than 2 minutes each. All videos were scripted and were produced with professional actors.[31] Scripts provided factual content and sought to empower patients

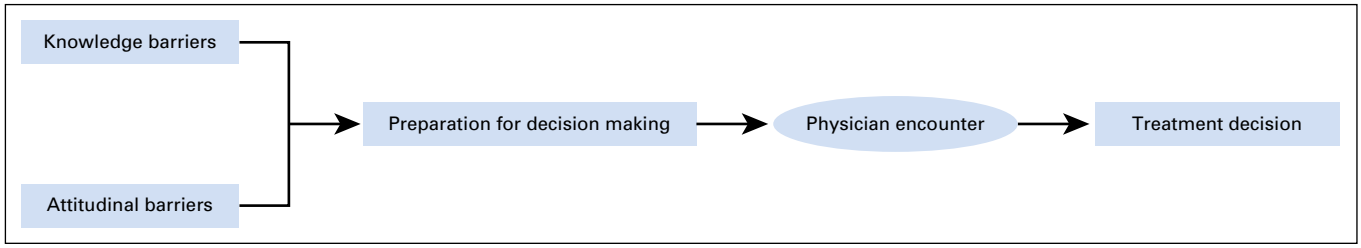

Fig 1. Preparatory Education About Clinical Trials (PRE-ACT) theoretical model.

to ask questions and obtain additional information. In the PRE-ACT arm, participants received a values clarification page, which contained a summary of their quality of life versus length of life preferences and shared decision-making preferences. Knowledge barriers were defined as incorrect/don't know responses to factual items on the baseline survey, whereas attitudinal items were scored on five-point Likert scales and were defined as barriers if the patient responded with a 4 (somewhat agree) or 5 (strongly agree). Participants were then assigned videos on the basis of their highest knowledge or attitudinal barrier scores. If more than seven videos were identified for a patient, he/she was asked to choose five to seven topics of interest. In addition to their tailored videos, all participants viewed three core videos regarding research: "What is informed consent?", "What is an IRB?", and "What are clinical trials?" During analysis, a minor programming error was identified that led to incorrect delivery of 4.1% of the videos, and omission of 5.3% of video assignments.

Patients in the control arm were provided educational text about clinical trials that was excerpted from the NCI Web site (Data Supplement). This was organized into nine topics from which patients could select. In both arms, patients were offered a hyperlink to the NCI Web site if they desired additional information after completion of the postintervention assessment. The video topics and full text from the control condition are in the Data Supplement.

Statistical Analyses

The primary objective was to determine the impact of PRE-ACT versus control on patient knowledge and attitudes about clinical trials, and preparation for decision making (primary outcome). Secondary objectives included the impact of PRE-ACT versus control on patient decisional conflict, satisfaction with information received, and clinical trial participation. A target sample size of 1,000 (500 per arm) completing the postintervention survey was chosen to provide 90% power to detect a 3.7-point difference between the study arms in the Ottawa Preparation for Decision Making Scale using a two-sided, two-sample t test with a type I error of 5%, assuming a standard deviation of 18. A proposed sample size of 1,560 randomly allocated subjects was selected to provide slightly more patients than the target, after accounting for attrition, expecting that approximately 75% (1,170) would complete the baseline survey and 90% (1,053) would complete the postintervention survey. Exploratory analyses also sought to determine whether specific demographic groups may differ in study end points.

When computing scale and subscale scores for measures computed from sums or averages of multiple questionnaire items, individual subject scores were calculated after replacing missing items with the mean of the nonmissing items for the same subject, where the score was set to missing if more than 50% of the component items were missing for that individual.

Comparisons were made between treatment arms using two-sample t tests for continuous outcomes and χ^2 tests for categorical outcomes. Changes in knowledge, attitudes, and preparation scores from baseline to postintervention were computed for each subject having both measures. Mean changes in these scores were compared between treatment arms using two-sample t tests, and within arms, changes were examined using paired t tests. One- and two-way analyses of variance were used to compare means across more than two groups, and to examine whether there were treatment by covariate interactions, respectively. Logistic regression was used to examine treatment by covariate interactions with binary outcomes. All P values reported are for two-sided tests. Statistical analyses were performed using SAS, 9.4 (SAS Institute, Cary, NC).

RESULTS

Participant Characteristics

A total of 6,878 potentially eligible patients were identified, of which 3,859 were reached by phone. A total of 2,568 verbally agreed to participate in the study, and these patients were given access to the study Web site. One thousand two hundred fifty-six provided consent, and 1,255 were randomly allocated to either the PRE-ACT intervention arm (n = 623) or to the NCI text control arm (n = 632). Patient demographics are listed in Table 1. Ninety-seven percent of randomly allocated patients completed the baseline assessments. Of these, 89% completed the postintervention assessment before the physician consultation (Fig 2). Compared with the control arm, the PRE-ACT arm had a higher dropout from baseline to postintervention (17.1% [105 of 615] v 6.4% [40 of 621], $P < .001$), but a slightly lower dropout between postintervention and postconsultation (29.7% [151 of 509] v 35.1% [204 of 581], $P = .056$). Participants who dropped out after the baseline assessment tended to be not married or partnered ($P = .0049$) and were more likely to have metastatic cancer ($P = .0554$). Those who dropped out after the postintervention were less educated ($P = .0431$) and were more likely to have metastatic cancer ($P < .001$). Despite different rates of dropout between treatment arms at different phases, treatment groups did not differ by age, sex, race, ethnicity, education, or metastatic status at either of the postintervention or postconsultation measures (Data Supplement).

Intervention Effects

Knowledge, attitudinal barriers, and preparation to consider clinical trials. The relevance of each potential clinical trial barrier among study participants is shown in Table 2. Both PRE-ACT and control interventions resulted in improved knowledge, attitudes, and preparation for consideration of clinical trials (Table 3). Compared with simple text, PRE-ACT was more effective in increasing knowledge ($P < .001$) and reducing attitudinal barriers ($P < .001$), with a trend toward superior preparedness ($P = .09$).

Exploratory analyses were conducted to determine whether any demographic factors may be associated with a greater benefit from either arm of the study. The relative effects of the educational interventions on knowledge, attitudinal barriers, and preparation scores were generally consistent in favoring PRE-ACT across subgroups, where all treatment by covariate interactions were nonsignificant ($P > .05$). Furthermore, there were no significant differential effects of PRE-ACT versus control on knowledge, attitudes, or preparation on the basis of metastatic status (Fig 3).

We next looked at the relationship between viewing a particular video for patients in the PRE-ACT arm and its impact on barriers. For knowledge barriers, there was a consistent relationship between viewing a video and the likelihood of providing a correct answer to each knowledge question (Data Supplement). Although the impact of viewing the assigned video to address an individual's attitudinal barrier was generally positive, there was greater variability in this dose-response relationship. In particular, the video designed to address concerns regarding the costs of participating in clinical trials seemed to increase those concerns rather than mitigate them (Data Supplement).

Postconsultation outcomes. The decisional conflict scores did not differ between treatment groups, and there was no interaction between treatment group and demographic characteristics (age, sex, race, education, marital status) for this end point. However, certain demographics were associated with greater decisional conflict regarding clinical trial decision making. Within the control group, greater decisional conflict was observed among men (25.2

Table 1. Demographic and Clinical Characteristics

Characteristic	Control (n = 621)	PRE-ACT (n = 614)	Combined (n = 1,235)
Age, mean ± SD, years	58.23 ± 11.75	57.57 ± 11.82	57.90 ± 11.78
Sex			
Male	258 (41.55)	255 (41.53)	513 (41.54)
Female	363 (58.45)	359 (58.47)	722 (58.46)
Race			
White (non-Hispanic)	528 (85.30)	538 (87.91)	1,066 (86.60)
Nonwhite	91 (14.70)	74 (12.09)	165 (13.40)
Missing	2 (0.32)	2 (0.33)	4 (0.32)
Education			
High school graduate or less	148 (23.83)	143 (23.33)	291 (23.58)
Some college or college graduate	473 (76.17)	470 (76.67)	943 (76.42)
Missing	0 (0.00)	1 (0.16)	1 (0.08)
Marital status			
Married/domestic partner	462 (74.40)	454 (74.06)	916 (74.23)
Other	159 (25.60)	159 (25.94)	318 (25.77)
Missing	0 (0.00)	1 (0.16)	1 (0.08)
Employment			
Employed	282 (45.63)	271 (44.14)	553 (44.89)
Unemployed	136 (22.01)	145 (23.62)	281 (22.81)
Retired	200 (32.36)	198 (32.25)	398 (32.31)
Missing	3 (0.48)	0 (0)	3 (0.24)
Metastatic status			
Metastatic	274 (44.12)	249 (40.55)	523 (42.35)
Nonmetastatic	304 (48.95)	311 (50.65)	615 (49.80)
Other*	43 (6.92)	54 (8.79)	97 (7.85)
Tumor types			
Breast	158 (25.48)	159 (26.07)	317 (25.77)
Lung	94 (15.16)	83 (13.61)	177 (14.39)
Colorectal	63 (10.16)	63 (10.33)	126 (10.26)
Prostate	54 (8.71)	50 (8.20)	104 (8.46)
Pancreatic	27 (4.35)	34 (5.57)	61 (4.96)
Other	224 (36.13)	221 (36.23)	445 (36.18)
Missing	1 (0.16)	4 (0.65)	5 (0.40)

Abbreviations: PRE-ACT, Preparatory Education About Clinical Trials; SD, standard deviation.
*Unsure, missing, or nonapplicable.

v 20.6, $P = .01$), those with a high school education or less (26.2 *v* 21.5, $P = .03$), and those who were not married or partnered (25.7 *v* 21.3, $P = .03$). Among the PRE-ACT group, greater decisional conflict was also seen among those participants who were not married or partnered (26.8 *v* 19.1, $P < .001$).

In the 6 months after participation in this study, 21% of patients in both arms subsequently enrolled onto a clinical trial (including 13% onto therapeutic trials).

Satisfaction with educational interventions. Compared with the control group, PRE-ACT participants reported greater mean levels of satisfaction with the amount of information received (five-point scale 3.74 *v* 3.60, $P = .002$), and the way the information was presented (3.86 *v* 3.65, $P < .001$), and felt more prepared to consider clinical trials as a way to treat their cancer (3.62 *v* 3.43, $P < .001$; Table 4). The PRE-ACT participants were more likely to feel the length of the program was reasonable (71.5% *v* 54.3%, $P < .001$) and to feel that the program was useful for making a treatment decision (78.3% *v* 72.1%, $P = .02$).

DISCUSSION

To our knowledge, the PRE-ACT study is the largest prospective randomized trial to date to address barriers to clinical trial participation. Our data show that patient education before the first oncologist visit improves knowledge, attitudes, and preparation for decision making about clinical trials. Both text and tailored video were effective. PRE-ACT, a theory-guided, tailored, interactive video-based educational program, was more effective than NCI text in improving knowledge and reducing attitudinal barriers. PRE-ACT was also associated with greater patient satisfaction than NCI text alone. The fact that our control condition also reduced barriers and improved preparation for decision making supports the high quality of NCI educational materials.

Tailored video delivery was consistently effective in improving the accuracy of responses to specific knowledge questions. There was greater variability observed in response to attitudinal barriers to clinical trial participation, although the overall effect was positive. This variability highlights the complex nature of personal attitudes and the difficulty of addressing concerns in a short video. Certain concerns (eg, fear of side effects or distrust in the medical system) are likely to be based on deeply rooted values and perceptions that may require more intensive interventions to overcome. Exploratory analyses suggest that PRE-ACT was effective across demographic groups.

Of note, financial concerns were among the most commonly expressed concerns by patients. Recent research studies have

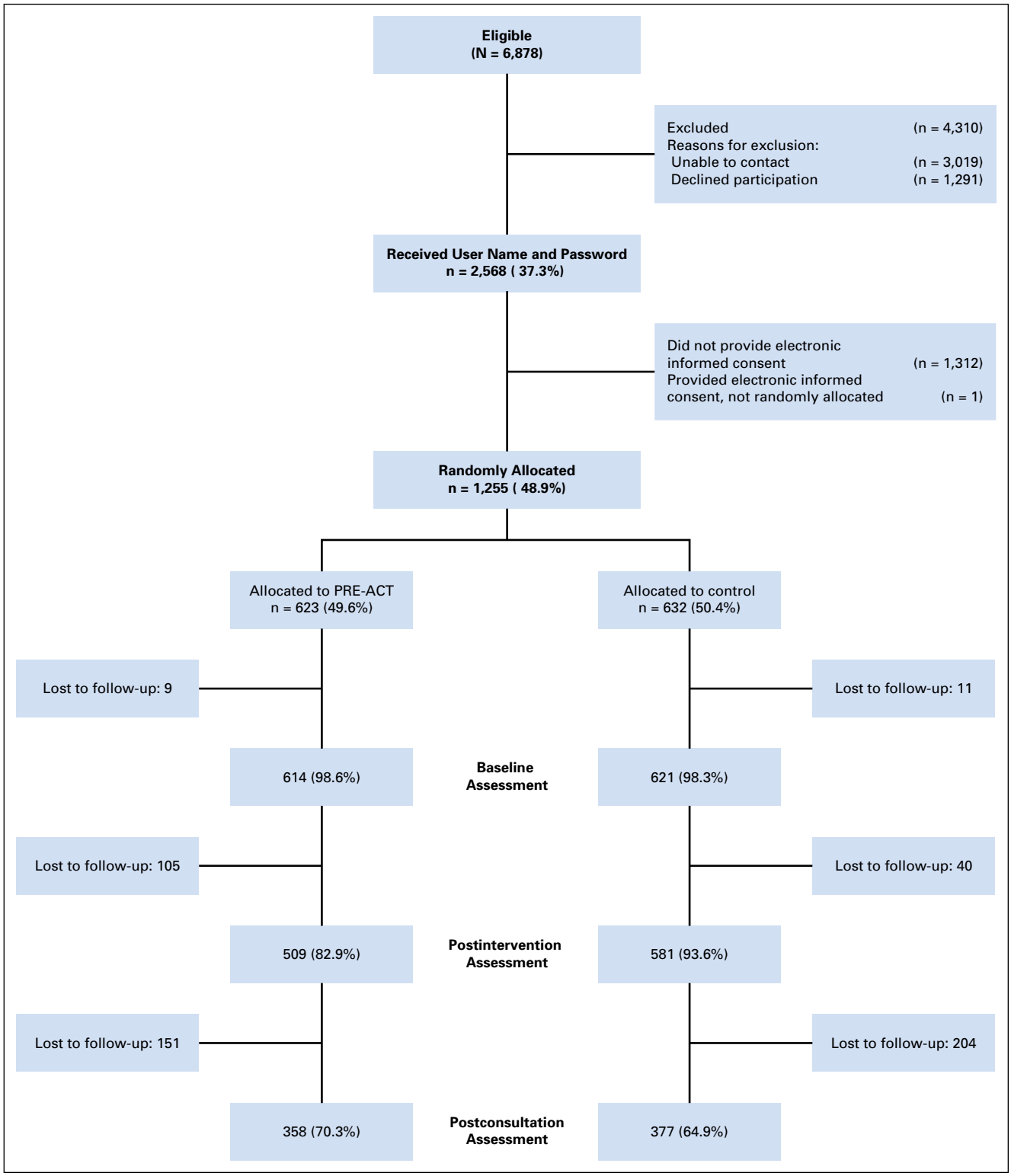

Fig 2. CONSORT diagram. PRE-ACT, Preparatory Education About Clinical Trials.

confirmed the impact of out-of-pocket costs on patients, and the potential effect on care received.[47-51] The study was conducted before implementation of the Affordable Care Act provision that requires insurer coverage of routine clinical costs associated with participation in approved clinical trials.[52] The video that addressed cost concerns provided factual information regarding the uncertainty of coverage. Thus, it is not surprising that viewing of this video by patients already concerned about finances may have

Table 2. Knowledge and Attitudinal Barrier Survey Items

Survey Item	Incorrect and Unsure (%)	Percentage of Patients Agreeing
Knowledge survey item (correct response)*		
Most clinical trials involve a placebo (sugar pill). (disagree)	75.45	
Adverse effects in clinical trials are usually worse than with standard treatments. (disagree)	65.22	
"Standard treatments" are the best treatments currently known for a cancer. (agree)	61.9	
Informed consent mainly protects researchers from lawsuits. (disagree)	59.87	
Patients in clinical trials must get their care at different places from patients getting standard treatments. (disagree)	58.74	
Standard treatments are never as good as new research treatments. (disagree)	58.22	
A clinical trial is available for anyone with cancer who wants to take part. (disagree)	56.71	
The only way to find out about clinical trials is from my doctor. (disagree)	48.11	
Once I join a clinical trial, my own doctor will not know what happens to me. (disagree)	43.69	
Clinical trials are only used as a last resort. (disagree)	36.17	
Institutional review boards review and monitor clinical trials to keep patients safe. (agree)	29.4	
Randomization means that my treatment will be chosen by chance. (agree)	28.81	
Treatments used in clinical trials may cause side effects. (agree)	26.17	
My doctor can start a clinical trial without the approval of professionals who protect patient rights. (disagree)	23.98	
If I were to join a clinical trial, I could decide to stop at any time. (agree)	17.25	
Clinical trials are not appropriate for patients with cancer. (disagree)	16.94	
Clinical trials are done to improve standard treatments. (agree)	13.67	
Informed consent means that I am given information about the trial so I can freely decide whether to participate. (agree)	4.5	
It is up to me to decide whether to be in a clinical trial. (agree)	2.37	
Attitudinal Barrier survey item†		
I'm afraid of the side effects I'll have on a clinical trial.		51.90
I'm worried that the treatment I'd receive on a clinical trial wouldn't work for me.		41.51
I'm afraid I'll get a sugar pill (placebo) instead of real medicine on a clinical trial.		39.29
I'm afraid that my health insurance won't pay for a clinical trial.		38.73
I wouldn't ask about clinical trials unless my doctor brought them up first.		38.04
I don't know where to find a clinical trial for me.		32.84
I wouldn't be willing to travel extra distance to take part in a clinical trial.		31.51
I'm worried that I wouldn't be able to afford the costs of treatment on a clinical trial.		31.22
I'm afraid that if I take part in a clinical trial my treatment will be selected at random by a computer rather than by my doctor.		31.13
I think clinical trials are best used for people with cancer that can't be treated any other way.		30.01
I don't like to try new treatments until they've been around for a while.		28.46
I don't trust drug companies.		24.30
I'm afraid that taking part in a clinical trial would make me sicker than I am now.		24.09
I'm afraid I'll be used as a guinea pig if I'm in a clinical trial.		23.45
I'm worried that going on a clinical trial would burden my family.		20.79
I don't know what clinical trials are.		19.97
I'm worried I'd be treated like a number, not a person, on a clinical trial.		19.57
I'm worried that my family wouldn't want me to go on a clinical trial.		17.66
I think that being on a clinical trial is dangerous.		16.48

(continued on following page)

Table 2. Knowledge and Attitudinal Barrier Survey Items (continued)

Survey Item	Incorrect and Unsure (%)	Percentage of Patients Agreeing
I'm concerned that people other than my doctor would see my personal information if I was on a clinical trial.		14.44
I'm worried that my medical care won't be as good if I join a clinical trial.		13.53
I wouldn't be able to find transportation to get me to my clinical trial treatment center.		11.32
I wouldn't be able to keep up with the clinical trial treatment schedule.		9.60
I don't trust the medical system.		8.76
I'm too upset now to think about taking part in a clinical trial.		8.53
I don't have time to take part in a clinical trial.		7.68
It would be too upsetting for me to be on a clinical trial.		6.95
I don't trust doctors.		5.03

*Responses for knowledge items were agree, disagree, or unsure.
†Responses for attitudinal barrier items were 1 = strongly disagree, 2 = somewhat disagree, 3 = neither agree nor disagree, 4 = somewhat agree, 5 = strongly agree.

augmented these apprehensions. In preparation for dissemination of PRE-ACT, the video regarding cost concerns was updated to reflect new legislation.

Postintervention decisional conflict did not differ between the study arms, and there was no interaction between patient demographics and the impact of PRE-ACT on this end point. However, we found that men, patients with a lower educational level, and those who were not married or partnered tended to have more difficulty with decision making. Recent data suggest that videos targeted toward a specific demographic population can significantly increase the likelihood of enrollment onto clinical trials.[28] These findings suggest that further tailoring of educational interventions to improve decision making for these patient subsets may show additional benefits.

The overall goal of PRE-ACT was to improve knowledge and attitudes about clinical trials, with the hypothesis that the resulting improved preparation for decision making would lead to greater participation in clinical trials. In this study, 21% of patients took part in research studies in the 6 months after our online educational interventions, and there was no difference between the study groups. Several potential explanations may account for this result. First, clinical trial enrollment in both arms was relatively high, which could reflect participant or site selection bias and dilute the differential effects of video versus text education. Second, it is plausible that both video and text were effective in increasing clinical trial enrollment, by reducing barriers and motivating patients to ask their oncologists about clinical trials. Finally, there are factors that influence clinical trial enrollment that could not be assessed reliably, including the availability of relevant studies, the quality of the interaction between the patient and the physician during the discussion of clinical trials as an option, and patient eligibility.

Several potential limitations of our findings should be noted. First, although we permitted the educational interventions to be conducted at the clinical site or at home, the requirement for high-speed internet access may have resulted in a more educated study population, which would limit the generalizability of these results. Second, the effect sizes for control text and PRE-ACT were large for knowledge, but modest for attitudes and preparation. As with many behavioral

Table 3. Knowledge, Attitudes, and Preparation Scores (Control *v* PRE-ACT)

	Control			PRE-ACT			Comparison of PRE-ACT and Control	
Measure	No.	Mean (SD)	95% CI	No.	Mean (SD)	95% CI	Difference in Mean Change (95% CI)	*P*
Knowledge								
Pre	573	11.77 (3.77)		504	11.93 (3.68)			
Post	573	14.28 (3.78)		504	15.09 (3.05)			
Change	573	2.51 (3.05)	2.26 to 2.76*	504	3.16 (3.10)	2.89 to 3.43*	0.65 (0.28 to 1.01)	< .001
Attitudinal barriers								
Pre	570	2.54 (0.64)		502	2.50 (0.67)			
Post	570	2.39 (0.67)		502	2.23 (0.66)			
Change	570	−0.16 (0.38)	−0.19 to −0.12*	502	−0.27 (0.45)	−0.31 to −0.23*	−0.12 (−0.17 to −0.07)	< .001
Preparation								
Pre	578	73.1 (15.2)		505	73.4 (15.7)			
Post	578	76.5 (15.5)		505	78.1 (14.1)			
Change	578	3.4 (13.5)	2.3 to 4.5*	505	4.7 (12.8)	3.6 to 5.8*	1.4 (−0.2 to 2.9)	.09

Abbreviations: PRE-ACT, Preparatory Education About Clinical Trials; SD, standard deviation.
*Within-group mean change significantly different from zero, $P < .001$.

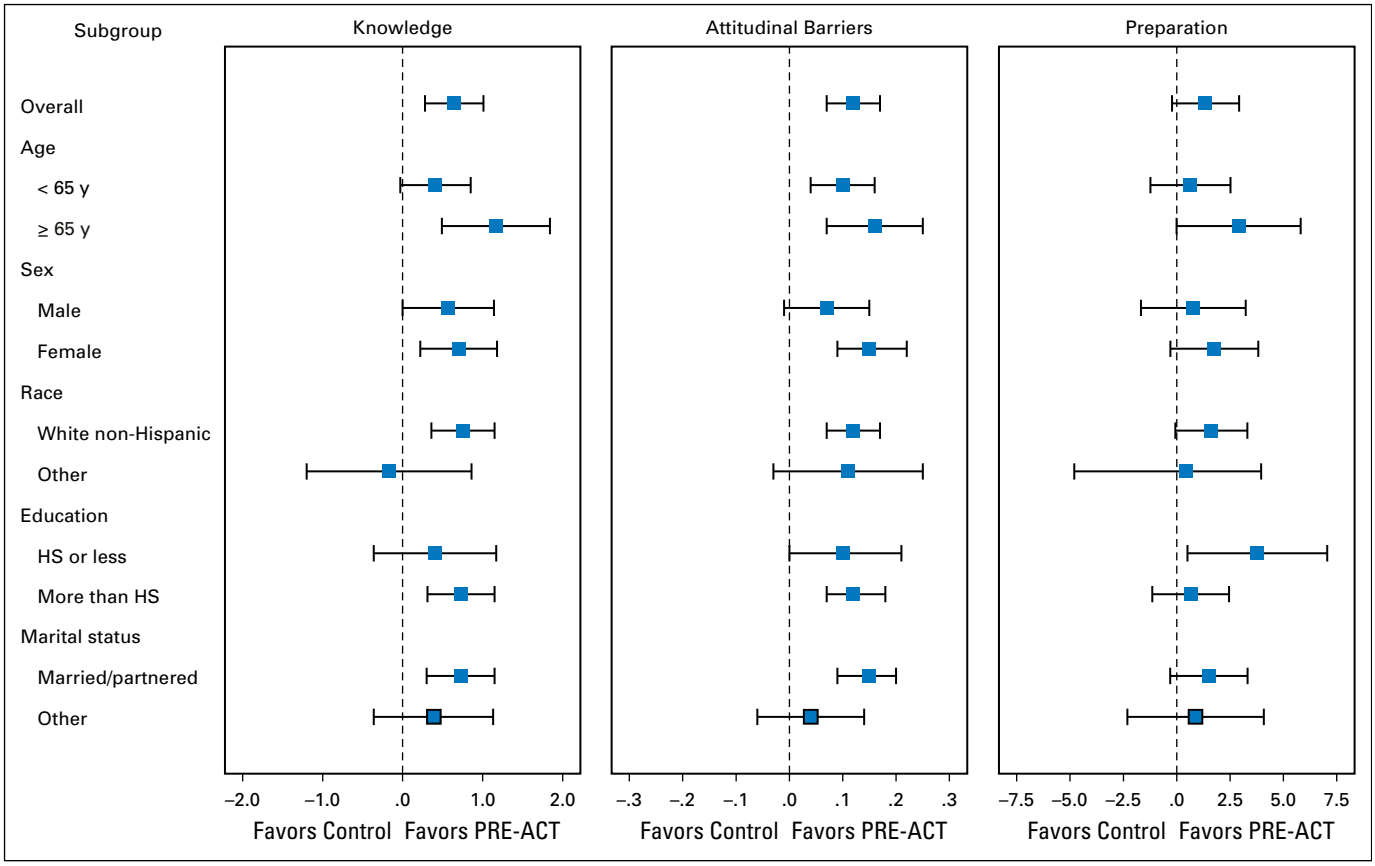

Fig 3. Demographic influences on treatment effect. Means and 95% CIs for demographic influence on treatment effect. Means calculated are post-pre for PRE-ACT minus post-pre for control, for knowledge and preparation. Means for attitudinal barriers are calculated as post-pre for control minus post-pre for PRE-ACT, to allow same direction of differences for all scales. HS, high school; PRE-ACT, Preparatory Education About Clinical Trials.

measures, the clinical significance of the improvements in our main end points is difficult to define. Third, although we found no evidence of differences in groups caused by dropout, it is possible that greater attrition in the PRE-ACT arm could have introduced bias into the results. Fourth, a programming error led to incorrect video delivery in a small minority of patients. These dosing errors may have resulted in a diminution of the overall PRE-ACT treatment effect.

Our data indicate that Web-based patient-directed educational programs can improve the process of decision making about

Table 4. PRE-ACT Program Satisfaction, Control *v* PRE-ACT

Question	Control	PRE-ACT	*P*
How satisfied are you with the amount of information you received? (1-5 most satisfied), mean (SD)	3.60 (0.79)	3.74 (0.77)	.002*
How satisfied are you with the way the information was presented to you? (1-5 most satisfied), mean (SD)	3.65 (0.84)	3.86 (0.79)	< .001*
Did this program help you feel more prepared to consider clinical trials as a way to treat your cancer? (1-5 a great deal), mean (SD)	3.43 (0.89)	3.62 (0.92)	.001*
Which of the following best describes your feelings about the length of this program? No. (%)			< .001†
Reasonable	310 (54.3)	358 (71.5)	
A little long	218 (38.2)	129 (25.7)	
Much too long	43 (7.5)	14 (2.8)	
Did you find this program useful for making your decision about treatment for cancer? No. (%)			.02†
Yes	405 (72.1)	389 (78.3)	
No	157 (27.9)	108 (21.7)	

Abbreviations: PRE-ACT, Preparatory Education About Clinical Trials.
*P value from t test.
†P value from χ^2 test.

clinical trials. Further research is needed to guide additional tailoring of video and/or text information on the basis of patient characteristics. In addition, effective efforts to improve participation in clinical trials by patients with cancer will likely need to be multitargeted, addressing provider, community, organizational, and access barriers.[25] Building on the PRE-ACT experience, we recently initiated the development of a Web-based, tailored education program using videos for oncology nurses (NCI R25CA177574) to enhance communication with patients about clinical trials. In addition, PRE-ACT is now freely available at www.cancer.net/preact.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at www.jco.org

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