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“Entering a Clinical Trial: Is it Right For You?”-- A Randomized Study of The Clinical Trials Video and Its Impact on the Informed Consent Process

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Abstract

PURPOSE—This randomized study was designed to assess the utility of an educational video in preparing cancer patients for decisions about clinical trial participation. The study assessed the effect of the video on patients’ understanding and perceptions of clinical trials, its impact on decision making and patient-provider communication, and patients’ satisfaction with the video.

METHODS—Ninety adults considering cancer clinical trials were randomized to receive (n=45) or not receive (n=45) the video. Using the validated Quality of Informed Consent (QuIC), respondents’ knowledge about clinical trial participation was assessed. All subjects completed additional questions about satisfaction with the video, decision making, and patient-provider communication. Data were analyzed using the Wilcoxon rank-sum test, regression model and descriptive statistics.

RESULTS—Although intent-to-treat analysis found no significant group differences in objective understanding between those randomized to view or not view the video, the majority of participants reported favorable experiences with regard to watching the video: 85% found the video was an important source of information about clinical trials; 81% felt better prepared to discuss the trial with their physician; 89% of those who watched the video with family indicated that it helped family better understand clinical trials; and 73% indicated it helped family accept their decision about participation.

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CONCLUSIONS—Although the video did not measurably improve patients' knowledge about clinical trials, it was an important source of information, helped educate families, and enhanced patient communication with their oncology providers.

Keywords

Informed consent; clinical trials; patient decision making; patient-provider communication; patient education; multi-media technology

Introduction

Numerous obstacles, including overwhelmed patients and families, time constraints, miscommunication among patients and providers, and difficult-to-read consent forms, can impede the informed consent process for clinical trials.^{1, 2} Thus there is a clear need to identify ways to improve this process. Indeed, it has been postulated that poor clinical trial accrual rates (3% of all adult patients) may be partially attributable to the lack of informational support for patients.^{3, 4}

With an appreciation of the obstacles and recognizing the importance of accurate information presented in a clear and unpressured manner, the Dana-Farber Cancer Institute (DFCI) created the video, "Entering a Clinical Trial: Is it Right for You?" (The Clinical Trials Video). The goal of the video, funded by an educational grant from the National Institutes of Health (NIH), was to help dispel patients' misconceptions by explaining clinical trials in a clear, simple, and balanced way. Our current culture of technologically based information presentation, whether in the form of PowerPoint presentations, videos, websites, or audio tools, suggests that adding such technology to the existing written informed consent process may improve patient understanding and satisfaction.

The need for such an intervention has been repeatedly demonstrated by studies showing that many clinical trial participants have misconceptions about clinical trials, which might compromise the informed consent process.^{5, 6} Frequently misunderstood topics include randomization, overestimation of the benefits or the proven nature of the study intervention, and failure to recognize the primary purpose of the trial.^{5, 7} Joffe et al.^{6, 8} found that three-fourths of the patients queried shortly after trial enrollment did not understand that clinical trials evaluate treatments that are not yet recognized as standard. About two-thirds did not recognize any increased risk from trial participation, and 70% did not realize that the treatment under investigation had not been proven effective. In addition, one-quarter of the patients thought that clinical trials were designed to benefit trial participants directly. Lidz and colleagues also found that many patients do not fully understand the risks and benefits of trial participation.⁹ Taken together, these data underscore the need for better patient education and improved communication between patients and providers when discussing clinical trials.

A well-known principle of communication states that there are frequent discrepancies between what is said and what is heard.¹⁰ When first approached about participation in a clinical trial, potential participants are often overwhelmed and not in an ideal frame of mind to receive new information. Most potential participants are given a clinical trial consent form to take home to read, consider, and discuss with family members. However, consent forms are typically long and, despite best efforts, may not be written at an appropriate reading level.^{5, 11} In fact, sample texts provided to investigators by the Institutional Review Boards (IRB) of medical schools in the United States generally fail to meet the IRBs' own readability standards.¹² Thus even with organizational procedures in place to protect patients, informed consent inadequacies persist.

In their systematic review of 42 studies, Flory and Emanuel concluded that interventions involving “extended discussion” (i.e., spending more time talking with patients about the trial) were most effective in improving research participants’ understanding.¹³ Such thorough discussions improved understanding by providing an opportunity for active engagement and responsiveness. Therefore, it is important to explore and identify interventions that will stimulate such discussions and thereby enhance patient-provider communication. Interestingly, the authors noted that two trials that used video technology found improvements in retention of disclosed information, but no increase in understanding. Thus, interventions aimed at improving understanding of clinical trials may have important secondary gains including retention of information.

Recent interventions to improve the informed consent process in clinical trials have relied on multi-media technology as an adjunct to the written information mandated by law. Olver and colleagues examined the utility of an educational CD-ROM in improving the informed consent process for patients considering chemotherapy.¹⁴ The study did not show improved understanding among those patients who viewed the CD-ROM; however, this study did not measure secondary benefit derived from the CD-ROM format, including patient and/or family satisfaction with the informed consent process. A study by Hack et al. found that providing either a standardized or personalized audiotape to reinforce the information presented in an informed consent discussion had a favorable effect on patient understanding.³

Thus, inadequacies in the current standardized informed consent process are clear. Furthermore, existing data suggests a role for multi-media interventions in the informed consent process. The current study was designed to assess the impact of viewing The Clinical Trials Video on patients’ understanding of clinical trials and to evaluate how that understanding contributed to the informed consent process.

Methods

Upon review and approval of the Institutional Review Board, eligible patients were identified and referred by oncology care providers from the Phase I, Thoracic Oncology, Gastrointestinal Oncology, Lymphoma, and Sarcoma clinics at DFCI in Boston, Massachusetts. Eligibility criteria included confirmed cancer diagnosis, age 18 years or older, able to understand English, and considering participation in a Phase I, II, or III clinical trial (treatment trial).

This study was explained in detail immediately following the patient’s initial clinical trial consult, and written consent was obtained from those wishing to participate. Participants were then registered and randomized centrally to either intervention or control groups. A total of 110 potential participants were approached. Ninety consented (88% recruitment rate) and were randomized equally between the experimental (Video, n=45) and the control arm (n=45), with a total of 77 completing QuIC A/B (Figure 1). The reasons for attrition (n=13, 14.4%) were as follows: became ineligible for treatment trial (n=2), changed mind (n=6), too sick (n=1), and lost to follow up (n=4). Seventy-two participants completed the final questionnaire, Perceptions of the Clinical Trials Video.

Intervention group participants were given The Clinical Trials Video to take home along with the clinical trial consent form, whereas control group participants received only the clinical trial consent form to take home. For participants who did not have a DVD player at home, a portable DVD player was provided. Within one week, the modified Quality of Informed Consent (QuIC) questionnaire was administered to all study participants by telephone at a mutually convenient time. For the intervention group, participants were asked

whether they had in fact watched the Video prior to administration of the questionnaire. After administration of the QuIC, control group participants received The Clinical Trials Video by express mail delivery, so that all study participants would have an opportunity to watch the video prior to their next clinic appointment. All participants then completed the 9-item questionnaire about their perceptions of the video at their next clinic visit when they met with their oncologist to discuss the clinical trial and provide consent.

Measures

Understanding Clinical Trials—A modified version of the validated Quality of Informed Consent (QuIC) questionnaire was used to measure understanding of the information conveyed to the patient regarding clinical trial participation.⁸ The QuIC is divided into sections A and B. Section A included 23 statements measuring objective knowledge, to which the participant could respond ‘agree,’ ‘disagree,’ or ‘unsure.’ Section A was modified from the original version by the addition of 3 new questions related to the potential for additional risk associated with study participation, the inclusion of non-standard treatments or procedures in the study, and the requirement that the investigator follow study rules in modifying treatments. Section A includes statements such as “I understand that I am being offered participation in a clinical trial” and “Compared with patients receiving standard treatment, some participants in this trial may experience additional risks or discomforts.” Questionnaires were scored according to published methods⁸; both phase-independent and phase-specific questions were included in the scoring.

Section B of the QuIC consisted of 14 questions assessing subjective (self-reported) understanding on a five-point ordinal scale ranging from ‘I didn’t understand this at all’ (1) to ‘I understood this very well’ (5). Section B includes questions such as “How well did you understand the fact that the clinical trial involves research?” and “How well did you understand the treatments and procedures you would undergo?” Each section is scored on a normalized scale ranging from 0 to 100, with higher scores indicating greater objective knowledge (Section A) or self-assessed understanding (Section B).

Perceptions of The Clinical Trials Video—A 9-item questionnaire designed by this study team was used to assess satisfaction, patient-clinician communication and decision-making with regard to The Clinical Trials Video. The first eight items were statements that used a five-point Likert-type scale (1= strongly disagree to 5= strongly agree). These items addressed such issues as feeling better prepared to communicate with clinicians about the clinical trial, perceiving the video as worthwhile and easy to understand, facilitating communication with family about the clinical trial, and influencing decision to participate in clinical trial. The last item used a “yes/no” response and asked if watching the video prompted the patient to ask new questions to the doctor or nurse.

Intervention

The 20-minute video entitled “Entering a Clinical Trial: Is it Right for You?” was developed by a multi-disciplinary team of health care professionals, an ethicist, health communications experts, institutional review board specialists, and patient and family advisors, with funding support from the NIH National Center for Research Resources. Extensive reviews by health care providers, patients, and families contributed to refinement of the final product. In the video, both clinical trial participants and health care providers provide their own perspectives (unscripted) in a friendly, honest and easy to understand manner.

Statistics

The study utilized a two-arm, randomized design with randomization via permuted blocks (Zelen, 1974) stratified by disease specialty clinic. The initial design called for 128 patients (64 on each arm), which would have provided at least 80% power to detect a 5-point difference in mean QuIC Section A scores between the two arms using a two-sided *t*-test and assuming a standard deviation of 10. Preliminary data suggested that the standard deviation of the QuIC Section A score was closer to 8, suggesting that only 82 patients (41 per arm) needed to be accrued to achieve similar power.

Results

Sample Characteristics

See Table 1 for details of the participant characteristics. Characteristics were balanced between the two groups. Overall the sample consisted of slightly more men than women (57%). Most respondents were married or in a committed relationship (82%), caucasian (93%), and college educated (57%). Nearly two-thirds were considering participation in a clinical trial for the first time (62%), and most were considering Phase I trials (81%). After watching the video and participating in a standard informed consent process, most (69%) consented to participate in the clinical trial.

Understanding Clinical Trials: Group Differences

Descriptive statistics for the QuIC Sections A and B total scores are given in Table 2. There was no significant difference between control versus treatment groups in clinical trial understanding as measured by the QuIC Sections A and B. Both groups scored approximately 87% on the QuIC section A and approximately 90% on the QuIC section B. The slightly higher scores on section B on are consistent with the initial validity testing of the instrument which showed better subjective understanding (as measured by section B) versus objective understanding (as measured by section A).⁸ An exploratory analysis to determine whether previous clinical trial participation affected QuIC scores demonstrated that controlling for this variable was not statistically significant (two-tailed $p = 0.7166$). A recent study by Bergenmar et al. also used the QuIC to measure understanding of informed consent and also found that previous clinical trial participation did not affect mean QuIC scores.¹⁵

QuIC Section A – Objective Knowledge of Clinical Trials—Scores for the QuIC Section A were approximately normally distributed. A general linear model with QuIC Section A score as the response and treatment arm, specialty clinic (disease center), and their interaction was fit. This model was not significant at the $\alpha=0.05$ level ($p=0.75$; $F=0.65$, 9 df_N , 67 df_D). The interaction term was dropped and the model was refit. Again, this model was not significant at the $\alpha=0.05$ level ($p=0.62$; $F=0.71$, 5 df_N , 71 df_D). Therefore, consideration for the disease center was dropped altogether and a two-sided, independent samples *t*-test was used to test the null hypothesis that the true mean QuIC Section A total scores were equivalent between the two treatment arms. This hypothesis was not rejected at the $\alpha=0.05$ level ($p=0.75$; $t=0.32$, 75 df).

QuIC Section B – Self-Reported Understanding of Clinical Trials—Scores for the QuIC Section B were not approximately normally distributed. A two-sided Wilcoxon-Mann-Whitney test was used to test the null hypothesis that the true median QuIC Section B total scores are equivalent between the two treatment arms. This hypothesis was not rejected at the $\alpha=0.05$ level ($p=0.67$, $W=1439.5$). Average scores were used for ties.

Perceptions of The Clinical Trials Video

Table 3 describes participants' perceptions of The Clinical Trials Video. Overall most responded favorably: 89% found it worthwhile to watch, 85% found it an important source of information, and 81% found it better prepared them to communicate with their clinicians about the clinical trial. Additionally, participants were asked if they thought of new questions to ask their doctor and nurse about the clinical trial after watching the video, and 26% responded "yes." One-third of respondents reported that the video influenced their decision about whether or not to participate in the clinical trial. Approximately half of the sample watched the video with family and/or friends; of those, 89% found it helped family and friends to better understand clinical trials. One-quarter of the participants identified new questions to ask their doctor or nurse after watching the video. Secondary analyses explored differences in response patterns based on participant characteristics; the only striking finding was a higher percentage of men (40%) found the video helped them in deciding to participate in the clinical trial compared to women (19%).

Discussion

We conducted a randomized controlled trial to evaluate whether watching The Clinical Trials Video would increase patients' knowledge of the clinical trial that they were considering, as measured by the QuIC. The results of our study, however, do not suggest an increase in knowledge among those randomized to view the video. These findings are consistent with other studies that failed to document increased knowledge as a result of multi-media supplementation to the standard informed consent process.^{15, 13, 3} Such findings suggest that patients derive the majority of their knowledge regarding clinical trials from their provider consultation, the consent form, or other outside sources.

Nonetheless, our data indicate that patients found watching the video to be clearly beneficial. Of clinical significance, patients reported that the video fostered communication with the health care team about the clinical trial. This finding supports recommendations by Flory and Emanuel (2004) that promoting "extended discussion" between patient and physician is essential to those considering clinical trial participation. Indeed we also found that over one-quarter of our participants identified new questions to ask their doctor or nurse which confirms the video enhanced patients' communication and promoted a more thorough informed consent process.

The video was also very helpful to family and friends, according to the patients, in enhancing their understanding of clinical trials and accepting the patient's decision about participation in the clinical trial. Since it may be difficult for family members and friends to attend in-person consultations, the video can serve to answer questions and ease the burden of the patient trying to describe clinical trials to his/her loved ones. Additionally, patients often rely on family and friends as a source of information after cancer diagnoses,¹⁵ and as such it is critical to educate these members of the patient support network.

Despite participants' overall favorable responses to the video, only about one-third reported that the video helped them decide whether or not to participate in the trial. This finding is not surprising, as other variables such as patients' prior expectations, the influences of their referring physicians, and conversations with the physician-investigator and his or her research team might be anticipated to have considerably greater impact on the decision about the trial.² Of note, there were more than twice as many men (40%) who found that the video helped them in deciding to participate in the clinical trial compared to women (19%). Very few studies have commented on gender differences in clinical trial decision-making based on multi-media interventions and therefore it is difficult to speculate on a cause. One other study on informed consent in clinical trials comparing an audiotape intervention versus

an interactive computer program intervention found that a significantly higher percentage of men decided to participate in the clinical trial.¹⁶ If such findings persist in future studies, intervention designs may need to account for gender differences.

Several limitations merit comment. First, mean scores on Section A of the QuIC were substantially higher than those in our previous work, potentially leading to a ceiling effect. The higher scores might be due to the high levels of education among our sample or to temporal improvements in informed consent practice and outcomes since our original study.^{6,8} The high scores among participants in the control group make it difficult to detect improvements associated with interventions to enhance informed consent. Second, although the intervention and control groups were very similar with regard to measured characteristics, we cannot rule out the possibility that unmeasured differences between groups may have confounded evaluation of differences in understanding of the trial. Third, the homogeneous nature of the sample limits the generalizability of our findings. Finally, the nine-item questionnaire that assessed perceptions about the video had not been used or validated previously.

In conclusion, although we did not identify improvements in understanding associated with viewing this video, our findings support the value of multimedia education in the delivery of clinical trial information to potential participants. The Clinical Trials Video fosters valuable communication between the patient and clinicians, thus enhancing the informed consent process. Family members also benefit from watching it. Future research ought to focus on more sociodemographically diverse samples and on the ways in which such multimedia supplementations support the informed consent process. Next steps might include evaluation of trial-specific video or multimedia presentations where feasible, development of alternative interventions that might have greater effects on knowledge, as well as examination of a larger set of outcome measures, including confidence in decision making and patient-provider communication. It would also be valuable to explore whether multimedia interventions help family members and ultimately how their involvement impacts patient understanding and decision-making.

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Figure 1.
Participant Flow Diagram

Table 1

Participant Characteristics

	Treatment Arm				Total	
	Control		Video			
	N=39	%	N=38	%	N=77	%
RACE						
White	36	92.3%	36	94.7%	72	93.5%
Black or African American	2	5.1%	2	5.3%	4	5.2%
Asian	1	2.6%	0	0.0%	1	1.3%
GENDER						
Male	22	56.4%	22	57.9%	44	57.1%
Female	17	43.6%	16	42.1%	33	42.9%
EDUCATION LEVEL						
Unknown	2	5.1%	0	0.0%	2	2.6%
Some College or Less	16	41.0%	16	42.1%	32	41.6%
College Graduate or Advanced Degree	21	53.8%	22	57.9%	43	55.8%
PREVIOUS CLINICAL TRIAL PARTICIPATION						
Unknown	1	2.6%	1	2.6%	2	2.6%
No	25	64.1%	23	60.5%	48	62.3%
Yes	13	33.3%	14	36.8%	27	35.1%
PHASE OF CLINICAL TRIAL CONSIDERED						
Unknown	1	2.6%	1	2.6%	2	2.6%
Phase I	32	82.1%	30	78.9%	62	80.5%
Phase II	4	10.3%	6	15.8%	10	13.0%
Phase III	2	5.1%	1	2.6%	3	3.9%
AGE						
Mean (SD)	55 (12)		57 (10)		56 (11)	
DIAGNOSIS					23	

	Treatment Arm				Total	
	Control		Video			
	N=39	%	N=38	%	N=77	%
Sarcoma						29.9%
Colon					15	19.5%
Lung					10	13.0%
Other GI					9	11.7%
Genitourinary					3	3.9%
Other					9	11.7%
Missing					8	10.4%

Table 2

Descriptive Statistics for QuIC Sections A and B Total Score by Treatment Arm

	TREATMENT ARM	N	Mean	Std Dev	95% CI
Section A	Control	39	87	7.3	(84.7, 89.3)
	Video	38	86.5	5.7	(84.8, 88.2)
Section B	Control	39	90	8.7	(87.3, 92.7)
	Video	38	89.8	8.1	(87.2, 92.4)

Table 3

Perceptions of The Clinical Trials Video (N=72)

ITEM		RESPONSE (%)			
	Strongly Agree	Agree	No opinion	Disagree	Strongly Disagree
The clinical trials video kept my attention.	56.9	36.1	7	0	0
The video was an important source of information about clinical trials.	48.6	36.1	11.1	4.2	0
I felt better prepared to discuss the clinical trial with my physician and nurse after watching the video.	33.4	47.2	6.9	12.5	0
The video helped me decide whether or not to participate in my clinical trial.	11.1	20.8	23.6	27.8	16.7
The video was easy to understand.	80.6	19.4	0	0	0
Overall, I feel that watching the video was worthwhile.	66.7	22.2	9.7	0	1.4
The video helped my family and friends understand clinical trials better. (n=37)	62.1	27.1	10.8	0	0
The video helped my family and friends to accept my decision about clinical trial participation. (n=37)	54.1	18.9	16.2	8.1	2.7