Title: Identification of Patient-Level Barriers and Facilitators to NRG Oncology/RTOG Clinical Trials Recruitment

Short/Running Title: Identification of Patient Level Barriers

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Conflict of Interest Statement

For Original Research Only:

Specific contributions to the study and/or manuscript of each author should be listed below:

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Key Message

Among multiple variables, patient perceptions of time commitment, experimentation, altruism, and physician endorsement differentiated participants and non-participants of RTOG clinical trials. Results suggest that points of intervention are during clinical trial design and a shared decision-making process.

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ABSTRACT:

Aims: Very few cancer patients participate in clinical trials despite significant recruitment effort, time and expense. The primary objective of this pilot study was to assess patient-level barriers and facilitators to NRG Oncology Radiation Therapy Oncology Group (RTOG) clinical trials in order to develop improved patient recruitment strategies.

Methods: Forty-two patients who were eligible for an NRG Oncology RTOG clinical trial, evenly divided between previous participants who consented and nonparticipants who declined, were administered surveys to collect data. The Fisher-Freeman-Halton test was used to evaluate response differences in Likert items, and multiple choice items were analyzed using the Fisher exact test to evaluate responses between the two groups.

Results: Previous participants were more likely to disagree that a clinical trial would be too time consuming (p=.001) and more likely to agree to participate to help others (p=.0002). Previous non-participants were significantly more likely to agree that taking part in a clinical trial feels like being a "guinea pig" (p=.006). Misunderstanding of treatment randomization was prevalent in both groups. The majority of patients expected a 50% or greater personal benefit from participating in a clinical trial.

Conclusions: Design of clinical trials should include ethical strategies that minimize perceived and real barriers of time burden and strategies that maximize the benefits of participation. During a shared decision-making process, the fears of experimentation and understanding of clinical trials concepts, such as randomization, should be addressed.

Introduction

Only about 3% of new cancer patients participate in clinical trials.[1] Barriers to and facilitators of participation have been focus of many studies, but data are lacking on the cognitive factors of patients that impact enrollment into radiation therapy clinical trials.[1-7] Radiation therapy plays a crucial role for many cancers, yet is often underutilized. Additional clinical trials are required to demonstrate its optimal utilization and effectiveness. Thus, the primary objective of this pilot study was to assess patient-level barriers and facilitators to NRG Oncology Radiation Therapy Oncology Group (RTOG) clinical trials.

Materials and Methods

The study population consisted of a convenience sample of 42 patients from five NRG Oncology RTOG institutions. The 42 patients were equally distributed between eligible patients who had previously participated in an NRG Oncology RTOG clinical trial and patients who refused participation in an NRG Oncology RTOG clinical trial. NRG Oncology RTOG institutions were chosen based on a positive past record of patient accrual and the presence of a research nurse or coordinator at the site who expressed interest in recruiting for this study. The NRG Oncology RTOG institutions accrued eight–ten patients at each site. Eligibility criteria included being at least 18 years old, ability to speak and read English, and being offered participation in an NRG Oncology RTOG Phase I, II or III symptom management or cancer treatment trial within the past120 days. Both men and women of all races and ethnic groups were eligible for participation in the current study.

A ten-minute Likert-based, semi-structured survey was administered to each participant by the site Clinical Research Associate (CRA) either in clinic or via telephone. The survey was designed by senior NRG Oncology RTOG investigators based on a review of the literature and

their more than 20 years of clinical trial experience, including recruitment for NRG Oncology RTOG clinical trials. It consisted of three sections: 1) a question assessing whether or not the participant had previously participated in a clinical trial within the past year; 2) specific questions to procure demographic information, including age, race, ethnicity, place of birth and marital status; and 3) an assessment of participant opinions about clinical trials. The assessment of clinical trial opinions included a 14-item Likert scale, three multiple choice questions, and three open-ended questions.

The Likert portion of the survey was designed to examine the most common reasons for patient willingness or refusal to participate in clinical trials based on current literature. Items assessed patient opinions regarding time required to participate in a study, transportation, altruism, consent form and trial comprehension, the number of tests and procedures required for participation, physician recommendation, health insurance coverage, and the level of care and treatment provided while on a clinical trial. Multiple choice and closed-ended questions were utilized to explore other factors influencing clinical trial participation including distance from the cancer treatment center, knowledge of randomization, personal benefit expected from participation, and acceptability of side effects. An open-ended question was used to elicit other reasons patients were either willing or unwilling to participate in a study that was not captured in other aspects of the survey. The survey was approved by each site's Institutional Review Board (IRB) before data collection was initiated.

The Fisher-Freeman-Halton test was utilized to determine response differences to Likert items assessing barriers and facilitators of clinical trial participants and non-participants. Due to the pilot nature of this study and associated small number of responses in each category, the "Strongly Agree" and "Agree" responses in the five-point Likert portion of the survey were

combined, as well as the “Strongly Disagree” and “Disagree” responses, for the purposes of analysis resulting in a three-level Likert scale of Agree, Neutral, and Disagree.

Descriptive statistics, including means, standard deviations and percentages, were also used to evaluate differences between groups. Fisher’s exact test for discrete data and Wilcoxon-Mann-Whitney test for continuous data were used to evaluate sociodemographic differences between clinical trial participants and non-participants. Wilcoxon-Mann-Whitney tests were also utilized to evaluate differences between groups regarding distance to the cancer center, perceived personal benefit from trial participation, and acceptability of side effects. Multiple choice responses were grouped into correct and incorrect responses and differences between participants and non-participants were evaluated using Fisher’s exact test.

For questions that required a response in the form of a percentage, the subjects who responded provided a percentage or a percentage range. When a range was provided, the mean score was taken for analysis. All statistical tests were assessed with a significance level of 0.05 (two-sided). No adjustments for multiplicity of responses were used in the analyses.

Results

Participants

Forty-two patients enrolled and completed this study. Twenty-one patients had participated in an NRG Oncology RTOG clinical trial and 21 patients had refused participation in an RTOG clinical trial. Most patients (67%) had previously participated or were asked to participate in a cancer treatment trial, as opposed to a symptom management trial (14%). There was no significant difference in trial types between the participant and non-participant groups [p=0.739, Fisher-Freeman-Halton]. Demographic information, separated by NRG Oncology RTOG trial participants and non-participants, can be found in Table 1.

Participants included in this study ranged in age from 20–83 years, with a median age of all participants at 64 years. The majority of the participants was Caucasian (98%), non-Hispanic (95%), married (96%), and had at least a high school degree or GED (97.5%). There was no significant difference in age between the two groups of patients, [W=383, p=0.944]. There was also no significant difference in ethnicity, race, marital status, or education between the two groups [$p \geq 0.5$, Fisher's exact].

In regards to medical history, half of the patients had been diagnosed with prostate cancer. Three-fourths had one or more co-morbidities. There was no significant difference between the cancer stage [p=0.65, Fisher-Freeman-Halton] or the number of co-morbidities (i.e., 0, 1, ≥2) of clinical trial participants and non-participants [p=0.43, Fisher-Freeman-Halton].

Logistical obstacles

Patients who had participated in an NRG Oncology RTOG clinical trial were significantly more likely to disagree that a clinical trial would take up too much of their time [p=.001, Fisher-Freeman-Halton] (Table 2). However, no other significant differences in logistical obstacles were found between the groups. Two-thirds of all patients did not feel they would have trouble finding transportation to the hospital for a clinical trial. Furthermore, distance to the treatment center was similar between clinical trial participants (median=17.5 miles, [min, max]=[1,500]) and non-participants [(median= 22 miles,[min, max]=[1,400]), W=325.5, p=0.630].

NRG Oncology RTOG trial non-participants were just as likely as participants to agree that there would be a greater number of tests and procedures in clinical trials compared to standard treatment (p=0.728). Additionally, participants and non-participants had similar concerns regarding insurance coverage of study-related tests (p=0.852). Deterrents to trial

participation identified by patients in the open-ended portion of the survey were anxiety, feeling a loss of control over choice of treatment on a clinical trial, and fear of potential side effects.

Comprehension of study methods and concepts

The majority of patients (71%) did not feel the informed consent form for the clinical trial was too difficult to understand. There with no significant response difference regarding the informed consent form between groups [p=0.26, Fisher-Freeman-Halton]. Ninety-three percent of patients agreed that the study doctor or staff took the time to explain the study, and likewise, 90% of patients agreed that their doctor took the time to explain the study. These response rates also did not significantly differ between groups [p=0.23, p=0.61, respectively, Fisher-Freeman-Halton].

Despite these findings, understanding of the concept of randomization was problematic. Forty percent of patients did not correctly identify that in a randomized clinical trial the treatment you receive is decided by chance (Table 3). This incorrect response rate was similar in both groups (38% of clinical trial participants, 43% of clinical trial non-participants). Furthermore, 43% of patients could not correctly identify their percent chance of receiving an experimental treatment versus a standard treatment within a randomized study. This incorrect response rate also did not significantly vary between clinical trial participants and non-participants [p=0.74, Fisher's Exact].

Motivating Factors

More NRG Oncology RTOG trial participants agreed that they would enroll in a clinical trial because of the recommendation of their physician [p=0.007, Fisher-Freeman-Halton]. In comparison, similar percentages of participants and non-participants (57% vs 65%, respectively) disagreed with the statement that they would participate in a clinical trial because their family members wanted them to. There was also no group difference in what percent chance patients

would accept of developing the side effect of a severe condition if provided an effective cancer treatment [W=255.5, p=0.76].

Sixty-one percent of patients agreed that they would receive the most cutting-edge treatment within a clinical trial; however, only 26% of patients agreed that better care would be received if enrolled in a clinical trial than if not enrolled. Responses to these items did not significantly differ between clinical trial participants and non-participants [p=0.65; p=0.72 respectively, Fisher-Freeman-Halton]. Despite similarly perceived advanced treatment, non-participants were more prone to concur that taking part in a clinical trial made him or her feel like a "guinea pig" as compared to participants [33% vs. 5%, p=.006, Fisher-Freeman-Halton].

Clinical trial participants were more apt to agree to participate to help others whom they may or may not know (p=.0002, and help family members who may get cancer in the future (p=.014). A two-sided Wilcoxon rank sum test did not show a significant difference between participants and non-participants regarding their expected level of personal benefit from trial participation [W=229, p=0.44]. However, seven non-participants did not provide a response to this survey question, which may have contributed to an underestimation of the expected personal benefit of patients refusing clinical trial participation.

Patients in this study did not provide many examples of motivating factors that influenced their participation within the open-ended portion of the survey. For those who did respond, one patient expressed that he felt the benefits of participation outweighed the risks. Another patient stated that a reduction in the length of time of treatments on study was a motivating factor for participation.

Discussion

Lack of accrual to cancer clinical trials is an ongoing problem for which there are currently few definitive strategies for improvement. Some research has been conducted on identifying patient-level factors which influence recruitment utilizing qualitative analysis of patient response or expert opinion. Almost none of the research to date has examined patient-level factors influencing recruitment to radiation therapy clinical trials. Findings from this pilot study begin to elucidate some of the patient-level factors that impact accrual to radiation studies, and allow for hypothesis generation for future studies to examine recruitment strategies.

Some patient facilitators to clinical trial accrual found in this study have been identified in previous literature. Results support existing research that a physician recommendation positively impacts a patient's willingness to participate in a clinical trial.[8-10] It also aligns with current research indicating that fears related to experimentation deter participation.[11]

Future research should be conducted in order to examine recruitment strategies that incorporate the best practices for more standardized, brief physician discussion of clinical trials with patients, as well as explore how physician attitudes towards clinical trials are conveyed to and impact attitudes in patients. In addition, recruitment strategies should incorporate the exploration of patient fears related to research participation to promote understanding of these fears and how they may impact patient decision-making. A validated brief assessment of fears related to clinical trials would be useful as part of the informed consent process so interventions to address fears could be tested and implemented on a personalized basis.

Although transportation and travel did not appear to be significant deterrents to clinical trial participation in this study, more than half the sample consisted of men with local prostate cancer, men who were not gravely ill and who were more likely to be of retirement age with

more flexibility in their schedules. This finding bears further study in larger more disease, stage, gender and age diverse populations.

Contrary to non-participant perceptions, clinical trial participants did not perceive that a clinical trial would take up too much of their time. This is consistent with other studies that suggested that the perception of time requirements and inconvenience to everyday life dissuade participation in cancer clinical trials.[12-14] Further research must be completed to further characterize what constitutes a time commitment or level of inconvenience that would deter participation in a clinical trial. Related, recruitment strategies should include an accurate and clear explanation of the time involved. Study design should focus on streamlining study procedures in order to minimize the potential burden on the participant.

This study suggests that altruistic attitudes positively impact clinical trial participation and contradicts other research that demonstrated trial participants primarily seek personal benefit.[15-17] This high incidence of altruism may be influenced by social desirability bias. Future recruitment strategies should frame clinical trial discussions with patients to maximize their understanding of altruistic benefits and determine the level of impact altruism has on radiation therapy clinical trial participation.

A lack of understanding of randomization was explicated in prior studies as a barrier to clinical trial participation.[18] The results from this study challenge this viewpoint. A lack of understanding of randomization was prevalent among both clinical trial participants and non-participants. Both groups had difficulty understanding that treatment in a randomized study is decided by chance, as well as understanding their percent chance of receiving experimental treatment versus standard of care treatment.

Although randomization was not understood well, most participants and non-participants felt that the physician and study staff took adequate time to explain the study to them. They also felt that the consent form was not difficult to understand. This implies that subjects were satisfied with the level of explanation they received, even if they did not seem to fully understand the concept of randomization. Further research must be conducted in order to determine the impact of this lack of understanding on a patient's decision to participate in a clinical trial, what constitutes "adequate" knowledge of randomization, and the ethical implications of this lack of knowledge.

A limitation of this study is that its pilot nature and associated small sample size limit the generalizability of the survey results. The study population was primarily male, Caucasian and non-Hispanic, and had a history of prostate cancer. This limits the applicability of results to other populations. Studies have consistently documented the underrepresentation of women and minorities in clinical trials.[19,20]

A further limitation is the potential bias of the participating NRG Oncology RTOG institutions, which were high accruing NRG Oncology RTOG sites. Findings may differ between high and low accruing sites due to potential differences in number, processes, and level of communication among research staff. Future research must be completed evaluating the patient-level barriers to radiation clinical trial participation as they relate to both gender differences and minority populations to determine effective recruitment strategies for these inadequately represented groups.

This research provides preliminary information on patient-level barriers to clinical trial participation among an understudied population of cancer trial participants and non-participants. While findings did not identify barriers unique to radiation therapy clinical trials, the study did

help pinpoint factors that may be important than others. Motivating factors for clinical trial participation included physician recommendation and altruism. A high level of personal benefit from participating was also widely expected. Barriers included time commitment and fears of experimentation. For all patients, an identified obstacle to the ethical conduct of clinical trials was a misconception of randomization.

Study results suggest that design of clinical trials should consider ethical strategies that minimize perceived and real barriers and maximize the benefits of participation. Furthermore, clinical trial discussions within a shared decision-making process may allow physicians that opportunity to clarify their perspective on a clinical trial and address concerns of patients. Furthermore, a shared decision-making process may allow physicians to educate patients about clinical trial concepts, such as randomization.

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Table Legends

Table 1. Patient Characteristics

Table 2. Clinical Trial Opinion Questions

Table 3. Clinical Trial Opinion Questions

Table 1. Patient Characteristics

	Non-Participants (n=21)	Participants (n=21)	P-value§
Site of cancer	(n=20)	(n=20)	
Prostate	11 (55.0%)	10 (50.0%)	Prostate
Brain/CNS	4 (20.0%)	5 (25.0%)	0.1459†
HN	1 (5.0%)	5 (25.0%)	
Lung	3 (15.0%)	0 (0.0%)	
Skin	1 (5.0%)	0 (0.0%)	
Stage of Cancer	(n=17)	(n=17)	
Stage 1	0 (0.0%)	2 (11.8%)	0.6487†
Stage II	4 (23.5%)	2 (11.8%)	
Stage III	1 (5.9%)	1 (5.9%)	
Stage IV	4 (23.5%)	6 (35.3%)	
Unknown	8 (47.1%)	6 (35.3%)	
Age	(n=19)	(n=20)	
Median	65	63	0.9439‡
Min - Max	33 - 82	20 - 83	
Q1 - Q3	60 - 68	57.5 - 71	
Ethnicity	(n=17)	(n=20)	
Hispanic	0 (0.0%)	2 (10.0%)	0.4895
Not Hispanic	17 (100.0%)	18 (90.0%)	
Race	(n=20)	(n=20)	
White	20 (100.0%)	19 (95.0%)	0.9999
Non-White	0 (0.0%)	1 (5.0%)	
Education	(n=19)	(n=21)	
Up to 11th Grade	0 (0.0%)	1 (4.8%)	0.9999
At least HS Grad/GED	19 (100.0%)	20 (95.2%)	
Marital Status	(n=21)	(n=21)	
Married	14 (66.7%)	11 (52.4%)	0.5303
Other	7 (33.3%)	10 (47.6%)	
Distance traveled to medical center	(n=19)	(n=18)	
Median	22	17.5	0.6295‡

	Non-Participants (n=21)	Participants (n=21)	P-value§
Min - Max	1 - 400	1 - 500	
Q1 - Q3	10 - 51	8 - 83	

Q1 = first quartile; Q3 = third quartile.

†Fisher-Freeman-Halton test (extension of Fisher's Exact test)

§Fisher's Exact test

‡Two-sided Wilcoxon rank sum test with normal approximation

Table 2. Clinical Trial Opinion Questions

	Non-Participants (n=21)	Participants (n=21)	P-Value†
Taking part in a clinical trial would take up too much of my time	(n=21)	(n=21)	
Disagree	9 (42.9%)	19 (90.5%)	0.0014
Neutral	5 (23.8%)	2 (9.5%)	
Agree	7 (33.3%)	0 (0.0%)	
I would have trouble getting transportation to the hospital to take part in a clinical trial	(n=20)	(n=21)	
Disagree	12 (60.0%)	16 (76.2%)	0.4052
Neutral	4 (20.0%)	4 (19.0%)	
Agree	4 (20.0%)	1 (4.8%)	
I wanted to take part in a clinical trial to help other people who I may or may not know, who may get cancer in the future	(n=21)	(n=20)	
Disagree	3 (14.3%)	1 (5.0%)	0.0002
Neutral	9 (42.9%)	0 (0.0%)	
Agree	9 (42.9%)	19 (95.0%)	
I wanted to take part in a clinical trial in case any of my family members got cancer in the future	(n=21)	(n=21)	
Disagree	3 (14.3%)	1 (4.8%)	0.0143
Neutral	10 (47.6%)	3 (14.3%)	
Agree	8 (38.1%)	17 (81.0%)	
The informed consent document was difficult to understand	(n=21)	(n=21)	
Disagree	13 (61.9%)	17 (81.0%)	0.2638
Neutral	6 (28.6%)	4 (19.0%)	
Agree	2 (9.5%)	0 (0.0%)	
There were more tests and procedures for me on the clinical trial that I would have had to do if I was not on the clinical trial	(n=21)	(n=21)	
Disagree	4 (19.0%)	6 (28.6%)	0.7279
Neutral	6 (28.6%)	7 (33.3%)	

	Non-Participants (n=21)	Participants (n=21)	P-Value†
Agree	11 (52.4%)	8 (38.1%)	
Taking part in a clinical trial makes me feel like a guinea pig	(n=21)	(n=21)	
Disagree	11 (52.4%)	20 (95.2%)	0.0060
Neutral	3 (14.3%)	0 (0.0%)	
Agree	7 (33.3%)	1 (4.8%)	
I had concerns that my health insurance would not cover the costs of the tests	(n=20)	(n=21)	
Disagree	9 (45.0%)	9 (42.9%)	0.8516
Neutral	5 (25.0%)	4 (19.0%)	
Agree	6 (30.0%)	8 (38.1%)	
The study doctor or staff took the time to explain the clinical trial to me	(n=21)	(n=21)	
Disagree	2 (9.5%)	0 (0.0%)	0.2317
Neutral	1 (4.8%)	0 (0.0%)	
Agree	18 (85.7%)	21 (100.0%)	
On a clinical trial you would get the most cutting edge treatment	(n=21)	(n=20)	
Disagree	1 (4.8%)	1 (5.0%)	0.6518
Neutral	9 (42.9%)	5 (25.0%)	
Agree	11 (52.4%)	14 (70.0%)	
My doctor took the time to explain the clinical trial to me	(n=21)	(n=21)	
Disagree	1 (4.8%)	0 (0.0%)	0.6060
Neutral	2 (9.5%)	1 (4.8%)	
Agree	18 (85.7%)	20 (95.2%)	
I participated because my family wanted me to	(n=20)	(n=21)	
Disagree	13 (65.0%)	12 (57.1%)	0.1143
Neutral	6 (30.0%)	3 (14.3%)	
Agree	1 (5.0%)	6 (28.6%)	

	Non-Participants (n=21)	Participants (n=21)	P-Value†
I participated because my doctor recommended the clinical trial to me	(n=19)	(n=21)	
Disagree	10 (52.6%)	7 (33.3%)	0.0007
Neutral	6 (31.6%)	0 (0.0%)	
Agree	3 (15.8%)	14 (66.7%)	
If you participate in a clinical trial you will receive better care than if you do not take part	(n=21)	(n=21)	
Disagree	11 (52.4%)	9 (42.9%)	0.7203
Neutral	6 (28.6%)	5 (23.8%)	
Agree	4 (19.0%)	7 (33.3%)	

†Fisher-Freeman-Halton test

Table 3. Clinical Trial Opinion Questions

	Non-Participants (n=21)	Participants (n=21)	P-Value§
In a randomized clinical trial the treatment that you get is decided by chance	(n=21)	(n=21)	
Incorrect	9 (42.9%)	8 (38.1%)	0.9999
Correct	12 (57.1%)	13 (61.9%)	
Chance of getting on the new treatment vs. the standard care or treatment	(n=18)	(n=19)	
Incorrect	7 (38.9%)	9 (47.4%)	0.7431
Correct	11 (61.1%)	10 (52.6%)	
Interpretation of hypothetical situation in which your doctor is describing a new cancer treatment	(n=21)	(n=20)	
Incorrect	6 (28.6%)	8 (40.0%)	0.5204
Correct	15 (71.4%)	12 (60.0%)	
What percent benefit you would expect from participating in a clinical trial?	(n=14)	(n=21)	
Median	0.5	0.8	0.4367‡
Min - Max	0 - 1	0 - 1	
Q1 - Q3	0.25 - 1	0.5 - 1	
What percent chance of developing a severe condition would you be willing to accept?	(n=16)	(n=16)	
Median	0.5	0.5	0.7568‡
Min - Max	0 - 1	0 - 1	
Q1 - Q3	0.35 - 0.75	0.225 - 0.775	

Q1 = first quartile; Q3 = third quartile.
§Fisher's Exact test
‡Two-sided Wilcoxon rank sum test with normal approximation

Insert Supplemental Materials (If applicable)