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Lung Cancer Patients' Decisions About Clinical Trials and the Theory of Planned Behavior

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Abstract

The theory of planned behavior explores the relationship between behavior, beliefs, attitudes, and intentions presupposing that behavioral intention is influenced by a person's attitude about the behavior and beliefs about whether individuals, who are important to them, approve or disapprove of the behavior (subjective norm). An added dimension to the theory is the idea of perceived

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behavioral control, or the belief that one has control over performing the behavior. The theory of planned behavior suggests that people may make greater efforts to perform a behavior if they feel they have a high level of control over it. In this examination of data, we explored the application of the theory of planned behavior to patient's decisions about participating in a clinic trial. Twelve respondents in this study had previously participated in a clinical trial for lung cancer and nine respondents had declined a clinical trial for lung cancer. The data were analyzed with regard to the four constructs associated with the theory of planned behavior: behavioral intention, attitude, subjective norm, and perceived behavioral control. Results indicate that the theory of planned behavior may be a useful tool to examine psychosocial needs in relation to behavioral intention of clinical trial participation.

Keywords

Lung cancer; Theory of planned behavior; Clinical trials; Qualitative methods; Clinical research

Introduction

Clinical Research

Cancer is the second leading cause of death in the USA, accounting for approximately 565,340 deaths annually [1]. Clinical research offers opportunities for cancer patients providing them access to innovative therapies that potentially lead to improved outcomes, prognosis, and quality of life. Despite this, accrual rates for adult patients remain low at approximately 3% [2, 3]. These low accrual rates undoubtedly have negative impact on the progress of promising treatments, frequently prolonging trial duration, and they can lead to premature study closure [3, 4]. Clinical trials are essential in the evaluation of scientific efficacy, safety, and validity of new treatments, and without the accrual of eligible participants, many promising therapeutics are delayed. Given the importance and the value of clinical research, the underrepresentation of adult participants on clinical trials warrants continued research to understand the reasoning behind these low accruals and can help identify modifiable barriers to enrollment.

Approximately 40% to 50% of newly diagnosed cancer patients who have access to and qualify for a clinical trial decline to participate [5]. There are multiple reasons behind why a patient makes the decision not to participate in a research trial. Cited reasons included geographical barriers, fear of randomization, safety concerns, insurance payer difficulties, and desire for "non-investigational" treatments (Appendix) [2, 3, 5].

Understanding the attitudes, knowledge base, and decision-making of those affected by this has been the focus of recent research. The hope is that better understanding the reasons individuals consent to participate in clinical research and the attitudes and beliefs of individuals towards participation will help to tailor interventions aimed at reducing barriers and ultimately increasing clinical trial accruals. The ability to recruit adult patients for future clinical trials will depend, in part, on the understanding of these attitudes and intentions [6].

Theory of Planned Behavior

The theory of planned behavior [7, 8] derived from the theory of reasoned action [9] has emerged as one of the most predictive models for explaining behavior and has frequently been used to gauge the likelihood of engaging in health behaviors. According to the theory, behavior is guided by the beliefs about the likelihood of the consequences (behavior beliefs), beliefs about the normative expectation of other people (normative beliefs), and beliefs about the presence of factors that may further or hinder performance of the behavior (control beliefs) [7–10]. The theory of planned behavior (TpB) may facilitate understanding of clinical trial decision-making in patients facing the option of a clinical trial and may be used as a plausible way to understand the decision-making process.

Understanding Clinical Trial Participation and Decision-Making

With a plethora of information and resources available, patients are now seeking and gathering information to assist them in making informed decisions about their care. Being diagnosed with a life-threatening disease such as cancer can affect decision-making, and many patient and caregivers struggle with complex and difficult treatment decisions [11, 12]. Many patients are invited to participate in clinical research shortly after diagnosis when the current emotional state can easily affect their attitude about participation [11, 12].

Research cites many influencing factors that attribute to the behavior of participating in a clinical trial, including trust in the physician or institution, opportunity to obtain new treatment, contribution to research, and altruism [4, 6, 11, 13]. Understanding the psychosocial outcomes related to decision-making processes of eligible and potential trial participants is important [14]. These psychosocial outcomes include knowledge and expectations about treatment, satisfaction with treatment decision-making, and regret about decisions [14].

Purpose and Relevance Statement

The ultimate goal of quality care is to provide an opportunity for a patient to make an informed decision about his or her cancer treatment. When a patient prepares to make a decision about participation in a proposed clinical trial, it is the combination of attitudes towards research trials, subjective norms, and the perceived control that leads to the intention to participate in the clinical trial.

The purpose of the following study was to utilize the theory of planned behavior framework to better understand the clinical trial decision-making process. Data obtained from this study will aid in the development of education tools and future initiatives aimed at addressing modifiable barriers to participation and increasing accession rates for thoracic clinical trials.

Materials and Methods

These results are part of a large project—Faces of Lung Cancer—designed to increase awareness and develop decision tools about participation in clinical trials for lung cancer. The project consists of a website displaying essays and photographs of patients discussing their decisions to participate (or not) in a clinical trial related to their lung cancer, health care

providers and family members who were involved in clinical trials, a book, a framed display of poster-sized photo-essays (21), and an on-going series of health education community-centered forums (www.facesoflungcancer.org). The framed photo-essays are showcased during the community forums and are also sent across the USA for loan to other health education efforts seeking to improve awareness of clinical trials.

Background

In 2002, a series of qualitative studies were conducted at Moffitt Cancer Center (MCC) to better understand patients' beliefs about clinical trials. These data indicated that the majority of people, even those who had previously been in a trial, had misconceptions about clinical trials [2]. In an effort to address these misconceptions, MCC created the *Faces of Lung Cancer* project, photo-essays generated through qualitative interviews with thoracic patients and caregivers. The goal was to identify trends among lung cancer patients' perceptions that may lead to effective interventions for increasing patient knowledge and awareness of clinical trials. The essays on the website are updated yearly with new faces, using the same interview guide and protocol. The results of the Faces of Lung Cancer project suggest that it is a successful intervention to aid patients in making fully informed decisions about clinical trials and not decisions based on inaccurate perceptions [15]. The current assessment was to explore the influencing factors of the TpB and how those constructs shaped the intentions of lung cancer patients' decisions about participating in a thoracic clinical trial.

Recruitment Procedures

Data were collected from June 2008 to November 2008. Using purposive sampling (participants were selected based on their experiences with the phenomenon of interest), we recruited 12 thoracic patients who had previously participated in any phase of treatment clinical trial at the MCC and 9 patients who were offered a clinical trial but declined to participate. Patient eligibility criteria included men and women who (a) were ≥18 years of age, (b) had no documented or observable psychiatric or neurological disorders that would interfere with study participation (e.g., dementia, psychosis), (c) were capable of speaking and reading standard English (study materials in English), and (d) provided written informed consent. Patients were provided information about the project by their physician and gave permission for the researcher to contact them. From the comprehensive list of nominated patients, the committee selected patients based on the following criteria: gender, age, type of lung cancer diagnosis (small cell lung cancer, non-small cell lung cancer (NSCLC), and mesothelioma), and stage of diagnosis.

Institutional Approval

The study was approved by the Institutional Review Board at the University of South Florida. Patients were provided a project description and copy of informed consent documents by the nominating physician. Patients provided verbal permission for the photodocumentarist and research team to contact them. All patients signed consent forms giving the research team permission to audio-record their interview, take photographs, use the photos and interview data in the creation of the photo-essays for the website, and for

further analysis for publications. Patients also signed a consent authorizing for creation and use of media.

Interview Guide

The interview guide included 16 open-ended questions designed to assess patients' (a) experience with the diagnosis of lung cancer; (b) beliefs and attitudes about clinical trials; (c) perception of control or input in the decision to accept or decline a clinical trial; (d) thoughts on how the decision was made, including the role of others in the decision; and (e) satisfaction with the decision made about the clinical trial. Probes were used during the interview to elicit a deeper conversation about clinical trial decision-making (Table 1).

Data Collection

Qualitative open-ended, semistructured interviews were used. The interviews were recorded using a hand-held tape recorder. The data were professionally transcribed verbatim by a local transcriptionist with experience in qualitative health-related research. The interviews were scheduled at a time and location convenient for the participant, typically in their home. Interviews lasted approximately 1 h with an additional hour of photography conducted by a professional photodocumentarist.

Data Analysis

Interview transcripts were analyzed using content analysis (via hand-coding) with "intuitive" analysis plan, whereby the researchers reviewed all the data and culled out those aspects most relevant to the objectives [16]. The content analysis of the interview text provided common themes regarding patients' experiences with clinical trials in the context of the TpB. A priori themes were broadly based on the subcodes as outlined in the constructs of the TpB (i.e., attitudes towards behaviors, perceived control, and subjective norms). A codebook was developed to operationalize and define each of the codes. The research team independently reviewed the data and then collaboratively discussed the codes and identified potential additional codes. After a consensus was reached, two members of the research team re-read the transcripts and updated the code categories from the first coding pass. The second coding pass served to "clean up" codes that were not anticipated in the first coding pass and expanded and refined the coding system where the codes were initially too broad. For example, an initial code of "knowledge" was further refined into the subcodes of "knowledge of lung cancer" or "knowledge of clinical trials." Five transcripts were randomly selected to establish inter-rater reliability whereby two coders independently coded the same transcripts. The number of lines on the transcripts in relation to the number of times the coders selected the same code for each line was used to establish reliability with an average rate of 0.92 agreement. Validity was determined by peer debriefing where the entire research team reviewed, validated, and verified all interpretations and conclusions of the data (consensual validity).

Results

The results are presented comparing the responses of clinical trial participants (CTP) and those who declined participation (DP). Ten women and 11 men participated in the

interviews (*n*=21). Respondents had all previously participated in a treatment clinical trial and ranged in age from 42 to 84 and 2 were Asian, 12 were White, 4 were Black, and 3 were Hispanic. Among the nine respondents who declined a trial, five cited transportation issues, two stated they preferred to receive standard treatment, and two cited their family did not support clinical trial participation. Although we anticipated that there may be differences in responses based on age, gender, or ethnicity, we did not find overt differences within this sample. The majority had a diagnosis of stage IV NSCLC. Although we were permitted to interview as many as 50 patients, data saturation was obtained after conducting 12 interviews with CTP and 9 interviews with DP. This determination was made by the team of coders, as they were no longer eliciting new information from the interviews about the clinical trial decision-making process.

Attitude

Participants were asked to describe their first reaction to the lung cancer diagnosis and to describe how the diagnosis and their own attitudes at that time may have impacted their decision to participate in a clinical trial. All patients noted that their initial reaction to the lung cancer diagnosis was a sense of fear. These initial fears were coupled with the concern that treatment options for lung cancer were limited and the overall prognosis for lung cancer in general is not positive. Half of the CTP and DP respondents described their fears as being compounded by the health care professional from whom they received their initial diagnosis. These same people perceived the physician had conveyed to them that their options were limited and there was little hope for a good prognosis.

Subjective Norm

Participants were asked to describe if there had been a particular event, circumstance, or person that had an impact on their decision about the clinical trial. The majority of CTP patients described a previous personal or family history of cancer and how the treatments for themselves or a family member played a role in deciding to go on a trial. In contrast, the DP group noted cancer and major illness was unique to their personal health histories and commented on the lack of familial cancer as well.

All CTP respondents noted that trust was a key issue in the decision-making process and that they had trust in either the physician who discussed the trial or the research facility in which they were receiving care. The majority of participants who declined a trial also noted trust in their physician and the institution but noted the approval of a family member or desire to reduce caregiver burden was ultimately more important.

Perceived Behavioral Control

All patients interviewed mentioned “control” at some point in the interview. Often it was in response to how they felt at the time of diagnoses and the feeling of having no control over the disease. However, the majority of respondents also talked about treatment choices and their requests to speed up or delay tests and treatments as a way of re-gaining or establishing control over their disease management (Table 2).

Discussion

All respondents in this study had been approached about participation in a treatment clinical trial for lung cancer. The TpB was used to explore the relationship between accepting and refusing a clinical trial and beliefs, attitudes, and intentions. TpB presupposes that behavioral intention or actual behaviors are influenced by a person's attitude about the behavior and beliefs about whether individuals who are important to them approve or disapprove of the behavior (subjective norm). An added dimension to the theory is the idea of perceived behavioral control or the belief that one has control over performing the behavior. TpB suggests people may make greater efforts to perform a behavior if they feel they have control over it. In this examination of data, we explored the application of the TpB to patient's decisions about participating in a clinic trial.

The respondents in this study described attitudes related to fear about the cancer diagnoses and a perception that lung cancer was an incurable disease with limited, if any, treatment options. At least half the patients who had accepted a trial and half who had declined reported having these fears reinforced by the health care professional who initially presented the diagnosis. This is consistent with numerous other studies that indicate lung cancer patients have less accurate perceptions of their prognosis than patients with other cancer types [17, 18] and typically perceive the diagnosing physician as having little hope for them or offering them limited to no treatment options [19–21].

The majority of respondents who accepted a clinical trial had either a previous knowledge of clinical trials (relative or self had participated) or felt their physician was supportive of a clinical trial. One or both of these characteristics were described by every respondent as being the impetus for their decision to participate in a trial. In contrast, the majority of clinical trial decliners reported having no personal or family history of cancer. Additionally, the majority of decliners felt that participation in a trial may impose caregiving burdens on their family or that participation was not supported by a family member. Thus, the subjective norm between acceptors and decliners differed, with acceptors believing a family member and/or their physician felt positive about clinical trials as a treatment option and decliners perceiving a trial was a burden or seen as negative by family. While there are few qualitative studies published to date to compare these responses, existing studies exploring lung cancer patients' thoughts on clinical trials found that patients identified clinical trials as "a last ditch effort" or only for consideration when all standard treatment had failed [2, 22].

Finally, with regards to perceived control, all respondents expressed a sense of feeling a loss of control when given the diagnosis of lung cancer. These feelings are similar to most cancer patients, regardless of the disease site, upon learning of the diagnosis [23, 24]. However, in this study, patients who accepted a clinical trial perceived it as a way to gain control over their medical and psychological situation. Similarly, decliners also felt selecting standard treatments provided a sense of control. Thus, it appears that having a choice about treatments gave all patients an improved sense of control, regardless of whether they chose a trial or not. Respondents found satisfaction in their decisions in ways that align with the constructs of the TpB framework. This may be a phenomenon that is unique to lung cancer or other cancers in which the initial prognosis is negative or largely unknown; however, we

were unable to identify any studies that examined this construct in cancer decision-making. One meta-analysis and one large study examined the psychological impact of clinical trial participation among women with breast cancer and concluded that those who were most uneasy about their health outcome were more likely to choose a clinical trial and to cite the trial as an opportunity to increase a sense of personal control [25, 26]. A sense of control over one's health is a key factor in quality of life measures and indicators of cancer survivors [27].

Conclusion

The purpose of this study was to utilize the TpB framework to better understand the clinical trial decision process among lung cancer patients. The results indicate the TpB may be a useful tool to examine psychosocial needs in relation to behavioral intention. These data support the idea that taken together, a combination of preconceived attitudes about lung cancer, the perception that one's physician and/or family members were supportive or not of a trial decision (subjective norm), and the sense that the choice of a treatment (clinical trial vs standard treatment) could increase or improve the loss of control they felt over their health (perceived behavioral control) resulted in the ultimate outcome of accepting or declining a clinical trial.

As always, qualitative data are not meant to be generalizable and this was a retrospective study about patient decision-making. This could be seen as a limitation to the current study and future studies could utilize a prospective design. It is possible that the results may have been different had we prospectively followed patients at the time of their diagnosis. More research is needed into the psychosocial aspects of clinical trial decision-making to improve patient opportunity for informed decision-making.

Appendix

Attitude	Fear	MD response	Subjective norm	Perceived control
"I heard the words lung cancer and I felt I was kicked in the gut…. I was terrified" (DP)	"I felt my back was to the wall; I had lung cancer… I didn't have too many options"(CTP)	"He (physician) was telling me 'I'll never let you have chemotherapy but… of course, that's your decision'; he was very, very negative about chemotherapy. Because he thought it would take away from the little time I had left." (CTP)	"My mother died of breast cancer; both of her sisters died of breast cancer and mine was in the lungs so I felt like OK, this is something totally different so we'll see how this goes." (CTP)	"At first I thought, I don'tknow (about a clinical trial); when you're in a fox hole, you'll grab for anything that looks good, to get out of it. But then I realized it was a choice and that felt good." (CTP)
It was absolutely overwhelming for me. I was scared. I'd wake up in the morning with fear."(CTP)	"I have lung cancer…The odds are not good." (CTP)	"… we're already freaked out, scared to death,… and this doctor walks in and opens up the file. She never looks at us… and basically flat out said 'there's no hope; you might as well get your affairs in	"I had cancer of the cervix (previously…., so I knew about cancer and how to get through it." (CTP)	"They told me what they were going to do a… clinical test and see if I could be in one (clinical trial). I thought… no more tests so I said forget it. Then the nurse explained it was always ok to say no, and I thought OK… I have

Attitude	Fear	MD response	Subjective norm	Perceived control
		order… you know, you have lung cancer and there is no cure.'"(CTP)		some say in this… I just might do it." (CTP)
"We were just numb, shocked, numb, just didn't, you know, 42 years old, how… how does that happen?"(CTP)	I took it as a death sentence; what can they do? Who do you know who survived lung cancer?" (CTP)	"The nurse told my wife to take me on trip while I could still get around she told her in 6 months I'dbe a wreck and unable to leave my bed." (DP)	"I have never been sick a day in my life. I've been to the hospital to have my children and that's it."(DP)	"There was just too many unknowns with the trial and I felt everything in my life was out of control so deciding on regular treatment was my best choice and I could still see my doctor and that was important to me because I trusted him." (DP)
"There are no words to describe the terror and horror you feel." (DP)	"I thought about the chemotherapy and wondered which I would die from first—the cancer or the treatments."(DP)	"My former doctor didn'tlook me in the eye—hetold me to get a lawyer, draw up a will, and pray"(DP)	"I have a lot of trust in my doctor… he's doing things for my benefit, my wellbeing…" (CTP)	"He (physician) explained it(CT) very well and he kept telling me it was my choice and although I wanted to help other people by being in it, in the end I felt the best for me was not to be part of an experiment." (DP)
	"I wanted to ask how much time I had left, but I didn't,because I didn'twant the answer."(DP)		"Going to (Cancer Center) …they're on the cutting edge and they're improving the treatment minute by minute whereas the community hospital, it may be a month before that trickles down to them and I don't trust it. I trust the cancer center—they do this all day long."(CTP)	
			"Well, I knew right away that I would join, you know; when Dr.___ mentioned it to me, I made up my mind right then and there but I also talked to my sons about the clinical trial and, you know, they're all in favor of it." (CTP	
			No one in my family has had cancer. It just doesn't run in my family so I thought I was immune." (DP)	
			"I knew he (physician) wouldn't tell me about a trial if it weren't a good thing for me—he's always got my back. But, at the end of the day, I just could not see me and (wife) driving back and forth hereto do the trial. It wasn't fair to her and I think the treatment at my local place is going to be just as good." (DP)	
			"My daughter is a nurse and she just flat out told me not to do it (clinical trial). She said it was something I	

Attitude	Fear	MD response	Subjective norm	Perceived control
			could do when I failed the standard treatments." (DP)	

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Table 1

Lung cancer patient interview guide

1	Please tell me your name, age, and the name of the last book you read?
2	How are you feeling today? Is that better or worse than you have been feeling this past week?
3	Tell me the one thing about which you are the most proud (probe for accomplishments, etc.)
4	Tell me how you received your lung cancer diagnosis?
5	Have you ever had any other type of cancer?
6	How has lung cancer affected your life?
7	How has your health been for most of your life?
8	Why did you decide to receive care at Moffitt?
9	At what point in your treatment was a clinical trial discussed?
10	How did you make the decision about enrolling in the clinical trial? (probe for discussion with MD, family, research, second opinion, etc.) [skip to 15 for decliners]
11	Describe the clinical trial experience?
12	Did you feel comfortable with your decision? Did that change at any time during the trial?
13	How did participating in a trial affect your life?
14	Did you have any concerns about the trial?
15	How do you feel now about your decision?
16	What would you tell a friend who came to you for advice about participating in a trial? What would you advise?

Table 2

Diagnosis, stage, age, and gender of participants

	Diagnosis	Stage	Age	Gender
1	NSCLC	IV	65	F
2	NSCLC	IIB	58	M
3	NSCLC	IV	49	F
4	NSCLC	IV	42	F
5	MESO	III	50	M
6	NSCLC	IB	84	F
7	NSCLC	IV	82	M
8	SCLC	IV	63	F
9	NSCLC	IV	60	F
10	NSCLC	IIIA	72	M
11	NSCLC	IIIB	65	F
12	NSCLC	IV	59	F
13	NSCLC	IIIB	78	M
14	SCLC	IIIB	58	M
15	NSCLC	IV	42	F
16	NSCLC	IV	62	M
17	NSCLC	IV	80	M
18	NSCLC	IIIA	68	F
19	MESO	III	72	M
20	SCLC	IIIB	56	M
21	NSCLC	IV	66	M

NSCLC non-small cell lung cancer, *SCLC* small cell lung cancer, *MESO* mesothelioma