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The relationships among knowledge, self-efficacy, preparedness, decisional conflict and decisions to participate in a cancer clinical trial

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Abstract

Background—Cancer clinical trials (CCTs) are important tools in the development of improved cancer therapies; yet, participation is low. Key psychosocial barriers exist that appear to impact a patient's decision to participate. Little is known about the relationship among knowledge, self efficacy, preparation, decisional conflict, and patient decisions to take part in CCTs.

Objective—The purpose of this study was to determine if preparation for consideration of a CCT as a treatment option mediates the relationship between knowledge, self-efficacy, and decisional conflict. We also explored whether lower levels of decisional conflict are associated with greater likelihood of CCT enrollment.

Method—In a pre-post test intervention study, cancer patients (N=105) were recruited before their initial consultation with a medical oncologist. A brief educational intervention was provided to all patients. Patient self-report survey responses assessed knowledge, self efficacy, preparation for clinical trial participation, decisional conflict, and clinical trial participation.

Results—Preparation was found to mediate the relationship between self-efficacy and decisional conflict (p=0.003 for a test of the indirect mediational pathway for the Decisional Conflict total score). Preparation had a more limited role in mediating the effect of knowledge on decisional conflict. Further, preliminary evidence indicated that reduced decisional conflict was associated with increased clinical trial enrollment (p=0.049).

Conclusions—When patients feel greater CCT self-efficacy and have more knowledge they feel more prepared to make a CCT decision. Reduced decisional conflict, in turn, is associated with the decision to enroll in a clinical trial. Our results suggest that preparation for decision making should be a target of future interventions to improve participation in CCTs.

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Keywords

cancer; oncology; clinical trials; preparation; decision-making; self-efficacy

INTRODUCTION

The National Comprehensive Cancer Network, a leading organization for clinical guideline development in oncology, states that “the best management for any cancer patient is in a clinical trial.” Given that clinical trials are necessary to develop improved systemic therapies for cancer, it is discouraging that only 2–7% of cancer patients take part in these studies [1–3]. Practical barriers to clinical trials include lack of insurance coverage, extra time required for tests or visits, lack of transportation, absence of a suitable trial, and ineligibility factors such as low functional status [1, 3–13]. Psychosocial barriers explored may include lack of awareness and detailed clinical trials knowledge [10, 12, 14–16], and patient attitudes that may impact their own feelings of self-efficacy to participate in a clinical trial [6, 17–19].

There are limited studies [20–22], however, that examine the relationships among the key psychosocial variables implicated in patient medical decision making as they ultimately impact clinical trial participation. In particular, there is scant empirical data that explores the network of linkages among knowledge, self-efficacy, and decisional conflict about CCT participation. Knowledge has been considered a central construct because 40% of patients do not fully understand the concept of a clinical trial [19]. Among cancer patients, 80% do not consider the possibility of participating in a clinical trial because they are unaware of the option [19]. In addition, self-efficacy—the patient’s self-confidence or belief in their ability to obtain and act on relevant decision making information—has recently been recognized as playing a central role in patient decision making and adaptation [23]. For example, our previous research [17, 23, 24] has shown that low self-efficacy with respect to patients’ perceived ability to talk with their healthcare team about healthcare decisions generally, and clinical trials specifically, negatively impacts their healthcare decision making. This suggests that decisional conflict, [25] that is, the extent to which patients report unresolved decisional needs such as personal uncertainty and related deficits in knowledge, values clarity, and support or pressure may also be an influential factor in clinical trial participation.

Clinical trial decision-making in oncology is particularly complex because treatment outcomes are uncertain and the treatments have a high potential for toxicity. Further, patients vary in terms of their beliefs about treatment efficacy, their preferred level of involvement in medical decision making regarding treatments, and their treatment preferences. Therefore, decisions about whether to participate in cancer clinical trials decision making for patients may be highly conflicted. Preparing patients to consider clinical trial participation is a critical but understudied component of cancer treatment decision making. Studies of decision making in oncology settings report that pre-consultation preparation facilitates cancer patients treatment decisions. [20, 26–28] Yet, little data are available in the domain of clinical trials. Improved methods of preparation for clinical trial decision making could decrease decisional conflict and the level of uncertainty about the correct course of action to take when choices among alternatives include risk, loss, regret or challenge to personal values.

The Cochrane reviews suggest that decision aids improve knowledge about clinical options, create more realistic expectations about outcomes, and increase active involvement in the decision making process [29]. For example, studies of decision support aids in cancer-related genetic testing have found that increasing knowledge, preparation and perceived

benefits of testing facilitate informed decision making [30, 31]. In an effort to more systematically identify appropriate targets for behavioral interventions to improve patient decision making about clinical trials, we conducted an exploratory study to assess the relationship between key psychological constructs in this context. Specifically, we sought to determine whether preparation for decision making would serve as an appropriate intermediate endpoint for a future intervention, and the relationship between preparation and upstream (i.e., knowledge, self-efficacy) and downstream (i.e., decisional conflict, clinical trial enrollment) factors.

Thus, the primary aim of this pilot study was to assess decisional conflict before and after a brief educational intervention to improve cancer patient knowledge about clinical trials, and to evaluate our model of factors influencing decisional conflict. We hypothesized that higher levels of knowledge and self-efficacy following an educational intervention would be associated with increased preparation to make decisions about participation in clinical trials, and this increase, in turn, would decrease decisional conflict. Our model is illustrated in Figure 1. Further, we hypothesized that reductions in decisional conflict would lead to greater enrollment in clinical trials.

METHODS

In an effort to obtain empirical evidence of the relationships among knowledge, preparation, self-efficacy, and decisional conflict, we conducted a one armed, pre-post test study consisting of surveys and an educational intervention in cancer patients before their initial visit with an oncologist.

Participants

Eligible patients (N=105) were at least 18 years old and had a cancer diagnosis, and were scheduled for their initial consultation with an oncologist at the study site. All read and were able to verbally communicate in English. The sample size was selected to assess feasibility of patient recruitment and variability of measures to serve as the basis for a future randomized clinical trial of an intervention to improve patient preparation for decision making about clinical trials. [32] Patients were not required to be eligible for, or considering participation in, a clinical trial to participate in the study.

Procedure

Patients were recruited before their initial consultation with a medical oncologist at an NCI-designated comprehensive cancer center. Twenty-seven medical oncologists referred patients to the study. All medical oncologists were invited to participate, regardless of their clinical trail recruitment patterns. Patients were identified by research team members who reviewed new patient schedules and medical information prior to the first appointment with the medical oncologist. Potential participants who met eligibility criteria were contacted by telephone and invited to participate in the study. Written informed consent was obtained on the day of the patient's appointment.

Study procedures were: (1) Completion of baseline paper survey before the physician consultation; (2) Review of clinical trials education text provided online by the National Cancer Institute (http://www.cancer.gov/clinicaltrials/resources/what-to-know-about-trials), also before the physician consultation; (3) Post-education paper survey immediately after review of the NCI website information; (4) Physician consultation; (5) Post-consultation survey one week later (paper or phone depending on patient preference). All patients were exposed to the same information, since the NCI website is intended to target a wide patient population and therefore is not tailored for different disease stages and trial types. A total of

216 patients were approached and 105 completed the baseline and Post-education surveys in an 8-week period (see figure 2). Reasons for non-completion included: no interest (30%), too ill to participate (23%), patient wanted to see the doctor first (22%), could not complete baseline before appointment (20%), patient cancelled their appointment (11%), patient discomfort with the survey (4%), patient death (2%), patient too busy to participate (1%). Eighty-nine (85%) post-consultation surveys were completed. Of the completers, a total of 87 participants had complete data for each of the three measurement time points. There were no significant differences between participants and those lost to follow-up at the post-consultation survey in terms of age, gender, education, insurance status or cancer status (i.e., new diagnosis versus recurrence). In addition, there were no statistically significant differences between participants and those lost to follow-up on baseline Ottawa preparation scale scores, baseline completeness of preparation scores, or baseline self-efficacy scores.

Educational Intervention

The NCI website was selected as the optimal standard of care condition with regard to providing general clinical trials information. The site includes CCT general information as well as prompts and content that guide patients on how to decide to take part in a CCT. The online education takes patients from contemplation about participation in the introduction and “What are clinical trials?” modules to action steps in “Questions to Ask” and “How to Find a Clinical trial?”

Measures

Study instruments measured demographics, diagnosis and treatment history, and items measuring CCT knowledge, attitudes, preparation, and decisional conflict.

Knowledge—Clinical trial-related knowledge items (14 items, agree-disagree-unsure ranging from 1 to 3) were adapted from Davis and colleagues’ Knowledge About Clinical Trials scale [33]. This instrument was administered at baseline and post-education. A summation of correct responses provided an overall score for each patient.

Preparation—Preparation for consideration of clinical trials was assessed with the Ottawa Preparation for Decision Making scale modified to address CCTs [34–36] (10 items, 5-point scale ranging from 1 to 5). The scale included items concerning decision making and preparation for physician visit. The ten items are summed and divided by 10 to attain an overall score for each patient. This instrument was administered at baseline and post-education.

Self-efficacy—Self-efficacy was assessed as a global construct using the Ottawa Decision Self-Efficacy scale adapted for use with CCTs (11-items, 5-point scale ranging from 0 to 4). This scale is summed to create one global item that measures the patient’s self-confidence or belief in their ability to obtain relevant decision making information including shared decision making [35, 37]. This instrument was administered at baseline and post-education.

Decisional Conflict—Decisional Conflict was measured using the Ottawa Decisional Conflict scale (16 items, 5-point scale ranging from 1 to 5) [25]. This scale has five factors that assessed (1) decision support-having advice, support and no pressure in decision making; (2) uncertainty- being clear about the choice and that it’s the best for the patient; (3) being informed - being informed of the alternatives, benefits and risks of CCTs; (4) clarifying values - clarifying personal values regarding CCTs; and, (5) effective decision making -making patients feel as though they were making and implementing effective decisions about CCTs. The overall score and subscale scores were computed by summing

items, dividing by the total number of items and multiplying by 25. This measure was administered at baseline and post-consultation.

Treatment Decision—Treatment decision was measured using a survey item that asked patients, “Have you made a decision about the type of treatment that you would like to receive?” Patients who answered yes and indicated that they had chosen a clinical trial were coded as enrolled in a clinical trial. This item was measured post-consultation only.

Data Analysis

Descriptive statistics were calculated to summarize the sample characteristics. Wilcoxon matched-pairs signed-rank tests were used to compare pre- and post-test preparation scores. Pearson correlations between pre and post education preparation for CCT decision making were calculated. A linear structural equation modeling approach was used to assess mediation [38]. A bootstrap procedure suggested by Shrout and Bolger [39] was used to evaluate whether the indirect mediational pathway was statistically significant. The models also controlled for age, race, sex, education, and recurrence. We did not control for ethnicity or insurance status due to low variability of these items in the sample. When path coefficients for the pathways of baseline self-efficacy yielding preparation and preparation yielding decisional conflict mediation were both statistically significant, there was evidence of mediation from baseline to post-education. Wilcoxon rank-sum tests were used to assess the relationship of decisional conflict with actual clinical trial enrollment decisions among those offered access to a clinical trial. As this was an exploratory and hypothesis generating analysis, the criteria for statistical significance was set to a nominal p-value of 0.05. STATA version 10 (StataCorp, College Station, TX) was used for all analyses.

RESULTS

Patient characteristics

Table 1 summarizes the characteristics of the sample. Overall, the sample was comprised mainly of white (90%), non-Hispanic (98%) patients. About half of the sample was female (51%). Most patients were insured (99%) and reported either some college (27%) or a college education (36%). Overall decisional conflict for the sample was reported as 26.29 (SD=19.28).

Changes in preparation for CCTs

At baseline, eighty three percent of patients had heard of clinical trials, but only 48% were “interested in taking part in a clinical trial that your doctor offered to you.” Only 11 (10%) patients felt that their understanding of clinical trials was “very clear” after receiving the educational material, while 71 (68%) felt that their understanding was somewhat clear. On knowledge, preparation, and self-efficacy scales, there were no significant differences found between pre and post-education results.

There was modest improvement in preparation for decision making after the education intervention. The post-education score mean of 68.55 (SD=16.35) was significantly higher than the baseline, pre-education score mean at 62.43 (SD=17.15) on a possible scale of 0–100 ($p < 0.001$). Knowledge and decision self-efficacy had moderate to strong positive correlations with preparation from baseline to post-education ($p < 0.001$) (Table 2).

Mediators of Decisional Conflict for CCTs

We also examined the role of preparation as a mediator of knowledge and self-efficacy for post-consultation decisional conflict. We used baseline self-efficacy to ensure that we had

temporal order in our measurements that would be consistent with the mediational pathway. Preparation did mediate the relationship of knowledge with decisional conflict (see table 3) and preparation was a significant mediator of the relationship of self-efficacy with decisional conflict (see table 4). In aggregate, baseline self efficacy was a significant predictor of the reduced total decisional conflict score (total effect $\beta = -0.22$, $P = 0.027$). Figure 1 shows the hypothesized meditational pathway for decisional conflict. Table 4 shows there was strong evidence that the relationship of decisional conflict with self-efficacy was mediated by preparation through participating in the education intervention. In particular, the direct effect of self efficacy on total decisional conflict was not statistically significant after controlling for post-education preparation (direct effect $\beta = 0.06$, $P = 0.649$). The total effect seemed to be driven primarily by the mediational pathway (mediational effect $\beta = -0.29$, $p=0.003$ for post-preparation model). There was evidence of mediation for each of the subscales (the paths a and a*b being statistically significant), even in two cases where the total effect of the subscales was not statistically significant ($p>0.05$ for the support and uncertainty subscales).

Relationship of Decisional Conflict with Clinical Trial Enrollment

Twenty four patients in our sample were offered participation in a clinical trial (Table 5). In this small sample size, point estimates for post-consultation decisional conflict were lower among patients who decided to enroll. This difference was statistically significant ($p<0.05$) with respect to the effective decision making subscale.

DISCUSSION

This study examined whether preparation would mediate the relationship of self-efficacy and knowledge on the one hand, with cancer patients' decisional conflict about participation in clinical trials on the other hand. Previous studies have focused mainly on knowledge as a direct motivator to engage in a CCT. Our findings suggest that the relationship is more complex and that preparation acts as a mediator between knowledge, self-efficacy and decisional conflict. Further, the impact of self-efficacy in decision support is essentially mediated by preparation rather than knowledge. This result reinforces previous findings that knowledge alone is not sufficiently potent to reduce conflict, even when patients feel prepared to act [6, 12, 15, 40, 41]. Finally, the potential for an educational intervention to impact the network of relations found among knowledge, self efficacy, preparation and decisional conflict is indicated.

The finding that preparation so strongly mediates the relationship between self-efficacy and decisional conflict is important in light of the currently oversimplified clinical research focus on the importance of educating patients about CCTs and increasing their CCT awareness. While recent data suggest that awareness is improving, with 60% of adults (non-cancer patients) having heard of clinical trials [19], clinical trial participation rates have not shown an equivalent improvement. Our findings indicate that enhancing self-efficacy related to CCT decision making may be the key factor in facilitating decisions in this context. In particular, it will be important to further explore whether interventions that enhance preparation—by helping patients clarify their values and increase the sense that they will make effective choices—not only reduce decisional conflict but also increase uptake of CCTs.

This study is the first to report on the association of self-efficacy with decisional conflict in a CCT setting. Previous studies have focused either on delineating patient barriers notably patient knowledge and attitudes towards CCTs, [1, 3–13, 42–48] as well as concrete health system barriers such as physician attitudes [49] and resource allocation. This study extends our current understanding of the impact of factors that affect CCT decision making through

exploration of the role of decisional conflict and self-efficacy and how these factors may impact patients' CCT choices.

Limitations of this study should be considered. First, though emotional barriers (e.g., fear of side effects [6, 7, 10–12, 16, 42, 50–52], fear of randomization [6, 11, 42, 45, 50, 53, 54], fear of receiving a placebo [11, 18, 42], fear of losing autonomy [6, 7, 50], concerns about the efficacy of treatment on a clinical trial [7, 11, 45, 47, 54], fear of becoming a "guinea pig" [7, 52], viewing clinical trials as a last resort for treatment [18, 51, 52, 55], and concerns about physician conflicts of interest [7, 54]) have been documented in the literature, they were not assessed in the present study. Therefore, we were unable to assess the interrelations of emotion, self-efficacy, and CCT decisional conflict. Secondly, there was a low proportion of ethnic minorities and a high proportion of more highly educated patients in this study. Further research is necessary to examine whether the mechanism underlying the effect of the intervention in this sample is representative of what might be found in a more diverse population. Finally, the sample size for this study was small, as it was determined for a feasibility endpoint. This may have limited our power to detect some relationships. A subsequent study of a larger, more heterogeneous population will be required to confirm and extend these results.

CONCLUSIONS

Although this was a single arm trial consisting of a limited brief educational intervention, our findings suggest that attending to patient preparation may be a time-and cost-effective strategy to enhance the effects of interventions to increase CCT enrollment. Previous studies have documented a variety of interventions targeted at addressing psychosocial barriers to improve patient knowledge about, and attitudes towards, clinical trials. They include informational videos, forums and panel discussions, audiotapes, educational brochures, and interactive computer programs [6, 12, 15, 31, 40, 41]. In general, the results have not been consistent [6, 12, 15, 40, 41]. This lack of consistency suggests that increasing knowledge and positive attitudes toward CCTs may not be sufficient to impact clinical trials participation. Our results indicate that enhancing preparation can be used to overcome self-efficacy barriers to clinical trial enrollment and that future interventions that increase preparation might be useful. To this end, we are conducting a randomized study of a tailored web-based intervention to improve cancer patient preparation for consideration of clinical trials as a treatment option (NCI registration NCT00750009, R01 CA127655)[32].

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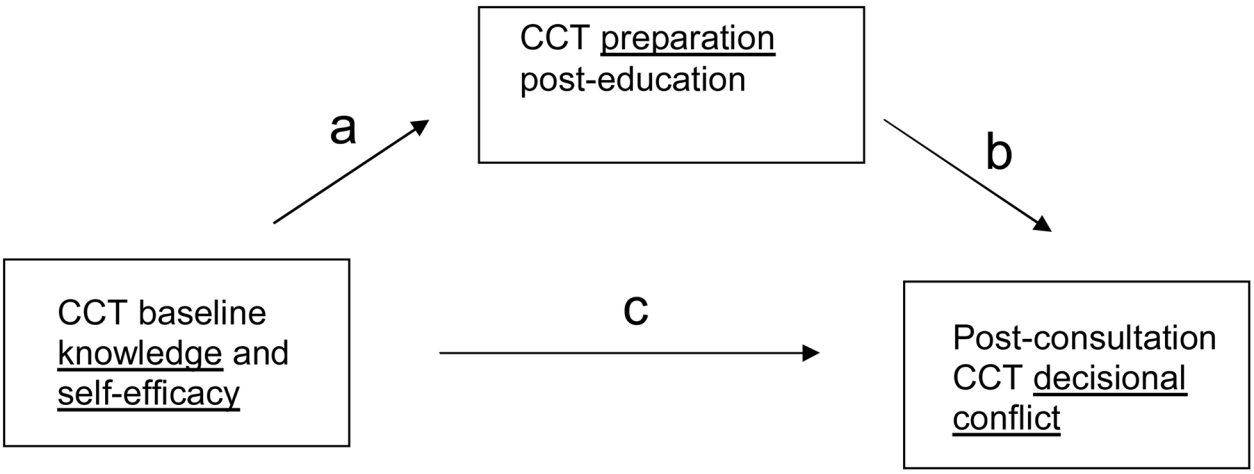

Figure 1.
Mediational Pathway of Knowledge and Self-Efficacy for Decisional Conflict

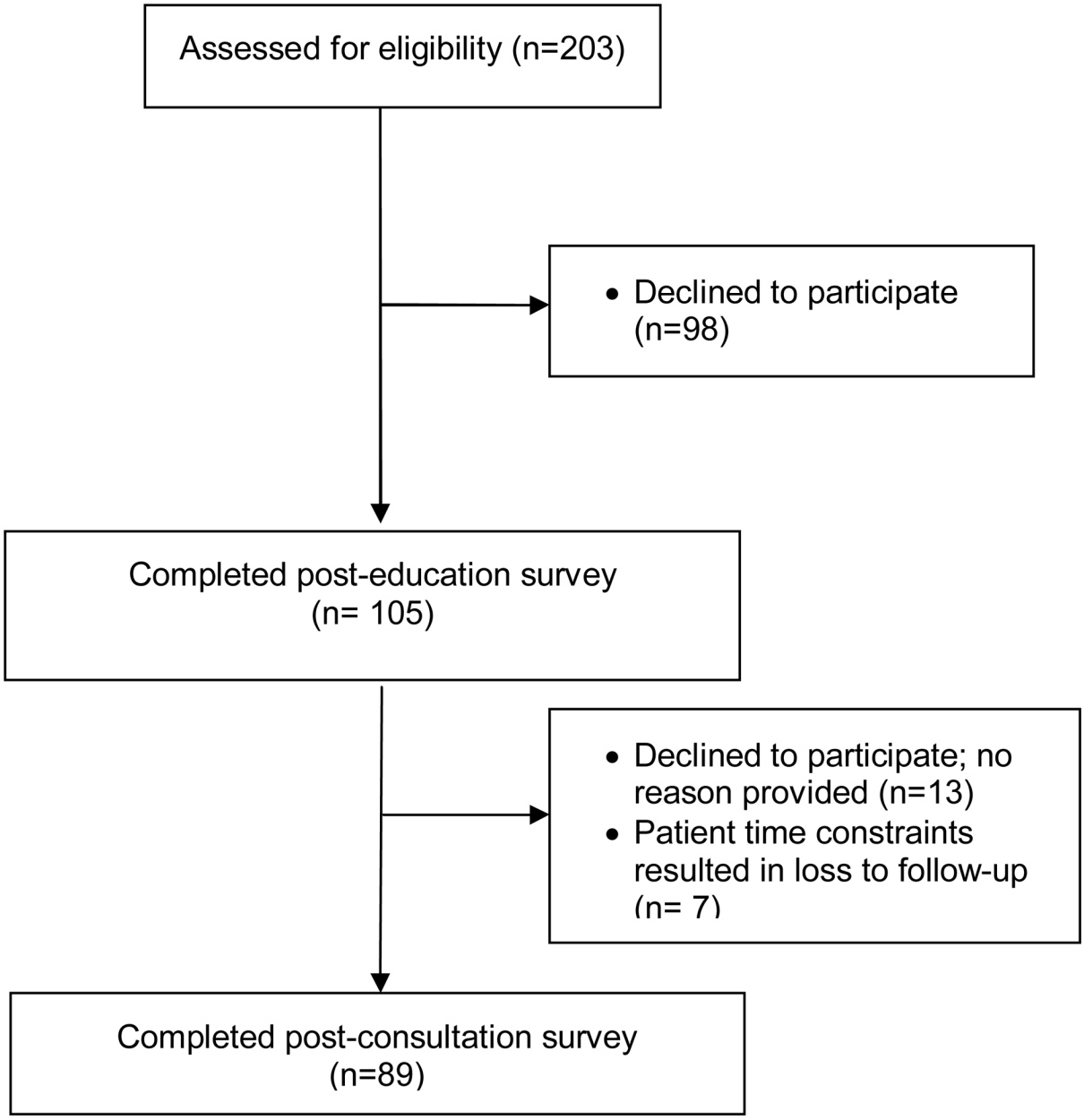

Figure 2.
Study Flow Diagram

Table 1

Patient demographics

Variable	Number	Percentage
Total Number	105	100%
Gender		
Male	52	49%
Female	53	51%
Race		
Black	8	8%
White	94	89%
Other	3	3%
Ethnicity		
Hispanic	2	2%
Non-Hispanic	103	98%
Education		
High school or less	38	36%
Some college	29	28%
College graduate	38	36%
Health Insurance		
Uninsured	1	1%
Insured	104	99%
Recurrence *		
New diagnosis	75	73%
Recurrence	28	27%
	Mean (SD)	Range
Age	57.3 (11.9)	
Decisional Conflict (overall)	26.29 (19.28)	0–75
Decision support	28.86 (18.86)	0–76.56
Uncertainty	28.83 (20.99)	0–91.67
Being informed	29.41 (20.37)	0–75
Clarifying values	23.75 (19.17)	0–75
Effective decision making	36.87 (24.53)	0–91.67

* Two individuals were missing recurrence information

Table 2

Barriers to Preparation

Measure	N	Possible Range	Mean	SD	Correlation with Post-Education Preparation for Decision Making	
					Correlation	p-value
Pre-Education Knowledge	105	0–14	7.65*	3.30	0.404	<0.001
Post-Education Knowledge	105	0–14	8.58*	2.73	0.315	0.001
Pre-Education Self-Efficacy	105	0–100	78.68*	21.74	0.697	<0.001
Post-Education Self-Efficacy	104	0–100	82.98*	18.83	0.660	<0.001

* $p < .001$ for pre-post differences in means

Table 3

Path coefficients for the impact of knowledge on decisional conflict pathway as a result of CCT education preparation (n=87 at follow-up with complete data post consultation)

	Pathway	Pre-Education Preparation		Post-Education Preparation	
Outcome Variable/Pathway		**Coefficient**	**P-value**	**Coefficient**	**P-value**
Decisional Conflict: Total Score					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.67	0.338	−0.67	0.338
Baseline self-efficacy → Preparation	a	2.15	<0.001	1.66	0.002
Preparation → Decisional Conflict	b	−0.51	<0.001	−0.51	<0.001
Baseline self-efficacy → Dec. Conf.	c	0.44	0.529	0.17	0.795
Mediational effect	a*b	−1.11	0.010	−.85	0.039
Decisional Conflict: Informed					
Baseline self-efficacy → Decisional Conflict	Total Effect	−1.31	0.096	−1.31	0.096
Baseline self-efficacy → Preparation	a	2.15	<0.001	1.66	0.002
Preparation → Decisional Conflict	b	−0.54	<0.001	−0.53	<0.001
Baseline self-efficacy → Dec. Conf.	c	−0.14	0.864	−0.44	0.565
Mediational effect	a*b	−1.18	0.021	−0.88	<0.001
Decisional Conflict: Values					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.96	0.195	−0.96	0.195
Baseline self-efficacy → Preparation	a	2.15	<0.001	1.66	0.002
Preparation → Decisional Conflict	b	−0.44	0.002	−0.43	0.003
Baseline self-efficacy → Dec. Conf.	c	0.01	0.989	−0.26	0.729
Mediational effect	a*b	−0.97	0.023	−0.70	0.058
Decisional Conflict: Support					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.36	0.620	−0.36	0.620
Baseline self-efficacy → Preparation	a	2.15	<0.001	1.66	0.002
Preparation → Decisional Conflict	b	−0.43	0.003	−0.44	0.002
Baseline self-efficacy → Dec. Conf.	c	0.59	0.432	0.37	0.613
Mediational effect	a*b	−0.95	0.021	−0.72	0.043
Decisional Conflict: Uncertainty					

	Pathway	Pre-Education Preparation		Post-Education Preparation	
Outcome Variable/Pathway		**Coefficient**	**P-value**	**Coefficient**	**P-value**
Baseline self-efficacy → Decisional Conflict	Total Effect	0.01	0.989	0.01	0.989
Baseline self-efficacy → Preparation	a	2.15	<0.001	1.66	0.002
Preparation → Decisional Conflict	b	−0.060	0.001	−0.64	<0.001
Baseline self-efficacy → Dec. Conf.	c	1.32	0.160	1.07	0.229
Mediational effect	a*b	−1.31	0.014	−1.06	0.029
Decisional Conflict: Effective					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.72	0.311	−0.72	0.311
Baseline self-efficacy → Preparation	a	2.15	<0.001	1.66	0.002
Preparation → Decisional Conflict	b	−0.52	<0.001	−0.52	<0.001
Baseline self-efficacy → Dec. Conf.	c	0.43	0.545	0.14	0.832
Mediational effect	a*b	−1.14	0.010	−0.86	0.025

The models also controlled for age, race, sex, education, and recurrence. We did not control for ethnicity or insurance status due to low variability of these items in the sample. If pathways “a” and “a*b” are both statistically significant, then there is evidence of mediation.

Table 4

Path coefficients for the impact of self-efficacy on decisional conflict pathway as a result of CCT education preparation (n=87 at follow-up with complete data post consultation)

	Pathway	Pre-Education Preparation		Post-Education Preparation	
Outcome Variable/Pathway		**Coefficient**	**P-value**	**Coefficient**	**P-value**
Decisional Conflict: Total Score					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.23	0.027	−0.23	0.027
Baseline self-efficacy → Preparation	a	0.49	<0.001	0.52	<0.001
Preparation → Decisional Conflict	b	−0.47	0.002	−0.55	0.001
Baseline self-efficacy → Dec. Conf.	c	−0.004	0.968	0.06	0.649
Mediational effect	a*b	−0.22	0.016	−0.29	0.003
Decisional Conflict: Informed					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.24	0.042	−0.24	0.042
Baseline self-efficacy → Preparation	a	0.49	<0.001	0.52	<0.001
Preparation → Decisional Conflict	b	−0.57	0.001	−0.63	0.001
Baseline self-efficacy → Dec. Conf.	c	0.03	0.802	0.09	0.531
Mediational effect	a*b	−0.27	0.015	−0.33	0.002
Decisional Conflict: Values					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.22	0.042	−0.22	0.042
Baseline self-efficacy → Preparation	a	0.49	<0.001	0.52	<0.001
Preparation → Decisional Conflict	b	−0.57	0.001	−0.45	0.013
Baseline self-efficacy → Dec. Conf.	c	0.03	0.802	0.01	0.925
Mediational effect	a*b	−0.27	0.015	−0.24	0.013
Decisional Conflict: Support					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.14	0.180	−0.14	0.180
Baseline self-efficacy → Preparation	a	0.49	<0.001	0.52	<0.001
Preparation → Decisional Conflict	b	−0.44	0.007	−0.53	0.003
Baseline self-efficacy → Dec. Conf.	c	0.06	0.621	0.13	0.340
Mediational effect	a*b	−0.21	0.029	−0.27	0.008
Decisional Conflict: Uncertainty					

	Pathway	Pre-Education Preparation		Post-Education Preparation	
Outcome Variable/Pathway		**Coefficient**	**P-value**	**Coefficient**	**P-value**
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.26	0.057	−0.26	0.057
Baseline self-efficacy → Preparation	a	0.49	<0.001	0.52	<0.001
Preparation → Decisional Conflict	b	−0.48	0.019	−0.64	0.004
Baseline self-efficacy → Dec. Conf.	c	−0.03	0.850	0.08	0.640
Mediational effect	a*b	−0.23	0.043	−0.33	0.008
Decisional Conflict: Effective					
Baseline self-efficacy → Decisional Conflict	Total Effect	−0.27	0.010	−0.27	0.010
Baseline self-efficacy → Preparation	a	0.49	<0.001	0.52	<0.001
Preparation → Decisional Conflict	b	−0.45	0.003	−0.51	0.003
Baseline self-efficacy → Dec. Conf.	c	−0.05	0.647	−0.003	0.980
Mediational effect	a*b	−0.21	0.018	−0.27	0.010

The models also controlled for age, race, sex, education, and recurrence. We did not control for ethnicity or insurance status due to low variability of these items in the sample. If pathways “a” and “a*b” are both statistically significant, then there is evidence of mediation.

Table 5

Relationship of decisional conflict scores with enrollment choices post-consultation.

Variable	Did not enroll (n=11) mean (SD)	Enrolled (n=13) mean (SD)	p-value*
Overall decisional conflict score	29.4 (17.2)	18.1 (14.1)	0.147
Decision Support	23.5 (18.6)	17.3 (13.8)	0.313
Uncertainty	41.7 (25.0)	22.4 (20.5)	0.053
Being Informed	27.3 (17.5)	18.6 (15.3)	0.198
Clarifying Values	23.5 (15.7)	18.6 (14.9)	0.397
Effective Decision Making	30.7 (18.8)	14.9 (13.6)	0.049

* p-values assessed by a Wilcoxon Rank-Sum test.