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14. ABSTRACT This study examined a method of patient education for men who were seeking treatment for management of localized prostate cancer. The primary goal was to evaluate a recently developed computer-based educational tool (CD-ROM) that was designed to provide treatment-related information and to assist men in making an informed treatment decision. Men were accrued post-biopsy for a baseline interview, and were randomized to receive a CD-ROM with a decision aid, or a CD-ROM with information only. We have completed accrual, randomization, baseline, one-month, and final telephone interviews. The study participation rate was 81.6% (133/163). We have conducted preliminary analyses of the baseline and one-month follow-up data, and will conduct further analyses now that the final telephone interviews have been completed.					
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INTRODUCTION

There is a controversy in the medical community surrounding the utility of treatment options for early stage prostate cancer. Although several options are available for management of localized prostate cancer, no option is clearly superior to others. The primary goal was to evaluate a method of patient education that was designed to provide treatment-related information and to help men clarify their preferences and values via a recently developed computer-based decision aid. We expected that men randomized to the decision aid condition would be more active in their treatment decision and would have improved patient outcomes relative to men assigned to the information-only condition.

Men were accrued post-biopsy and those with a positive biopsy result received the intervention following notification of the diagnosis but prior to their making a decision about treatment. Participants were followed at one month, six months, and twelve months post-intervention. The primary outcomes include patient outcomes (knowledge, quality of life, and decisional satisfaction) and shared decision making (SDM) practices.

In many areas of medicine, including treatment of localized prostate cancer, there has been a rapid expansion of research that has resulted in a growing number of diagnostic and treatment options that are available to physicians and patients. In many cases, there are several effective and viable treatment options, but randomized clinical trials assessing treatment effectiveness have not yet been completed. Although the availability of different options will undoubtedly be beneficial in the long run, at present it creates a difficult decision for individuals and physicians who are faced with the choices for which no best answer is known. The current study was designed to assist patients through this decision, by providing information and helping them to consider their values.

BODY

We have listed each of the tasks from our Statement of Work, and the associated accomplishments.

Task 1. Finalize accrual procedures and measures to be included (months 1-2).

This task was accomplished during year one.

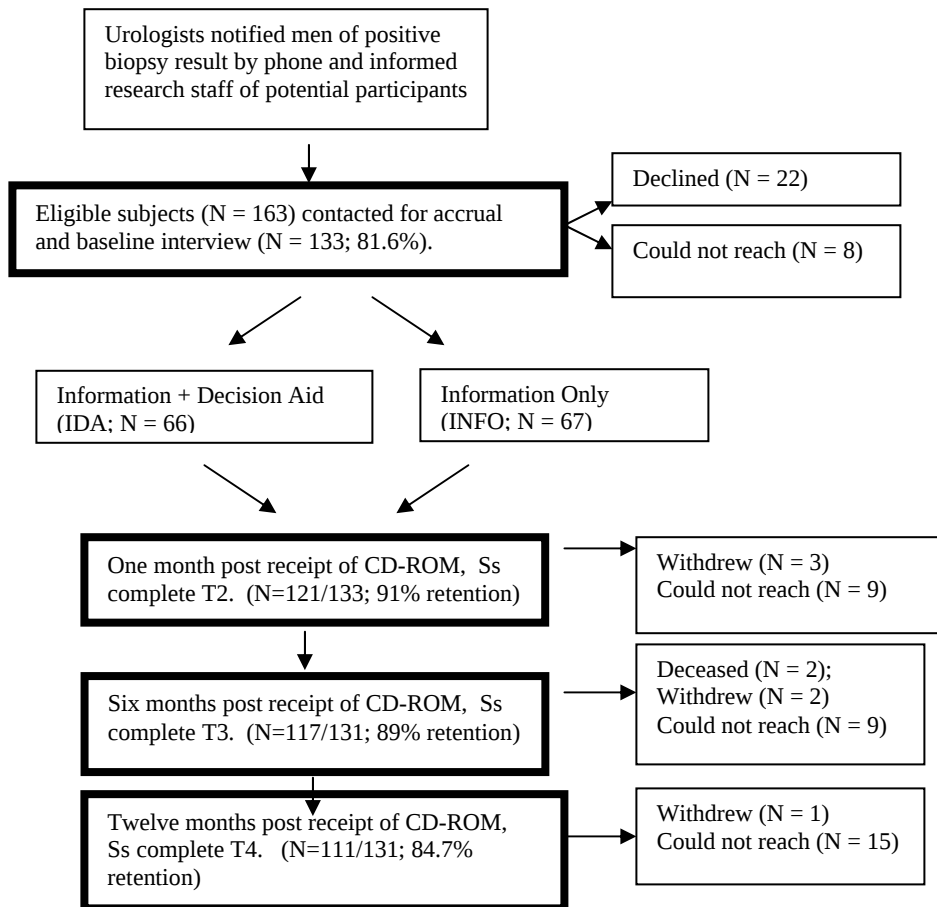
Task 2. Conduct participant accrual (months 3-27).

We received approval to conduct Human Subjects research in September, 2002 and began patient accrual at the Division of Urology, Georgetown University. We accessioned eligible participants and conducted baseline interviews over the telephone. For those who agreed to the study and were diagnosed with early-stage prostate cancer, we completed the baseline interview and randomized them to either receive the CD-ROM with a decision aid or a CD-ROM with information only. We finalized the medical record abstraction form and have accessed patient information from medical chart review.

Task 3. Conduct follow-up assessments (months 4-33).

For those who agreed to the study, we administered follow-up interviews at one-month, six months, and twelve months post intervention. Participation rates and retention rates are included in Figure 1.

Figure 1. Procedure and Retention Rates



Task 4. Preliminary data analyses and baseline manuscript (months 4-33).

We have conducted several analyses. Table 1 presents demographic information, stratified by intervention arm. There were no significant group differences on the demographic or medical variables.

Table 2 presents the CD-ROM Use and Evaluation questions, stratified by intervention arm. There were few group differences on these items, with the exception of 1) men in the IDA arm were less likely to use the CD-ROM relative to men in the INFO only arm, and 2) men in the IDA arm were more likely to rate the CD-ROM as ‘very helpful’ in making a treatment decision, relative to the INFO only arm. We are puzzled by the finding that men in the IDA group were less likely to use the CD-ROM. There are no procedural differences between groups that would have caused this, and there are no demographic or medical differences at baseline that would explain this. Other findings indicate that in both groups, among the men who used the CD, approximately 2/3 rated the CD as having about the right amount of information, being about the right length, and having clear information.

Task 5. Final analyses and manuscript preparation (months 34-36).

We are now in the midst of final analyses and manuscript preparation, as data collection was completed in December, 2005. Please see the attached poster presentations that were recently presented at the national meetings of the Society of Behavioral Medicine and the American Society of Preventive Oncology. We will complete the one-month outcome analyses, as well as the six- and 12-month analyses. In addition, we will analyze the tracking data that we obtained on 50% of participants, which will allow us to assess which parts of the CD-ROM were visited and for how long, and how these use data are related to the outcomes of interest. Unfortunately, it proved very difficult to obtain the computer disks that contained the tracking information back from participants. This was partially due to computer difficulties and partially due to men's inexperience in copying files to a disk, despite repeated efforts to assist them in this process. We have learned that in order to obtain complete information, it must be retrieved in an automated fashion (e.g., the educational material must be available on a website rather than from a CD-ROM).

KEY RESEARCH ACCOMPLISHMENTS

Our accomplishments include:

- the excellent accrual and retention rates
- the CD-ROM was well-received by the majority of participants, based on multiple items
- the collection of data on pre-treatment quality of life and prostate cancer-related symptoms, which will be important in interpreting the post-treatment quality of life and prostate-related symptoms outcomes. Further, it is rare for studies to access men prior to their treatment, and even more rare to access men prior to having made a treatment decision. Thus, these data will contribute new information to the literature.
- the collection of tracking data on CD-ROM use, which will provide a unique contribution to studies of computer-based interventions.
- Being the first study to our knowledge to determine whether the decision aid tools provide any benefit over and above the provision of information

REPORTABLE OUTCOMES

We have recently presented two poster presentations, one at the 2006 annual meeting of the American Society of Preventive Oncology in Bethesda, MD, and one at the 2006 meeting of the Society of Behavioral Medicine, San Francisco, CA. Please see the documents at the end of this document. We reported findings based on the analyses from the baseline and one-month follow-up data. These findings included the following:

- At the one-month assessment, we retained 91% of the sample ($N = 121/133$). There were no demographic differences between those who dropped out and those who remained.
- At the one-month assessment, knowledge increased ($F(2, 119) = 38.8, p < .0001$) and decisional conflict decreased ($F(2, 118) = 4.3, p < .05$) equally across the groups. There were no significant Group X Time interactions. As a result, we collapsed the two groups in order to have a larger group in which to examine men's use and evaluation of the CD-ROM as an educational tool.

- Of the 121 men who completed the one-month interview, 95 (78.5%) reported using the CD-ROM.
- Use of the CD was not associated with any demographic characteristics, knowledge, or decisional conflict, but was associated with being more involved in one's medical care (Krantz measure; $t(119) = 2.0, p < .05$).
- Significant predictors of desire for control over treatment choice included higher scores on knowledge of PCa, a dispositional measure of preferences for treatment approaches (KHOS), higher education and younger age ($r^2 = .32$)

CONCLUSIONS

This project seeks to aid men in making a decision about early-stage prostate cancer, through the use of a recently developed CD-ROM. From these preliminary analyses, it is clear that older men are largely receptive to the use of computer-based educational interventions to assist in their treatment decisions. Although we have not yet found a clear benefit for the inclusion of the decision tools, in terms of quality of life, knowledge, and decisional conflict at the one-month assessment, it is possible that the impact of the decision tools will be detected at the later assessments. In any case, it is clear that overall, collapsing across groups, knowledge did improve and decisional conflict did decrease at the one-month assessment, indicating the positive impact of the computer-based intervention.

Overall, the CD-ROM was well-received: a positive response was consistently provided on the evaluation items by the majority of the sample. Further, men reported an increase in knowledge and a decrease in decisional conflict at the one-month assessment.

However, a large minority (21%) of men retained at the one-month assessment reported not using the CD-ROM at all. Non-use was reportedly due to a lack of time and to computer problems/lack of comfort with computers. Further, men who typically become more involved in their medical care were more likely to use the CD-ROM.

In many areas of medicine, the uncertainty associated with treatment options has resulted in the need for extensive patient education. Although there were some limitations, this CD-ROM appears to be an effective and well-accepted tool for prostate cancer treatment decision making among a highly educated sample of men.

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Table 1: Demographic and Medical Information

	<u>Information + Decision Aid</u> (N = 67)	<u>Information Only</u> (N = 66)
Age (mean, SD)	63.9 (9.0)	65.1 (9.8)
Education		
≤ college degree	50.75%	39.4%
graduate work/ degree	49.25%	60.6%
Married	74.6%	81.8%
Employment status		
Working (FT/PT)	59.7%	60.6%
Retired	40.3%	39.4%
Race (% white)	73.1%	74.2%
Regular doctor	95.5%	89.4%
Have insurance	98.5%	100%
Family history of prostate cancer	20.9%	21.2%
Personal ca history (other than pr ca)	16.4%	15.2%
Comorbidities (1 or more)	44.8%	53.0%
Days since biopsy (median)	17	17
Treatment		
Predisposition at one- month assessment		
Surgery	37.1%	42.4%
External Beam RT	29.0	20.3%
Brachytherapy	14.5%	16.9%
Watchful Waiting	11.3%	5.1%
Hormone therapy	3.2%	11.9%
No predisposition	4.8%	3.4%
Computer access	92.5%	95.4%

Table 2: Use and Evaluation of CD-ROM from One-Month Follow-Up Assessment

	<u>Information + Decision</u> <u>Aid (IDA)</u> (N = 62)	<u>Information Only</u> <u>(INFO)</u> (N = 58)
Used the CD**	67% (N = 42)	89% (N = 52)
Did not use CD	33% (N = 20)	11% (N = 6)
Reasons:		
No time	60% (N = 12/20)	67% (4/6)
Did not feel needed more info	15% (N = 3/20)	0% (0/6)
Used some and did not continue	5% (N = 1/20)	0% (0/6)
Other (e.g., computer problems, lack of comfort with computers)	35% (N = 7/20)	50% (3/6)
Trouble using the CD-ROM	21.4%	19.2%
Number of times used CD		
Once	16.7%	23.1%
More than once	83.3%	76.9%
Time since used the CD		
Within the past few days	14.3%	19.2%
Within the past week	31.0%	17.3%
Within past 2-3 weeks	40.5%	57.7%
Four weeks ago or more	14.3%	5.8%
Discussed Pr Ca Issues with others after using CD	78.6%	71.1%
Rate <u>amount</u> of information in CD		
Much less than was needed to make a decision	0%	5.8%
A little less than was needed to make a decision	26.2%	17.3%
About the right amount of information	59.5%	67.3%
A little more information than was needed	14.3%	7.7%
A lot more information than was needed	0%	1.9%
Rate <u>length</u> of the CD		
Much too long	0%	1.9%
A little too long	23.8%	23.1%
Just about right	69.1%	65.4%
Should have been a little longer	7.1%	9.6%
Should have been a lot longer	0%	0%
How <u>clear</u> was the information in the CD		
Everything was clear	73.8%	65.4%
Most things were clear	26.2%	34.6%
Some things were clear	0%	0%
Many things were unclear	0%	0%

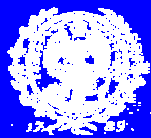
How <u>balanced and fair</u> did you find the CD?		
Clearly slanted toward one treatment decision	0%	0%
Moderately slanted toward one treatment dec.	0%	3.9%
A little slanted toward one treatment decision	9.8%	5.8%
Completely balanced	90.2%	90.4%
How <u>helpful</u> was CD in making a treatment dec. +		
Very helpful	66.7%	51.9%
Somewhat helpful	14.3%	38.5%
A little helpful	11.9%	7.7%
Not helpful	7.1%	1.9%
Did the CD make you think of new questions to ask your doctor? (% yes)	78.6%	82.7%
Did the CD help you explore differences and similarities between treatments?		
Helped very much	69.1%	61.5%
Helped somewhat	23.8%	30.8%
Helped a little	0%	5.8%
Not helpful	7.1%	1.9%
Did the CD address your questions about prostate cancer and its treatment?		
Yes, completely	21.4%	23.1%
Yes, mostly	61.9%	51.9%
Yes, some	16.7%	25.0%
No	0%	0%
Did the CD make you feel nervous or fearful about prostate cancer treatment?		
Yes, it made me nervous	7.1%	1.9%
Yes, it made me somewhat nervous	9.5%	3.9%
It made me a little nervous	19.1%	17.3%
No, it did not make me nervous	64.3%	76.9%
Did the CD make you feel more relaxed about prostate cancer treatment?		
Yes, it made me much more relaxed	14.3%	19.2%
Yes, it made me somewhat more relaxed	11.9%	13.5%
Yes, it made me a little more relaxed	26.2%	32.7%
It did not make me relaxed	47.6%	34.6%
Did using the CD impact your feeling of control over your treatment decision?		
It increased my sense of control a great deal	33.3%	28.9%
It moderately increased my sense of control	38.1%	51.9%
It did not affect my sense of control	26.2%	19.2%
It moderately decreased my sense of control	2.4%	0%

It decreased my sense of control	0%	0%
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To what extent did you use the CD compared to other sources of information?

I used the CD much more than other sources	26.2%	26.9%
I used the CD somewhat more than other sources	14.3%	13.5%
I used the CD equally with other sources	35.7%	36.5%
I used the CD somewhat less than other sources	11.9%	21.1%
I used the CD much less than other sources	11.9%	1.9%

+ p = .053 ** p < .01



Computer-Based Education for Treatment Decision-Making in Localized Prostate Cancer

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Background

- There is a controversy in the medical community surrounding the utility of treatment options for clinically localized prostate cancer. Although several options are available for management of localized prostate cancer, no option is clearly superior to others.
- As a result of the insufficient evidence, factors such as life expectancy, current health, and patient preference for therapeutic options should be considered in the treatment decision.
- Because men's preferences for outcomes of therapy may influence the decision regarding management choice, men should be informed of potential outcomes and should be encouraged to examine their own values in deciding upon a management strategy for their prostate cancer.
- Thus, easily accessible methods for educating men about treatment options and outcomes are needed.

Aims

- The primary goal of this study is to evaluate a method of patient education that is designed to provide treatment-related information and to help men clarify their preferences and values via a recently developed computer-based decision aid.
- These analyses are drawn from the baseline and one-month follow-up data from a randomized trial to evaluate two versions of a detailed, computer-based (CD-ROM) decision aid. As there were no group differences at the one-month follow-up assessment on the primary outcomes of knowledge and decisional conflict, we collapsed the two arms in order to describe the use and evaluation of the CD-ROM as an educational medium in this setting.

Method

- Participants included 133 men with newly diagnosed, localized prostate cancer (**Table 1**).
- Men completed telephone interviews at baseline (prior to making a treatment decision), and one, six, and twelve months post-intervention. The intervention was mailed to men for use at home. Measures included demographic and medical information, knowledge of prostate cancer treatments, the Decisional Conflict Scale, and the Krantz Health Opinion Survey.
- The **use and evaluation of the CD-ROM** was completed at the one-month assessment. We included a series of items on men's impressions of the content, the amount of information, and the impact they felt the CD had on their treatment decision (**Table 2**).

Results

- At the one-month assessment, we retained 91% of the sample (N = 121/133). There were no demographic differences between those who dropped out and those who remained.
- At the one-month assessment, knowledge increased (F (2, 119) = 38.8, $p < .0001$) and decisional conflict decreased (F (2, 118) = 4.3, $p < .05$) equally across the groups. There were no significant Group X Time interactions. As a result, we collapsed the two groups in order to have a larger group in which to examine men's use and evaluation of the CD-ROM as an educational tool.
- Of the 121 men who completed the one-month interview, 95 (78.5%) reported using the CD-ROM.
- The reasons for **not using** the CD-ROM were:

*No time	61.5% (N = 16/26)
*Did not feel more info was needed	11.5% (N = 3/26)
*Used the CD some/did not continue	3.8% (N = 1/26)
*Other (e.g., computer problems, lack of comfort with computers)	38.5% (N = 10/26)
- Use of the CD was not associated with any demographic characteristics, knowledge, or decisional conflict, but was associated with being more involved in one's medical care (Krantz measure; $t(119) = 2.0$, $p < .05$).

Table 1: Demographic/Medical Information (N = 133)

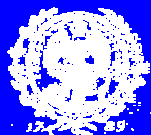
Age (mean, SD)	64.5 (9.4)
Education	
≤ college degree	45.1%
graduate work/degree	54.9%
Married	78.2%
Employment status	
Working (FT/PT)	60.2%
Retired	39.9%
Race (% white)	73.7%
Regular doctor	92.5%
Have insurance	99.3%
Family history of PCa	21.1%
Personal ca history (other than pr ca)	15.8%
Comorbidities (1 or more)	48.9%
Days since biopsy (med.)	17
Computer access	93.9%

Conclusions

- Overall, the CD-ROM was well-received: a positive response was consistently provided on the evaluation items by the majority of the sample. Further, men reported an increase in knowledge and a decrease in decisional conflict at the one-month assessment.
- However, a large minority (21%) of men retained at the one-month assessment reported not using the CD-ROM at all. Non-use was reportedly due to a lack of time and to computer problems/lack of comfort with computers. Further, men who typically become more involved in their medical care were more likely to use the CD-ROM.
- In many areas of medicine, the uncertainty associated with treatment options has resulted in the need for extensive patient education. This CD-ROM appears to be an effective and well-accepted tool for prostate cancer treatment decision making among a highly educated sample of men.

Table 2: Evaluation of the CD-ROM (N = 95)

No trouble using the CD-ROM	79.8%
Number of times used CD	
More than once	79.8%
Once	20.2%
Discussed PrCa Issues with others after using CD	74.5%
Rate amount of information in CD	
Much less/a little less than needed to make decision	24.5%
About the right amount of information	63.8%
A little/a lot more information than was needed	11.7%
Rate length of the CD	
Should have been a little/a lot longer	8.5%
Just about right	67%
Much/a little too long	24.5%
How clear was the information in the CD	
Everything was clear	69.1%
Most things were clear	30.9%
How balanced and fair did you find the CD?	
Clearly/moderately slanted toward one tx decision	0%
A little slanted toward one treatment decision	9.7%
Completely balanced	90.3%
How helpful was CD in making a treatment dec.	
Somewhat/Very helpful	86.2%
Not helpful/a little helpful	13.8%
Did the CD make you think of new questions to ask your dr? (% yes)	80.9%
Did the CD help you explore differences and similarities betw. Rx?	
Helped somewhat/very much	92.6%
Not helpful/helped a little	7.4%
Did the CD adequately address your questions about prostate cancer and its treatment?	
Mostly/completely	78.7%
Some	21.3%
No	0%
Did the CD make you feel nervous or fearful about PrCa treatment?	
Yes/yes, somewhat nervous	10.6%
It made me a little nervous	18.1%
No, it did not make me nervous	71.3%
Did the CD make you feel more relaxed about prostate cancer treatment?	
Yes, it made me much more relaxed	17.0%
Yes, it made me somewhat/a little more relaxed	42.6%
It did not make me relaxed	40.4%
Did using the CD impact your feeling of control over the decision?	
It increased my sense of control moderately/a great deal	76.5%
It did not affect my sense of control	22.3%
It moderately decreased/it decreased my sense of control	1.0%
To what extent did you use the CD compared to other sources of information?	
I used the CD much more/somewhat more than other sources	40.4%
I used the CD equally with other sources	36.2%
I used the CD much less/somewhat less than other sources	23.4%



Factors Associated with Desire for Control over Treatment Choice and Treatment Predisposition in Men with Early Stage Prostate Cancer

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Background

• Prostate cancer (PCa) is the most commonly diagnosed cancer among US men and the second leading cause of cancer death among men.

• The majority of newly diagnosed cases will be early stage /localized cancer with a 5-year survival rate of almost 100%.

• Primary treatment options include: radical prostatectomy (RP), radiation therapy (XRT, EBR), brachytherapy (BT), or watchful waiting (WW).

• There is a controversy surrounding the utility of the various treatment options for clinically localized prostate cancer because there is insufficient evidence demonstrating a clear benefit of one treatment option over another.

• Due to the lack of a “best” treatment option, factors such as life expectancy, current health, quality of life and patient preference for therapeutic options should be considered in the treatment decision process.

• Because men’s preferences for treatment outcomes may influence the decision regarding management choice, men should be informed of potential outcomes and should be encouraged to examine their own values in deciding upon a treatment strategy.

Aims

• The primary goal of this study is to conduct a randomized trial to evaluate a method of patient education that is designed to provide treatment-related information and to help men clarify their preferences and values via a recently developed computer-based CD-ROM decision aid.

• The goal of this paper is to describe the sample and factors associated with desire for control of treatment choice and treatment disposition.

• These analyses are drawn from the baseline data from this randomized trial.

Method

▪ Participants:

- Approached 163 who met eligibility criteria
- 22 (13.5%) declined for a variety of reasons including: lack of interest in study (10.5%), no need for further information (4%), and not comfortable using computers (2%).
- 8 (4.9%) men could not be reached
- Recruited 133 (81.6%) men with newly diagnosed early stage PCa (see Table 1)

▪ Measures:

- Demographic and medical information
- Knowledge of prostate cancer treatments scale
- Decisional Conflict Scale
- Krantz Health Opinion Survey (KHOS)
- UCLA Prostate Cancer Index (UCLA PCI)
- Desire for Control of Health Care (DCON)
- Control Preference Scale (CPS)
- Treatment Predisposition question
- Medical Outcomes Study (SF-12)

▪ Procedures:

- Men were recruited through the Departments of Urology (N= 94), Oncology (N=5), and Radiation Oncology (N= 11) at Georgetown University, Department of Urology at Washington Hospital Center (N=10), and local PCa support groups (N= 13).
- Men with a positive biopsy were approached within 1 month of receiving their biopsy results prior to making a treatment decision.
- Men were informed that the purpose of the study was to evaluate the impact of providing computer-based treatment information in an effort to help them make an informed treatment decision.
- Those who agreed to participate were asked to complete 4 telephone interviews over a 1 year period: at baseline (prior to making a treatment decision) and one, six and twelve months post-intervention.

Table 1 Demographic/Medical Information (N = 133)

Age (mean, SD)	64.5 (9.4)
Education	
≤ college degree	45.1%
graduate work/degree	54.9%
Married	78.2%
Employment status	
Working (FT/PT)	60.2%
Retired	39.9%
Race (% white)	73.7%
Regular doctor	92.5%
Have insurance	99.3%
Family history of PCa	21.1%
Personal ca history (other than pr ca)	15.8%
Comorbidities (1 or more)	48.9%
Days since biopsy (med.)	17
Computer access	93.9%

Results: Relationships Between Primary Outcomes

- Desire for control over one’s PCa treatment choices was positively associated with knowledge about PCa ($r = .32$; $p < .0002$) and a dispositional measure of preferences for treatment approaches (KHOS) ($r = .31$; $p < .0003$).
- Predisposition toward an active treatment (whether men were leaning toward a particular treatment choice vs. watchful waiting vs. not leaning toward a treatment) was positively associated with lower decisional conflict about one’s choice of treatment ($r = .22$; $p < .0001$).

Results: Multivariate Linear regression Indicated Significant Predictors of Desire for Control

- Multivariate linear regression was conducted and identified predictors of desire for control over treatment choice.
- Significant predictors of desire for control over treatment choice included higher scores on knowledge of PCa, a dispositional measure of preferences for treatment approaches (KHOS), higher education and younger age ($r^2 = .32$)

Results: Multivariate Cumulative Logit Regression Revealed Significant Predictors of Treatment Predisposition

Predictors	Estimate	95% CI	P-Value
Decisional Conflict	0.327	0.192 - 0.557	.0001
Age	0.947	0.905 - 0.991	.02
Education	0.472	0.207 - 1.076	.07
Family Hx.	0.205	0.0.053 – 0.791	.02

Conclusions:

- The association between desire for control of treatment choice and the above predictors (knowledge, the dispositional measure of preference for treatment approaches, and education) makes sense because often having more information is associated with a greater sense of control.
- Similarly, people who are able to make definitive treatment decisions may be younger and have less decisional conflict. Having less education may also be associated with making decisions more easily as there may be less information to consider.