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Evaluation of Computer-Based Patient Education

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13. ABSTRACT (Maximum 200 Words) 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, and the baseline and one-month follow-up interviews. The study participation rate was 81.6% (133/163). Currently, we have completed the one-month follow-up interviews, and the six- and 12-month follow-up interviews will be completed within the next 8 months. We have conducted preliminary analyses of the baseline and one-month follow-up data, and will complete the analyses once data collection has concluded.				
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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 and continue to be followed at 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).

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 post intervention and continue to conduct interviews at six months post intervention and twelve months post intervention. Of the 133 men who agreed to the baseline interviews and were randomized, 91.7% (122/133) of the men have completed the one month follow-up, 91.1% (102/112) of those who have become eligible have completed the six month follow-up, and 91.3% (73/80) of those who have become eligible have completed the twelve-month follow up.

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

We have conducted several preliminary 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.

Table 3 presents means and standard deviations for four of the outcome variables at the baseline and one-month assessments. It can be seen that none of the Group X Time interactions were significant at the one-month assessment. However, knowledge levels did increase in both groups, as expected. The physical component scale of the SF-12 decreased in both groups, suggesting a poorer quality of life over time, but decreased to a lesser extent in the IDA group. Regarding decisional conflict, the Group X Time interaction was marginally significant, suggesting that the IDA arm resulted in a greater decrease in decisional conflict compared to the INFO only arm.

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

Final analyses and manuscript preparation will be finished once data collection is complete, which we expect will be in December, 2005. This will include completing 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.

KEY RESEARCH ACCOMPLISHMENTS

Our accomplishments include:

- the excellent accrual and retention rates
- the IDA and INFO groups were equivalent at baseline on demographic and medical variables
- the CD-ROM was well-received by the majority of participants 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.
- 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

There have not yet been any papers or presentations resulting from this project. The abstract submitted to the American Public Health Association was not presented.

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.

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Table 1 Demographic and Medical Information, Stratified by Intervention Arm

	<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 Aid (IDA)</u> (N = 62)	<u>Information Only (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%

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

Table 3 Means and Standard Deviations for Outcome Variables at Baseline and One-Month Assessments
 (adjusting for significant bivariate and baseline value)

	<u>Information + Decision Aid (IDA)</u> (N = 63)	<u>Information Only (INFO)</u> (N = 59)	<u>Group X Time Interaction</u>
Knowledge Scale			P = .19
Baseline	13.1 (4.3)	14.4 (3.6)	
One-Month	15.7 (3.6)	15.8 (3.1)	
SF-12 Physical Subscale			P < .10
Baseline	52.4 (8.6)	53.1 (8.0)	
One-Month	51.4 (9.4)	49.1 (10.4)	
SF-12 Mental Subscale			P > .20
Baseline	52.5 (7.3)	49.0 (9.5)	
One-Month	52.6 (7.7)	50.3 (9.5)	
Decisional Conflict Scale			P = .10
Baseline	2.9 (.87)	2.6 (.78)	
One-Month	1.8 (.37)	1.9 (.58)	