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Informed decision making among first-degree relatives of prostate cancer survivors: A pilot randomized trial

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Abstract

Background—First degree relatives (FDRs) of men diagnosed with prostate cancer (PCa) are at increased risk for developing the disease, due in part to multiple concurrent risk factors. There is a lack of innovative targeted decision aids to help FDRs make an informed decision about whether or not to undergo PCa screening.

Purpose—This randomized pilot trial evaluated the efficacy of a targeted PCa screening decision aid in unaffected FDRs of PCa survivors.

Methods—Seventy-eight Black and White FDRs were randomized to one of two decision aid groups; 39 to a FDR-targeted decision aid and 39 to a general decision aid. The targeted decision aid group received a general PCa decision aid booklet plus a newly developed decision aid DVD targeted specifically for FDRs. PCa screening decision outcomes included knowledge, decisional conflict, distress, and satisfaction with screening decision. Outcomes were assessed at baseline and 4 weeks after baseline.

Results—There were no differences by intervention group for knowledge, decisional conflict, distress, or satisfaction with screening decision ($p > 0.05$). However, men in both groups had significant increases in knowledge and decreases in decisional conflict ($p < 0.001$). These changes were most pronounced ($p < 0.05$) for younger men compared to older men.

Conclusion—Results suggest that general and targeted information can play an important role in increasing knowledge and decreasing decisional conflict among FDRs. Additional research is needed to identify subgroups of men who benefit the most and better understand the outcomes of a screening decision aid among diverse samples of FDRs.

Keywords

Prostate cancer; first degree relatives; cancer education; cancer prevention and control; informed decision making; screening decision making

Introduction

Prostate cancer (PCa) is a leading cause of cancer related morbidity and mortality in American men [1]. Men with a family history of PCa are at greater risk for developing and dying from the disease compared to men without a family history [2, 3]. PCa risk doubles for first-degree relatives (FDRs), biological siblings or sons, of men with PCa [3, 4]. FDRs are often faced with a difficult decision about whether to undergo asymptomatic PCa screening, partly due to the uncertain benefits and harms of available screening and treatment modalities [5, 6]. Results from two landmark studies [5, 6], have lead health policy and medical organizations to recommend against routine asymptomatic PCa screening, and instead advise men to participate in informed decision making (IDM) [1, 7, 8]. IDM requires men receive information on potential benefits and harms of asymptomatic screening to make screening decisions based on their personal values and preferences [1, 7, 8].

Often, PCa screening decisions do not incorporate IDM [9]. Many men, including FDRs, tend to have limited knowledge of the controversy surrounding PCa screening and minimal discussions of these issues with their physician [10]. The use of decision aids is recommended to present balanced PCa information to help men undergo IDM [11]. PCa decision aids help average risk men undergo PCa screening IDM and improve knowledge, decrease decisional conflict, change screening intentions, and decrease screening rates [11–14].

Few IDM decision aids adequately address the multiple concurrent PCa risk factors (i.e., older age, African Ancestry and family history) faced by many FDRs [1]. Roughly 60% of all PCa cases occur in men 65 years of age and older. In addition, men of African ancestry are 60% more likely to develop PCa compared to White men [1]. Despite their increased risks, FDRs are often not presented with screening recommendations customized for their risk level. Multiple concurrent personal risk factors may lead FDRs to undergo asymptomatic screening without the benefit of IDM [4, 15–20]. FDRs would benefit from a targeted decision aid that discusses multiple concurrent risk factors and provides balanced information about the benefits and risks of asymptomatic screening to assist FDRs in making a personal screening decision that aligns with their values and preferences. Targeted decision aids are more likely, than general information, to be read, recalled, and have greater impact on a person's intentions and behavior [21, 22]. To address the need for IDM among FDRs, our team developed an innovative decision aid targeted for FDRs [23].

Development of the innovative decision aid targeted for FDRs and subsequent intervention was guided by the Decision Support Framework (DSF), an evidence based theoretical framework [24–26]. A detailed description of the decision aid materials is published elsewhere [23] and is summarized in the methods section (“Materials”). The DSF is used to

understand the determinants of decision making under uncertainty [25]. Consistent with the DSF, individuals need information about the pros and cons of asymptomatic PCa screening (Decisional Needs) and step-by-step guidance in clarifying their values relevant to decision making (Decision Support) and making a choice whether or not to be screened for PCa (Decision Quality) [24, 25]. In this study the DSF guided customization of the DA content to address multiple concurrent risk factors, identify a pragmatic step-by-step process to make a screening decision (decision support) [23] and guided assessment of knowledge, distress, decisional conflict and satisfaction with decision. These measures are consistent with the DSF model and decisional outcomes assessed in similar studies [12, 14, 27–33].

The goal of this pilot study was to evaluate the preliminary efficacy of an FDR targeted IDM decision aid on PCa knowledge, PCa related distress, PCa decisional conflict, and satisfaction with PCa screening decision among FDRs with multiple concurrent risk factors. Based on concepts from the DSF [24, 26] we hypothesized that FDRs randomized to receive the FDR targeted IDM decision aid would have higher PCa knowledge, lower PCa distress, lower PCa decisional conflict, and higher satisfaction with PCa screening decision compared to FDRs randomized to receive the non FDR targeted general educational materials. A secondary objective was to evaluate racial differences in PCa screening related outcomes post intervention by intervention group.

Methods

Research Design

This pilot trial, conducted in Southwest Florida, used a two-arm design comparing a FDR targeted decision aid intervention versus a non FDR targeted general education decision aid (standard intervention). Institutional review board approval was granted from the University of South Florida. All participants provided written informed consent before participation.

Recruitment

FDRs were recruited through either referral by PCa survivors or through community-based initiatives (See Figure 1: CONSORT Flow Diagram). PCa survivors were identified: 1) via the cancer registry at a National Cancer Institute (NCI) designated comprehensive cancer center; 2) approached in clinic while waiting to receive post-treatment follow-up at the cancer center; or 3) through community based PCa support groups. Using a well-documented methodology [15, 34], survivors were asked to nominate potentially eligible FDRs by providing names and contact information. Nominated FDRs were mailed an introductory letter asking them to call the study team if interested in participation or to decline participation. Individuals who did not respond to the mailed letter were contacted by telephone. FDRs who expressed interest in participation were evaluated for eligibility. Additional FDRs were also recruited from the community via health fairs, snowball referrals, or social media. FDRs recruited from the community were assessed by self-report to verify a positive family history of PCa and then screened for study eligibility. Specifically, FDRs who provided information about year of PCa diagnosis and type of treatment the relative received were included.

Procedures

Eligible participants were recruited from March 2010 to April 2013 based on the following criteria: (a) FDR (brother or son) of a man diagnosed with PCa; (b) non-Hispanic African American/Black or non-Hispanic White aged 40 to 70; (c) no self-reported history of any cancer, benign prostate hyperplasia, prostate biopsy, and/or transrectal ultrasound; (d) self-report access to a DVD player; (e) able to speak, read and write English; and (f) able to give informed consent. FDRs were excluded from the study if they had a relative(s); in active definitive PCa treatment, who completed treatment in the past 30 days, or multiple living relatives diagnosed with PCa. FDRs with multiple relatives with PCa were excluded to reduce heterogeneity of our sample. This exclusion criterion had minimal influence on accrual in this study as 7% (2 out of 28) of men excluded had multiple affected relatives.

All FDRs who met eligibility criteria and agreed to participate were mailed informed consent documents with instructions to sign and return the documents to the study team. Once consent documents were received, baseline telephone interviews were conducted and participants were randomly assigned to one of two study intervention groups: 1) standard intervention which consisted of the Centers for Disease Control and Prevention (CDC) PCa IDM booklet; or 2) the FDR targeted intervention which consisted of the CDC PCa IDM booklet and FDR-targeted decision aid DVD.

Participants were mailed intervention materials, along with brief written instructions. All participants were instructed to immediately read the CDC decision booklet and then watch the DVD (if randomized to the FDR targeted decision aid group). Participants were instructed to review intervention materials again about two weeks later, and as needed throughout the four-week intervention period.

Approximately two weeks after mailing the materials, participants were contacted by telephone to verify receipt of materials and encourage use of the materials as directed. A post-intervention telephone interview was completed four weeks after receipt of materials. Participants received \$30 for each completed assessment, a total of \$60.

Measures

Participants completed a battery of standardized and reliable questionnaires. Except where noted, all measures were completed at baseline and post intervention. The PCa outcomes evaluated in this study are consistent with measures assessed in studies of a similar nature assessing the impact of decision aids are well linked with the DSF model [12, 27–30].

PCa screening knowledge was measured using 13 PCa statements with response options of true, false, or not sure [34, 35]. One point was assigned for each item answered correctly (range 0–13). Cronbach's alpha within this sample was 0.63.

Decisional conflict was measured using the 16-item Decisional Conflict Scale [36, 37] with Likert response options ranging from 1 (strongly agree) to 5 (strongly disagree). Total scale range was 16 – 80. Lower scores represent lower decisional conflict. Cronbach's alpha within this sample was 0.88.

PCa-related distress was measured using the 15-item Impact of Events Scale [38, 39] with weighted response options: not at all=0, rarely=1, sometimes=3, or often=5. Total scale range 0–75, higher scores represent higher distress. Cronbach's alpha within this sample was 0.88.

Satisfaction with PCa screening decision was measured only at post-intervention with a PCa adaption of the 6-item satisfaction with decision scale [29, 40] using Likert response scale ranging from 1 (strongly disagree) to 5 (strongly agree). Total score range 6–30, higher scores represent higher satisfaction with screening decision. Cronbach's alpha within this sample was 0.95.

Intervention use assessed completeness of use of intervention materials (all of it, part of it, not used at all) for both intervention groups. Participants were asked to complete a study-specific diary/log to record intervention use (first and last date of use, date and time of subsequent use, material(s) used, sections reviewed). During the post interview, participants were asked if they used the materials, whether materials were useful in decision making, and PCa screening decision made [1) plan to have a screening test, 2) do not plan to have a screening test, 3) plan to discuss with doctor and then decide, or 4) not sure what to do] as a result of using the materials.

Demographic data collected at baseline consisted of date of birth, country of birth, marital status, race/ethnicity, education, employment status, health insurance, annual household income, prior screening behavior, and family history of PCa.

Materials

The FDR targeted intervention included a FDR targeted decision aid DVD titled “Deciding about PC screening: A family matter” and a CDC booklet titled “Prostate cancer screening: Decision guide” [41, 42]. The DVD, produced by the authors, was informed by formative research findings from PCa patients and FDRs. Details about the intervention development and content are reported elsewhere [23]. In brief, the targeted 12 minute DVD addresses multiple concurrent risk factors, deconstructs information about the PCa screening debate, and provides a balance of understandable and visually engaging information (pros/cons) to aid FDRs in their understanding of the controversy. The targeted decision aid also includes step-by-step guidance to help FDRs bring up the topic of PCa screening to their family members and health care providers, illustrated by examples from PCa survivors and FDRs [23].

The CDC PCa screening decision booklets include two easy-to-read booklets, organized in question and answer format, designed to help a man decide whether screening is right for him [41, 42]. The first booklet is for the general population and was distributed to White participants. The second booklet is for Black males and was distributed to Black participants. Participants randomized to the FDR targeted intervention group received it along with the DVD materials described above.

Statistical Methods

This pilot study was underpowered for hypothesis testing of effect sizes less than medium-large. The goal was to yield effect size estimates to facilitate planning of the next larger trial. A small to medium effect size (Cohen's d from 0.2 to 0.5) [43] in this study was considered sufficient evidence to support further studies of efficacy.

Intervention group differences on demographic and PCa screening related variables at baseline were tested using t-tests techniques. Statistically significant variables ($p < 0.05$) were to be included as control variables in the primary analyses. The primary analyses of the continuous self-report outcome measures were performed using a mixed-design ANOVA with time (pre- and post-intervention) as the within-subject variable and intervention group as the between-subject variable. A group difference in intervention response is reflected in a significant time-x-group interaction. An overall effect of intervention would be reflected in a main effect for time. A t-test was used to examine post intervention group differences for satisfaction with decision. Finally, exploratory analyses examined demographic and screening-related variables as predictors of pre-to-post change or post-intervention levels for the primary outcomes. All statistical tests were 2-sided with alpha set at .05.

Results

Approximately 1,792 PCa survivors were contacted to refer FDRs for study participation. Among the PCa survivors, 965 (54%) did not respond to three requests to recommend a FDR for study participation. The response yield for the remaining 827 PCa survivors (46%) varied: 453 did not have an eligible FDR, 155 declined to recommend an FDR, 35 were ineligible to recommend an FDR, 5 were deceased, and 179 PCa survivors recommended 227 FDRs for participation.

As shown in Figure 1, 249 FDRs were recruited to participate; 227 (91%) nominated by PCa survivors and 22 (9%) recruited directly from the community. Of the 249 FDRs, 109 (44%) did not respond to our invitation to join the study. 140 men were assessed for eligibility, ultimately 93 FDRs completed baseline data. Eight men were siblings of FDRs already in the study. These men were assigned the same condition as their randomized sibling and excluded from analysis. Eighty-five eligible FDRs were randomized ($n = 42$ targeted and $n = 43$ standard). Seventy-eight participants ($n = 39$ targeted and $n = 39$ standard) with complete baseline and follow-up data were analyzed. Participant attrition did not differ significantly by group allocation.

Descriptive data on demographics and PCa screening history at baseline are presented in Table 1. There were no statistically significant intervention group differences. Therefore, no control variables were added to the primary analysis. The mean age for the entire sample was 54 years and the majority was married, White, employed full time, college educated, and had health insurance. More than half reported having a father with PCa, as opposed to a brother with PCa. Approximately 70% of men reported prior history of DRE and/or PSA testing before study participation.

Intervention Comparisons

Table 2 presents primary outcomes PCa knowledge, PCa related distress, PCa decisional conflict, and satisfaction with PCa screening decision post intervention. There were no significant intervention group differences (main effects or significant interactions) suggesting no differential impact of the targeted intervention. Estimates of effect sizes (Cohen's *d*, positive for targeted over standard) were $-.10$ for knowledge, $.04$ for distress, $.28$ for decisional conflict, and $.34$ for satisfaction with decision. In other words, the targeted intervention relative to the standard intervention has an estimated small-medium effect on decisional conflict and satisfaction, but essentially no effect on knowledge or distress in this pilot.

Changes in Primary Outcomes

For the three primary outcomes with pre- and post-intervention assessments, there was a significant increase in PCa knowledge and decrease in decisional conflict (P 's $< .0001$). There was no significant change in PCa distress.

Predictors of change in PCa knowledge and decisional conflict were explored. Increases in PCa knowledge were greater for younger men ($b = -0.08$, $p = .011$), men having a father (versus brother) diagnosed with PCa ($b = 1.34$, $p = .024$), and men who reported a previous PCa screening within the past 5 years ($b = 1.16$, $p = .055$). Decreases in decisional conflict were greater for younger men ($b = 0.26$, $p = .005$) and men who were employed full-time (versus all other employment status categories; $b = -3.55$, $p = .045$). Given the likely correlation among these predictors, backward stepwise regression was used to assess whether or not the above variables would better predict changes in PCa knowledge and decisional conflict. Results showed that age was the single most important predictor of the increase in PCa knowledge and the decrease in decisional conflict.

Secondary Outcomes

Racial differences by intervention group were explored. There were no significant differences by race/ethnicity on PCa screening related outcomes by intervention group. Within the pooled sample, combining men from both intervention groups, separated by race/ethnicity, racial differences were found related to PCa distress. That is, Black men reported higher PCa distress ($M = 10.4$, $SD = 10.1$) compared to White men ($M = 5.4$, $SD = 6.9$) at post intervention.

Intervention Usage

Intervention usage was high and comparable in both intervention groups. Men randomized to the FDR targeted intervention were asked to read the CDC booklet and view a FDR targeted DVD. Majority of FDRs (95%) in both conditions read the entire CDC booklet. Majority of FDRs randomized to the targeted FDR intervention watched the entire DVD (84.6%), while 11% watched some of it and 5% did not watch any of it. The primary reason for not watching any or some of the DVD was lack of time. Among those who watched the DVD, 78.9% planned to undergo PCa testing, 15.8% wanted to discuss testing with their physician, and 5.3% were unsure what to do. For those completing the standard

intervention, 82.1% planned to undergo PCa testing, 13.0% wanted to discuss screening with their physician, 2.5% did not plan to take the test, and 2.5% were unsure what to do.

Discussion

The current study investigated the impact of an FDR targeted decision aid on IDM among unaffected male FDRs of PCa survivors. The study also explored decision aid population subgroups based on race/ethnicity. Contrary to our hypothesis, a FDR targeted decision aid was not associated with improved PCa screening related outcomes compared to a standard decision aid. In addition, racial subgroup analysis by intervention group did not reveal significant differences in PCa screening related outcomes. Previous studies have investigated the efficacy of PCa decision aids and found no significant group differences for knowledge [44], decisional conflict [13, 31, 32, 44, 45], distress[31] or satisfaction with decision [27].

The lack of significant difference between intervention groups may reflect the small sample size, the homogeneity of the sample, or both intervention groups having received a decision aid. Our data suggest that a larger scale study sufficiently powered to detect small to medium effect sizes (.20 to .40) may demonstrate intervention group differences. More importantly, the fact that both groups received PCa screening decision making information (standard vs targeted for FDRs) diminishes effect sizes compared to a control group receiving no information or information on a different topic.

This pilot trial did however, find clinically meaningful changes ($>.5$ standard deviation)[46] in PCa knowledge and decisional conflict over time. FDRs knowledge scores increased and decisional conflict scores decreased across time in both intervention arms. The comparable changes in decisional conflict and knowledge for both groups suggest the FDR targeted decision aid is acceptable and meaningful to FDRs. The benefit of the decision aids on knowledge and decisional conflict is consistent with other studies that found reduced decisional conflict [14, 27, 33] and improved knowledge [14, 27, 32, 33, 47] among asymptomatic predominately average risk men.

FDRs are primed for PCa screening IDM education as evidenced by a significant increase in the PCa knowledge and decrease in decisional conflict. FDRs in this study had unmet information needs and desired more information about IDM processes and screening options. The information presented in both the FDR targeted and standard decision aids, may work to help men validate their thinking about PCa and possibly lead to increased IDM or shared decision making with their healthcare provider. This may be especially true in younger men. It is possible that the greater increase in PCa knowledge and decrease in decisional conflict in this group may be due to younger men's belief that their newly acquired knowledge may facilitate their ability to make a good PCa screening decision and thus reducing their decisional conflict. The associations between knowledge and FDR status and previous screening are unclear. However, it is possible that greater changes in knowledge among FDRs with a father versus a brother diagnosed with PCa may reflect greater perceived risk and readiness to learn about IDM. Similarly, knowledge changes in men with a history of prior screening may be related to greater interest in IDM.

Our study found no significant temporal effects of the decision aid on PCa distress, consistent with other studies [31, 48]. However, PCa distress was higher for Black men compared to White men. These findings may be due to perceived multiple concurrent PCa risk factors.

Intervention usage in this study was high and comparable in both intervention groups. While no statistically significant differences were identified, the targeted intervention tended to promote more IDM (as indicated, for example by a higher proportion planning to discuss with their physician).

Limitations of this study are acknowledged. The generalizability of the study is limited because of the small sample size, potential self-selection bias, and majority were highly educated and had a previous history of screening. In addition, this study did not include other measures of IDM such as the consistency of screening decision with personal beliefs and values [49]. Thus the lack of significance may be due to unknown decision making needs that were not measured. Measures used in this trial relied on self-report data, data that may reflect response bias.

Despite these limitations, this study is novel in many respects. This randomized pilot trial, to our knowledge, is the first to investigate the efficacy of an FDR targeted decision aid intervention for PCa screening IDM among FDRs in the U.S., taking into account both family history and race/ethnicity. Decision aid tools that can be shared between patients and their unaffected FDRs may provide a pragmatic approach to IDM.

Additional understanding of the impact of decision aids on PCa IDM can provide significant guidance for future decision aid studies and translation of decision aid studies into community and clinical practice. An important research question still remains however, whether general or targeted decision aids produce comparable outcomes among FDRs as well as in men with no family history of the disease. That is, would a single decision aid suffice for all risk levels, potentially simplifying logistics of dissemination in clinic and community settings? Future research should include a larger sample, more racial-ethnically diverse men, and greater diversity in terms of educational levels and socioeconomic status. It is possible that men with more limited literacy skills could benefit more from a targeted intervention that is in a DVD vs. print format. A larger and more racial-ethnically diverse sample can help to explore how the decision aid might help address disparities. The trends found for increases in knowledge, decreases in decisional conflict and tendency towards more IDM in targeted intervention support the need for further testing. This study yielded effect size estimates (Cohen's *d*) for the targeted intervention (e.g., decisional conflict and satisfaction with decision) that will guide design of a future larger scale comparative study.

Conclusion

Given the ongoing debates and screening controversy about the benefits of asymptomatic screening for PCa, it is important to further understand the process and outcomes of IDM interventions in this population. Studies that include targeted IDM decision aids can offer important guidance for translation of research findings into community and clinical practice.

This study produced a meaningful targeted decision aid for FDRs and highlights that decision aids (general and targeted) can play an important role in increasing knowledge and decreasing decisional conflict among FDRs, particularly those who are younger.

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Abbreviations

PCa	Prostate Cancer
FDR	First Degree Relative
IDM	Informed Decision Making
CDC	Centers for Disease Control and Prevention
NCI	National Cancer Institute

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Fig 1.
Consort Flow Diagram

Table 1

Descriptive data (percentages) on demographic, social, and medical variables at baseline in the total sample and by intervention group (N=78)

Variable*	All (N=78)	FDR Targeted (N=39)*	Standard (N=39)*
Age(Years): M (SD)	53.9 (8.9)	53.4 (9.1)	54.4 (8.9)
Range: (Years) ^I	41–70 ^I		
Race/Ethnicity: %			
Black/non-Hispanic	26.9	25.6	28.2
White/non-Hispanic	73.1	74.4	71.8
Born in United States: %	92.3	92.3	92.3
Education: %			
Some College/Technical School or less	46.2	48.7	43.6
College Degree or more	53.8	51.3	56.4
Married or Living Together: %	69.2	74.4	64.1
Employed Full-time: %	61.5	56.4	66.7
Annual Household Income: %			
Less than \$20,000	11.5	12.8	10.3
\$20,000 – \$59,999	16.7	7.7	25.7
\$60,000 – \$99,999	21.8	23.0	24.3
Greater than \$100,000	32.1	30.8	33.3
'Prefer not to answer' ^I	17.9	25.6	10.3
Has Health Insurance: %	85.9	84.6	87.2
Father had PCa (versus brother): %	59.5	57.9	61.1
Additional Non-FDR family member had PCa: %	14.1	15.4	12.8
Past prostate specific antigen test: %	70.5	69.2	71.8
Past digital rectal exam: %	73.1	76.9	69.2

* No statistically significant differences found between intervention groups ($p > .05$).

^I Age ranges from 41–70 for entire sample and both groups.

Table 2
Means and standard deviations for pre- and post-intervention measures of primary outcomes

Primary Outcome	All Participants		FDR Targeted Intervention		Standard Intervention	
	Pre	Post	Pre	Post	Pre	Post
PCa Knowledge	5.7 (2.5)	7.4 (2.6)*	5.6 (2.7)	7.2 (2.3)**	5.8 (2.4)	7.6 (2.9)**
PCa Distress	8.6 (11.0)	6.8 (8.1)	9.0 (10.9)	7.0 (8.0)	8.1 (11.3)	6.5 (8.3)
Decisional Conflict	34.7 (9.0)	30.3 (7.8)*	36.3 (8.4)	30.8 (7.4)+	33.2 (9.4)	29.8 (8.1)+
Satisfaction with Decision	--	24.7 (4.3)	--	25.4 (2.9)	--	24.0 (5.4)

* Statistically significant changes pre vs post, p<.0001

** Statistically significant changes pre vs post, p<.001

+ Statistically significant changes pre vs post, p<.02