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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.

1. 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

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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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 to 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 (under the "Materials" section). 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 a 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.

2. Methods

2.1. 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.

2.2. Recruitment

FDRs were recruited through either referral by PCa survivors or through community-based initiatives (see Fig. 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.

2.3. 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