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Effects of a randomized trial comparing standard and enhanced counseling for men at high risk of prostate cancer as a function of race and monitoring style

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Abstract

Despite conflicting guidelines, a significant subset of high-risk men decide to undergo routine prostate cancer screening. Yet, there is a scarcity of available programs, and no studies evaluating interventions to support men in dealing with the psychosocial impact of screening. In this study, one of the first to explore the responses of high-risk men enrolling in a Prostate Cancer Risk Assessment Program ($N = 128$), patients underwent a prostate cancer risk counseling visit immediately followed by either a cognitive–affective preparation session designed to help them process the information they received or a general health education session. All men in this self-selected sample chose to participate in prostate cancer screening. Men were assessed 3 weeks and 6 months post-counseling. The impact of the enhanced counseling condition on knowledge, perceived risk, expectancies, and intrusive ideation was a function of racial and coping style group. Implications for tailored interventions to maximize preparedness for risk and screening counseling are discussed.

Keywords

African-American men; cognitive outcomes; intrusive ideation; monitoring; prostate cancer screening

Introduction

Current guidelines by the US Preventive Services Task Force (2012) do not recommend routine prostate cancer (PCa) screening, even for high-risk groups, including men with a

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family history of PCa and African-American (AA) men, who bear a disproportionate burden of PCa disease (Park et al., 2015). Other organizations continue to recommend screening be discussed with men from high-risk groups (American Cancer Society, 2015; National Comprehensive Cancer Network, 2015). As a result, some high-risk men still choose to undergo risk counseling and screening (Jemal et al., 2015; Pucheril et al., 2015).

AA men bear a disproportionate burden of PCa (Park et al., 2015), yet are less knowledgeable than Caucasian men about PCa issues (Barber et al., 1998). They also tend to underestimate their risk (Hemmerich et al., 2013; McDowell et al., 2009) and hold more negative beliefs and expectancies regarding the preventability and severity of the disease (Allen et al., 2007; Fearing et al., 2000). Caucasian men with a family history of prostate cancer, who are also at elevated risk, tend to overestimate their risk (Bratt et al., 2000; Miller et al., 2001) and experience higher levels of distress (Taylor et al., 1999). Similarly, a qualitative study of younger Caucasian men (between the ages of 30 and 55 years) reported limited knowledge about PCa and screening procedures (Grogan et al., 2015).

The Cognitive-Social Health Information Processing (C-SHIP) model delineates the cognitive and affective factors involved in processing and acting on health threats, notably, knowledge, perceived risk, expectancies, and distress (Miller et al., 1996). For example, Miller et al. (2001) showed that first-degree relatives of PCa patients are characterized by a distinctive psychological profile, notably a high perceived risk and the belief that the disease is not preventable. The model also identifies the extent to which individuals attend to and amplify ambiguous, potentially threatening health information (high monitoring), or the degree to which they distract from and attenuate potentially threatening cues (low monitoring) (Miller, 1995; Roussi and Miller, 2014). Because high monitors tend to focus on threat, they tend to seek more information, they are typically more knowledgeable, they tend to hold negative beliefs regarding the nature of the threat, and they experience more distress. Specifically, high monitors have been found to be more likely to be interested in genetic testing for PCa (Cowan et al., 2008; Culler et al., 2002), to undergo PCa screening (Consedine et al., 2006), and to report higher perceived risk (Culler et al., 2002). Low monitors show the reverse pattern in that they experience less distress, they are less likely to hold negative beliefs, they are less knowledgeable, and they are more dissatisfied when they are provided with voluminous information, presumably because it undermines their avoidant coping style. Therefore, high and low monitors have distinct cognitive–affective reactions to risk notification and thus preparatory interventions may have a differential impact on them (Miller et al., 1996).

Aims of the study

The goal of this study was to explore the psychosocial impact of an enhanced counseling intervention, cognitive–affective preparation (CAP), specifically designed to facilitate the processing of risk feedback through role-play and “pre-living” the receipt of PCa screening results (Miller et al., 2005; Roussi et al., 2010), compared to that of a time and attention control, general health education (GHE), intervention. Since CAP allows for fuller processing of the potential outcomes of screening in depth (Shoda et al., 1998), we hypothesized that participants who received CAP would (a) be more knowledgeable than

those who received GHE and (b) report less intrusive ideation than those who received GHE. In addition, we explored the impact of the interventions on the following cognitive–affective responses: PCa perceived risk and positive and negative expectancies regarding PCa screening. Finally, we explored whether the effects of the interventions would vary as a function of race and monitoring style.

Method

Study design and institutional review board approval

A parallel, prospective, two-arm (1:1 allocation), randomized controlled design was employed. The ClinicalTrials.gov registration number is NCT02126319. The Fox Chase Cancer Center (FCCC) institutional review board (IRB) approved this study.

Recruitment and study procedures

Participants were recruited from October 1998 through October 2001 from high-risk men enrolled in the Prostate Risk Assessment Program (PRAP) at FCCC. Men were eligible if they (a) were Caucasian, aged 35[1]–69 years, and had at least one first-degree relative or two second-degree relatives (from the same side of the family) with prostate cancer; or (b) were AA and aged between 35 and 69 years, independent of their family history of cancer. Furthermore, participants had to be cancer-free and able to communicate with ease in English. Efforts were made to enhance minority representation. Once an individual contacted the PRAP program, he was asked by clinic staff for their permission to be contacted by a member of the research team. A brief telephone interview was then initiated to determine eligibility, describe the research, and if the man met eligibility requirements solicit interest in participating.

Eligible men who consented to participate were mailed a packet of questionnaires and asked to return the completed packet during their first visit to PRAP (baseline). At this visit, participants took part in a 45-minute group Prostate Cancer Education session led by a PRAP program health educator who provided information and led discussion regarding hereditary risk of PCa, screening options and procedures, treatment options, and preventive health options. Approximately 2 weeks later, each participant met individually with a genetic counselor for approximately 45 minutes and was shown a draft of his family pedigree. The participant's personal medical history was also reviewed and the history of both the maternal and paternal sides of the family was explored as they pertain to cancer risk.

Immediately following the session with the genetic counselor, participants were randomized by a computer-generated randomization list to either the group that would receive CAP or the group that would receive GHE. Group assignment was completed by the data management team. Immediately following the CAP and GHE intervention sessions, participants in each group underwent a digital rectal examination (DRE) and a prostate-specific antigen (PSA) test per clinic protocol. Approximately 2 weeks later, a nurse-

[1]Although age-related eligibility criteria were for both Caucasian and African-American (AA) men to be between the ages of 35 and 69 years, one 34-year-old Caucasian man was included in the study by oversight.

oncologist informed the participant, individually, about his screening results and their implications, and recommended follow-up procedures consistent with the standard of care for prostate cancer risk assessment at the time.

All participants were assessed at baseline, 3 weeks post-intervention (1 week after they received the screening results), and 6 months post-intervention.

Interventions

Research staff who conducted the interventions underwent training and ongoing supervision to ensure fidelity to the protocols, each of which lasted 30–45 minutes.

CAP was designed to facilitate an explicit focus on the perceptions, expectations, and affects that an individual participant might experience following receipt of his screening results and associated information and thus to psychologically prepare for the consequences likely to arise as a result of their potential screening test results. Participants were instructed to anticipate ("pre-live") and role-play their psychological reactions to simulated receipt of a combination of normal PSA and DRE results and separately to receipt of elevated PSA test results and abnormal DRE results, as well as associated follow-up diagnostic and management recommendations based on their results and personal cancer risk. The participant was also provided information to educate him concerning topics related to possible test results, given their risk status.

GHE was designed so that participants received equivalent time, attention, and factual information from research professionals as those participants who received CAP. Specifically, they received information of relevance to men at risk for PCa that focused on recommendations for general health (i.e. diet, exercise, alcohol use, and smoking). GHE participants were also encouraged to freely probe and discuss their own attitudes, beliefs, expectations, and feelings about these topics in an interactive format.

Measures

Sociodemographic variables (racial group, age, education, and marital status) and a *clinical variable* (family history of PCa) were assessed at baseline.

Monitoring attentional style was assessed at baseline using the Monitoring Style Subscale of the Monitoring and Blunting Style Scale (MBSS) (Miller, 1987), which measures attentional responses to four structured stress-evoking scenarios (e.g. going to the dentist). Each scenario is followed by four possible monitoring responses (e.g. "I would ask the dentist exactly what he/she was going to do"). Respondents are instructed to endorse all responses that apply to them. A total monitoring score (range 0–16) was computed for each participant by summing the number of monitoring responses endorsed across the four scenarios. A median split was used to create high (greater than nine) and low (less than or equal to nine) monitoring groups.

Knowledge about PCa risk was measured using an 8-item scale, consisting of face valid true or false items (e.g. "An abnormal DRE and/or PSA could be the result of conditions other

than prostate cancer"). Correct responses received a value of 1 and false responses a value of 0. Scale scores ranged from 0 to 8.

Perceived risk of PCa was assessed using four 5-point Likert response scale items based on our prior work (Miller et al., 1996). Participants were asked to estimate their PCa risk in general (e.g. "Do you feel as though you are the kind of person who is likely to develop prostate cancer?") or to compare their risk of PCa to other men (e.g. "Given your ethnicity, what are your chance of getting prostate cancer?"). Cronbach's alpha in this study was 0.83.

Positive and negative expectancies related to PCa screening were assessed using 5-point Likert response scale items based on our prior work (Miller et al., 1996). Positive expectancies were assessed using two items (e.g. "Regular screening will ensure that I stay healthy" and "Regular screening will prolong my life"). Cronbach's alpha in this study was 0.76. *Negative expectancies* were assessed using five items that addressed the costs and risks of screening, in terms of time and effort, fears of discrimination, insurance and employment, and financial concerns (e.g. "Screening may have a negative impact on my health insurance"). Cronbach's alpha in this study was 0.80.

Intrusive ideation related to PCa risk was assessed using the intrusion subscale of the Impact of Event Scale (IES) (Horowitz et al., 1979). This instrument has been used extensively in the cancer literature (Schwartz et al., 2002). Cronbach's alpha for the subscale in this study was 0.82. Because of high skewness, a median split was used to create high and low groups.

Analytic procedure

The study hypotheses were examined by conducting a series of three-way analysis of covariances (ANCOVA's) separately for the 3-week and the 6-month follow-ups. A custom-made model was used which included the baseline value of the dependent variable, together with the demographic variables found to be significantly related to the dependent variable; intervention group, racial group, and monitoring style;, and two 2-way interactions, one between intervention group and monitoring style and the other between intervention group and racial group. In cases where the covariates were found to be non-significant, the analyses were rerun as analysis of variance (ANOVA) and these results are reported here. For intrusive ideation, a logistic regression analysis was conducted, separately for the 3-week and the 6-month follow-ups, with the same predictors. Degrees of freedom varied because of missing data.

Results

Flow through the trial and participant characteristics

In total, 282 PRAP enrollees were eligible and invited to participate in the study. A total of 52 declined because they were not interested or did not have time to participate. We administered the baseline questionnaire to the remaining 230 eligible participants. Three of these participants were subsequently excluded because they did not provide information regarding their racial group, leaving 227 to be randomized, 113 to the GHE session, and 114 to the CAP session. Due to loss to follow-up, 67 and 61 of the men randomized to GHE and

CAP, respectively, participated in these sessions. In total, 89 men (GHE = 47; CAP = 42) completed the first follow-up assessment at 3 weeks post-intervention and 83 men (GHE = 43; CAP = 40) completed the second follow-up assessment at 6 months post-intervention. Men who dropped out of the study were more likely to be AA, χ^2 (1, N = 128) =6.34, p < 0.01, and to have lower level of education, χ^2 (1, N = 121) = 8.12, p < 0.01. Table 1 shows demographic and clinical variable information by intervention group.

Background analyses

No differences were found among the two groups on demographic variables, family history of cancer, and the dependent variables at baseline. At the 3-week follow-up, age was positively related to intrusive ideation, r = 0.23, p < 0.05. At the 6-month follow-up, age was positively related to perceived risk of PCa, r = 0.24, p < 0.05, and education was negatively related to negative expectancies, r = −0.30, p < 0.01. Age and education were therefore included in the analyses as covariates when relevant. Furthermore, negative expectancies at the 6-month follow-up was negatively related to a family history of PCa, r = −0.49, p < 0.01, and positively related to race, r = 0.37, p < 0.01, that is, AA men reported more negative expectancies. In total, 98 percent of non-AA men had a family history of PCa, but only 42 percent of AA men did, in part due to the criteria for entry into the program.[2] Because race and family history of PCa were highly correlated, χ^2 (4, N = 92) = 37.36, p < 0.01, and because race was of interest as a moderator, we included race in all analyses.

Impact of CAP on knowledge

At the 3-week follow-up, there were no main effects but an interaction effect between monitoring style and intervention group was observed, F(1, 74)=5.87, p<0.05, η^2=0.07 (Table 2). Simple effects tests indicated that low monitors who received CAP were less knowledgeable than low monitors who received GHE. At the 6-month follow-up, again there were no main effects but an interaction effect was found between monitoring style and intervention group, F(1, 71)=5.39, p<0.05, η^2 = 0.07. Simple effects tests showed no significant differences, suggesting that variations in the impact of the intervention as a function of monitoring style was small.

Impact of CAP on perceived risk

At the 3-week follow-up, there were no main effects but an interaction effect between intervention group and race was observed, F(1, 82) = 5.88, p < 0.05, η^2 = 0.07, such that AA men who received CAP reported higher levels of perceived risk than AA men who received GHE (Table 2).

Impact of CAP on positive expectancies

For the 3-week follow-up, there were no main effects but an interaction effect between intervention group and race was observed, F(1, 83)=4.96, p<0.05, η^2 = 0.06, such that Caucasian men who received CAP had less positive expectancies regarding the effects of PCa screening than those Caucasian men who received GHE (Table 2).

[2]Including whether or not AA men had a family history of prostate cancer or whether the result was abnormal did not materially change the results. We did not include these variables in our analyses because of the small sample size.

Impact of CAP on negative expectancies

At the 6-month follow-up, a main effect for race was found, $F(1, 68) = 10.30$, $p < 0.01$, $\eta^2 = 0.13$, in that AA men reported more negative expectancies than Caucasian men (AA men: $M = 2.30$, standard deviation (SD) = 0.60; Caucasian men: $M = 1.90$, $SD = 0.45$). In addition, there was an interaction effect between intervention group and monitoring, $F(1, 68) = 6.55$, $p = 0.01$, $\eta^2 = 0.09$. Specifically, high monitors in the CAP group were more likely to believe that there are costs and risks to screening for PCa, when compared to high monitors who received GHE (Table 2).

Impact of CAP on intrusive ideation

At the 3-week follow-up, the logistic regression model was significant, $\chi^2 = 15.98$, $p < 0.05$. In total, 73 percent of men were classified correctly by the model. There was a main effect for monitoring, odds ratio (OR) = 4.94, $p < 0.05$, 95 percent confidence interval (CI) = 1.16–21.11, such that high monitors were more likely to experience high intrusive ideation. Furthermore, Caucasian men experienced less intrusive ideation than AA men, $OR = 0.25$, $p < 0.05$, 95 percent CI = 0.06–0.95. An interaction effect was observed between intervention group and race, $OR = 7.51$, $p < 0.05$, 95 percent CI = 1.15–49.05. Specifically, Caucasian men who received CAP were more likely to be in the high intrusive ideation group than Caucasian men who received GHE. The reverse effect was observed among AA men.

Discussion

Although the guidelines by the US Preventive Services Task Force (2012) do not recommend routine PCa screening, about a third of men over 50 continue to undergo screening (Jemal et al., 2015). However, there has been virtually no research that has evaluated interventions to support high-risk men in dealing with the psychosocial impact of screening. To fill this gap, this study evaluated a CAP intervention designed to psychologically prepare AA men and Caucasians with a PCa family history, both groups at high risk of PCa, for receipt of screening test results. The main finding of this study is that the impact of the interventions varied as a function of race and monitoring style.

AA men who received CAP reported higher perceived risk than AA men who received GHE, 3 weeks post-intervention. AA men have been reported to underestimate their risk of PCa[3] (McDowell et al., 2009). In this study, CAP may have raised AA men's awareness of PCa risk and this may have led to elevated risk perceptions. In addition, AA men who received CAP experienced less intrusive ideation, whereas Caucasian men who received CAP experienced more intrusive ideation. Thus, even though CAP raised risk perceptions among AA men, this increase was not accompanied by higher risk–related distress. For Caucasian men, who have been found to be more aware of their familial risk (Bratt et al., 2000; Miller et al., 2001), the extended focus on threat in the CAP condition may have resulted in higher distress levels, possibly reflecting their already heightened sense of threat (Watkins and Moberly, 2009). However, it is important to note that overall the men experienced low to moderate levels of intrusive ideation (Taylor et al., 2002).

[3]AA and Caucasian men did not differ on any of the dependent variables at baseline.

Furthermore, among Caucasian men, participants who received CAP reported less positive expectancies about the impact of screening on cancer control than those who received GHE. By encouraging an explicit focus on men's beliefs and expectations regarding the benefits/costs of PCa screening, given their risk, and by probing so as to increase the accuracy of these beliefs, CAP may have resulted in lower expectations among Caucasian men regarding the utility of screening. This finding is consistent with the observation that Caucasian men at familial risk are less inclined to participate in screening following receipt of a decision aid (Evans et al., 2005).

At the 6-month follow-up, among men in both conditions, AA men were more likely than high-risk Caucasian men to report negative beliefs associated with PCa screening. These beliefs included higher fears that they might encounter discrimination as a result of an abnormal screening test result and greater concerns about the time and money required for screening. AA men tend to be mistrustful of the health system, as well as concerned about the cost involved in screening and taking time from work (Allen et al., 2007; Fearing et al., 2000; Griffith et al., 2012). Clearly, these are important concerns and may reflect the realities of the personal and system challenges encountered by AA men.

The second major set of findings relates to the differential impact of the interventions on high and low monitors. Three weeks post-intervention, low monitors who received CAP were less knowledgeable than low monitors who received GHE. Low monitors tend to desire less information than high monitors (Miller, 1995; Roussi and Miller, 2014) and have been reported to fare better with low information messages. Thus, the extended focus on the health threat, as well as the probing of beliefs related to PCa screening entailed in CAP, may have led low monitors to actively block out information about their PCa risk and the implications of the screening feedback. In addition, six months post-intervention, high monitors who received CAP reported more negative expectancies related to PCa screening than high monitors who received GHE. High monitors tend to be more positive toward screening regimens and more likely to adhere to them (Roussi and Miller, 2014). By facilitating high monitors' explicit focus on the benefits and costs of PCa screening, high monitors in CAP may have increased their negative expectancies compared to those in GHE. Finally, high monitors were more likely to experience intrusive ideation than low monitors. In general, high monitors report more cancer-related worries and concerns and cancer-specific distress, such as intrusive ideation, than low monitors (Miller, 1995; Roussi and Miller, 2014).

Given recent studies showing no mortality benefit to screening, the US Preventive Services Task Force now recommends against routine PCa screening, even for high-risk groups, whereas several organizations continue to recommend that providers discuss the pros and cons of screening, especially with high-risk men. The conflicting recommendations have left men at increased risk feeling even more uncertain about the harms and benefits of screening for them personally. Thus, even though this study was conducted prior to the modifications in recommendations, the findings are still directly relevant to the high-risk context, as the question of how to best support high-risk men who decide to obtain screening has, if anything, become more paramount.

There are several limitations to the study. First, with a larger sample size, we might have been able to consider the impact of family history of PCa among AA men and include three-way interactions between racial group, monitoring style, and intervention type. The rather small sample size, combined with the small size-effects of the interactions, means that one should interpret the findings with caution, given the risk of Type I error. A second limitation is the inclusion of only two racial/ethnic groups. Hispanics were not included, and although there are studies showing that they are at lower risk of PCa than Caucasians, they tend to be diagnosed at younger ages (Zhu et al., 2012). Third, the drop-out rate was rather high. Of the original 230 men who consented, 56 percent received one of the two interventions and 39 percent adhered to the first follow-up. Men who dropped out were more likely to be AA and to have a lower level of education. The loss of specific groups of men limits the generalizability of the results. In the future, it will be important to develop tailored interventions to retain the specific groups of men who may be more in need of ongoing support over time.

High-risk men are currently the group most likely to opt to undergo PCa screening (Pucheril et al., 2015), thus intensifying the need to prepare them and support them for the receipt of their results. Consistent with the C-SHIP model, the results of this study demonstrate that a single CAP intervention session has an impact on key cognitive–affective outcomes, including knowledge, perceived risk, positive and negative expectancies, and intrusive ideation and this impact varies as a function of racial group and monitoring style, both important variables to consider when developing preparatory interventions. E-health interventions, including the use of multimedia which allow for *interactive* and *personalized* preparatory programs, may be pertinent to explore in future studies, especially given their potential for dissemination and implementation.

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Table 1

Participant demographic characteristics and family history of PCa.

	Intervention group	
	GHE group (*N* =67)	**CAP group (*N* =61)**
Age (mean, *SD*)	47.61 (8.81)	47.21 (8.86)
Education (*n*, %)		
Less than college	34 (53.10)	29 (50.90)
Some college or higher	30 (46.90)	28 (49.10)
Marital status (*n*, %)		
Married	33 (67.35)	30 (68.18)
Other	16 (32.65)	14 (31.82)
Racial group (*n*, %)		
African American	33 (49.30)	33 (54.10)
Caucasian	34 (50.70)	28 (45.90)
Family history of PCa (*n*, %)		
Yes	38 (80.90)	31 (68.90)
No	9 (19.10)	14 (31.10)

SD: standard deviation; PCa: prostate cancer; GHE: general health education; CAP: cognitive–affective preparation.

Table 2

Interaction effects: estimated mean values and standard deviation (*SD*s) for cognitive–affective variables.

Variable	*M*	*SD*		*M*	*SD*
Knowledge: 3-week follow-up					
Low monitors			High monitors		
CAP	6.57	0.24	CAP	7.24	0.23
GHE	7.37	0.20	GHE	6.94	0.24
Perceived risk: 3-week follow-up					
African-American men			Caucasian men		
CAP	3.46	0.18	CAP	3.00	0.18
GHE	2.75	0.18	GHE	3.14	0.16
Positive expectancies: 3-week follow-up					
Caucasian men			African-American men		
CAP	3.23	0.21	CAP	4.08	0.21
GHE	4.07	0.19	GHE	4.00	0.22
Negative expectancies—6-month follow-up					
High monitors			Low monitors		
CAP	2.34	0.12	CAP	1.97	0.13
GHE	2.00	0.12	GHE	2.24	0.12

M: mean; CAP: cognitive–affective preparation; GHE: general health education.

Significant results are presented on the first column of the table.