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TITLE: Evaluation of a Culturally Targeted, Personalized Mail-Home Brochure Directed to Partners of at-Risk Men to Facilitate Prostate Cancer Risk Assessment

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14. ABSTRACT Prostate cancer is the second leading cause of cancer death in men. Like other cancers, prostate cancer exists in both sporadic and hereditary forms. A family history of prostate cancer and African-American ethnicity are two key factors that have been found to place men at increased risk for developing the disease. However, at-risk men exhibit low levels of prostate cancer risk-related knowledge, despite their increased risk as a group. Prostate cancer risk assessment provides an opportunity to weigh available information and make decisions about screening options; it also provides a window of opportunity to offer concrete instruction in specific prevention behaviors. While there is controversy over the benefits and liabilities associated with prostate cancer screening, there is agreement that at-risk men need to understand the issues related to prostate cancer risk management. Family members can help facilitate health-related behavior and may serve as an important, but underutilized, gateway into the health care system. Thus, guided by the Cognitive-Social Health Information Processing (C-SHIP) model, the current study will evaluate the impact of a communication message intervention tailored to the partners of at-risk men enrolling in prostate cancer risk assessment to facilitate screening adherence.					
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INTRODUCTION

Prostate cancer represents a serious health issue for many men. Higher morbidity and mortality rates in this population may be due, in part, to lack of interest in prostate cancer risk assessment programs, as well as lower adherence to recommended detection and prevention guidelines for high-risk individuals. [1-3] Prostate cancer risk assessment programs provide an ideal opportunity to educate men about their risk status and inform them about the benefits and liabilities associated with available management options. Low participation in these programs suggests the need for innovative intervention message communications that target external channels of support and communication (i.e., spouses/partners). Yet, little information currently exists with respect to the psychosocial factors that facilitate participation in, and adherence to, available prostate cancer risk assessment and screening programs. Further, there are no established intervention protocols to address the needs of this population. Guided by the Cognitive-Social Health Information Processing (C-SHIP) model, [4, 5] the goal of the proposed study is to evaluate the efficacy of an innovative approach to enhancing participation in prostate cancer risk assessment among at-risk men through the use of psychoeducational, mail-home printed material oriented to the spouse/partner, an important support person. The printed material, culturally sensitive to the ethnicity of the at-risk man, provides the partner with structured communication strategies for addressing, in a preventive fashion, the proband's pattern of cognitive-affective barriers to risk assessment (i.e., proband risk-related perceptions; expectancies/beliefs; values/goals; and affect).

The specific aims are as follows:

Aim 1: To explore the efficacy of a partner-directed theoretically-based intervention in promoting prostate cancer risk assessment and knowledge among men at risk for prostate cancer.

Aim 2: investigate the mediating role of theory-guided communication/cognitive-affective factors on participation in risk assessment among at-risk men and their partners.

Aim 3: To explore the moderating role of individual differences in attentional style (i.e., high vs. low monitoring) of the proband, as well as that of the partner, on the impact of the intervention.

In a randomized controlled trial, eligible probands (African Americans/First Degree Relatives with a spouse/partner) who contact PRAP at FCCC (N=300) will be randomized to receive either: 1) Standard Care (SC) alone, consisting of receipt of a pre-appointment, culturally sensitive mail-home patient-based educational video and a pre-appointment reminder call; or 2) SC plus the receipt of a pre-appointment, mail-home psychoeducational brochure directed to the spouse/partner (PBS). We will assess proband participation in the initial PRAP appointment and in the 6-week follow-up session, as well as risk-related knowledge. We hypothesize that men in the PBS condition will display higher rates of participation in risk assessment and greater levels of

knowledge than men assigned to SC, since the intervention prompts the active role of a critical social contact to promote and support health-related behavior.

In this context, the impact of the partner-directed intervention on outcomes is hypothesized to be mediated by changes in the dyad's communication pattern (i.e., frequency/responsibility), as well as by changes in the dyad's individual cognitive-affective processing patterns (i.e., perceived risk; self-efficacy and outcome expectancies; decisional conflict; and level of risk-related distress). These psychosocial mediators will be assessed at baseline (upon entry into PRAP) and at the initial PRAP appointment for attendees or at one-month following the missed appointment date for non-attendees.

We will also explore how monitoring attentional style, for both proband and partner, influences actual participation in prostate risk assessment and risk-related knowledge among at-risk dyads. We expect that high monitors will exhibit a cognitive-affective profile characterized by greater perceived vulnerability to disease, lower expectancies of control, less decisional conflict, and higher levels of risk-related ideation than low monitors.

Study findings will guide the future design of tailored interventions by identifying the psychosocial mediators and moderators that underlie effective risk communication between the proband and the critical support person. Results will be relevant to other cancer contexts where the risks are personal, probabilistic, and preference-based. The intervention is designed to be easily transportable and readily disseminable, providing outreach to critical support persons of at-risk individuals. Overall, this study will provide important data for implementing prostate cancer health-promotion interventions for all men on a broader scale.

BODY

As outlined in our Statement of Work we have listed six tasks to accomplish for this study. Below are detailed descriptions of the tasks and sub-tasks we have completed in previous years including the tasks and sub-tasks that were carried out over the past year:

Task 1 involved submitting the protocol for approval, and finalizing all study materials. We subdivided this task into the following sub-tasks:

- a. Submit Protocol to Institutional Review Boards (FCCC and DOD)
- b. Convene with Consultants
- c. Revise, Finalize and Partner Brochures
- d. Finalize Baseline and Follow-up Measures

Task 2 involved developing a system for participant tracking, data collection (i.e., a Computer Assisted Telephone Interview), and data entry. We subdivided this task into the following sub-tasks:

- a. Establish a participant tracking system that is coordinated with PRAP tracking methods.
- b. Develop a Computer Assisted Telephone Interview (CATI) system for collection of proband and partner assessments
- c. Train research staff in study-specific consent process
- d. Provide CATI training
- e. Review procedures for on-site informed consent and interview processes

Task 3 involves study recruitment and data collection. Recruitment into the main study has begun, which includes consenting both proband and spouse/partner into the study. Once consented, each would be sent their respective materials (standard care materials, and/or psychoeducational brochure, if assigned to the intervention condition). We subdivided this task into the following sub-tasks:

- a. Enroll eligible probands into the study
- b. Consent and complete baseline assessment
- c. Send them the Standard Care materials
- d. Consent and complete baseline assessment for spouse/partner
- e. Send them the psychoeducational brochure (if assigned to intervention condition)

To date, we have completed all sub-tasks from *Task 1* and *Task 2* of the overall project. The sub-tasks of *Task 3* have been implemented. We have met with personnel from the Prostate Cancer Risk Assessment Program (PRAP) to facilitate more efficient patient identification and referral into the study. Overall, enrollment into PRAP has been lower than anticipated, thus our pool of eligible couples is also smaller. We have enrolled 2 dyads (PRAP participants and their spouse/partner) into the study. Last year we planned several changes to the overall procedure and recruitment method to increase accrual. Below is a summary list of those proposed changes that we considered submitting as an amendment:

1. Revising the main study outcome. Our original outcomes were participation in the initial and 6-week risk feedback appointments. Our revised primary outcome would be adherence to the participant's designated follow-up appointment. The scheduling of follow-up appointments would depend on the risk feedback information PRAP participants receive from their 6-week follow-up. Study participants would be recruited at the initial PRAP appointment.
2. The "Standard Care" condition would be changed to include the PRAP informational brochure and would no longer include the pre-appointment materials (i.e., educational video and reminder call) since the study participants would have already received these materials in advance of their initial appointment. In the intervention condition, the spouse/partner would continue to receive the partner-focused brochure, in addition to Standard Care.
3. The assessment schedule of the mediating/moderating variables would include the following time points: (1) initial PRAP appointment; (2) 5-weeks [pre-risk feedback; (3) 12-weeks [post-risk feedback]; (4) follow-up appointment (i.e., 6-

- or 12-months) depending on recommendations from the risk feedback information.
4. We would plan to assess the impact of the risk feedback information on study outcomes. We would predict that men who receive “abnormal” test results would display higher rates of participation, more communication with their spouse/partner and more risk-related knowledge at the follow-up appointment time point.

We anticipated these changes to be timely because the Prostate Risk Assessment Program was making significant changes to its appointment procedures. For instance, one of our study outcomes was to measure the impact of the Psychoeducational brochure on participation/adherence to PRAP appointments at baseline and at the 6-week risk feedback visit. The 6-week risk feedback appointment was no longer an in-clinic visit as one of the PRAP’s changes. PRAP decided to mail test results and other information directly to the participant.

Future Plan

Reviewing the above proposed amendment our team along with the consultation of PRAP decided to devise a more effective amendment. While reviewing the results of recruitment for this study through the PRAP clinic the effectiveness of probands providing recruitment of their spouse/partner was not feasible. Due to this deficit in the recruitment plan, we are proposing to use the Knowledge Networks, a full-service research provider with capabilities for customer Internet surveys, public policy and attitudinal research, concept and segmentation research, moderated online focus groups, market sciences and analytics, and statistical weighting and estimation, which has been utilized by other studies in our department and shown positive effectiveness. The KN Panel, recruited randomly through Random Digit Dialing, represents the broad diversity and key demographic dimensions of the U.S. population and provides the only probability sample of U.S. households that participate in a research panel using the Internet. The web-enabled panel tracks closely the U.S. population on age, race, Hispanic ethnicity, geographical region, employment status, and other demographic elements. The current web-enabled research panel consists of approximately 40,000 adults actively participating in research. KN will recruit participants; provide study description and informed consent to the potential participants; provide stratification/randomization of participants; provide the assessments to the participants; and, manage and provide us with the data set.

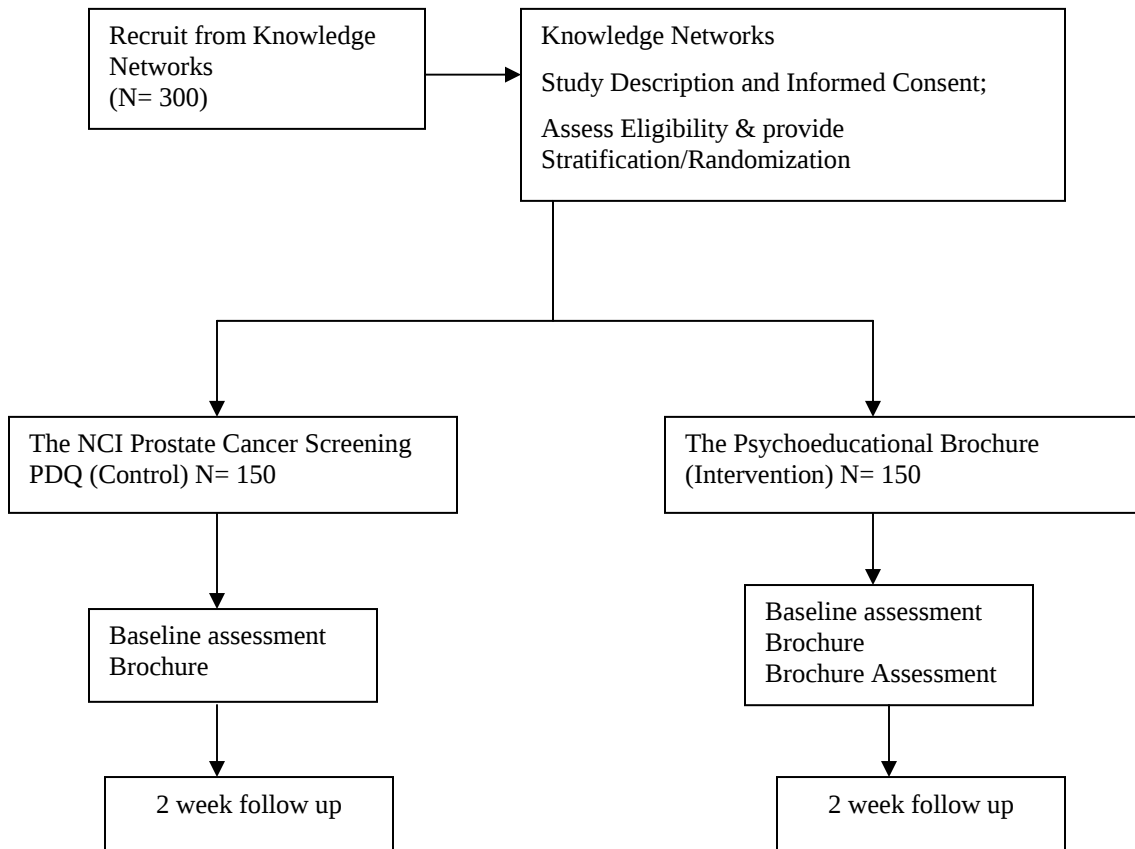
Below is a summary list of those proposed changes that we will be submitting as an amendment:

1. Biostatistician, Samuel Litwin, Ph.D., has been removed because he is no longer affiliated with this study. Brian Egleston, Ph.D. will be added to the study as the biostatistician
2. Joanne Buzaglo, Ph. D., has been removed because she is no longer affiliated with this study. Kuang-Yi Wen, Ph.D. will be added to the study as the Co-Investigator
3. Participants will be recruited from the Knowledge Networks (KN) Panel:

Fox Chase Cancer Center will provide KN with the Informed Consent documents needed for participants to be entered in to the study. The KN will provide the participants, describe the study plan and informed consents to the potential participants; assess eligibility and provide stratification/randomization. Participants will be randomized to one of two arms: 1) Standard Care (SC), consisting of on-line access to the NCI's Prostate Cancer Prevention PDQ; or 2) the intervention consisting of the on-line Psychoeducational Brochure, designed for the spouse/partner (PBS). The brochure has been developed to educate the spouse/partner about the man's risk status and to outline communication strategies to promote risk-related actions on the part of the partner/spouse.

Assessment of the initial spouse/partner on-line review of the Psychoeducational Brochure assessing time spent and section(s) visited are the primary outcomes, with level of risk-related knowledge a secondary outcome. Background variables and attentional style will be assessed at baseline for spouses/partners in both the Standard Care and Intervention groups. Cognitive-affective mediators and risk-related communication variables will be assessed at baseline and at two weeks post on-line brochure review. To facilitate examination of the brochure's impact on the participants' risk behavior, we will also assess the proband's history of screening, their intention for initial screening and their adherence to screening at both the Baseline Assessment and their 2-week Follow-up Assessment.

Below is a flowchart demonstrating the proposed study design:



New proposed aims for the study will be as follows:

1. To explore the efficacy of a partner-directed theoretically-based intervention in promoting prostate cancer risk assessment and knowledge among spouses/partners of men at risk for prostate cancer.
2. To investigate the mediating role of theory-guided communication/cognitive-affective factors on participation in risk assessment among spouses/partners of men at risk for prostate cancer
3. To explore the moderating role of individual differences in attentional style (i.e., high vs. low monitoring) of the spouse's/partner's influence, on the impact of the intervention.

Eligibility Criteria:

1. able to communicate with ease in English
2. competent to give consent
3. spouse/partner of an African American male above the age of 35
4. spouse/partner of any man with a First Degree Relative (FDR) with a Prostate Cancer diagnosis

Exclusion Criteria:

1. proband has prostate cancer history
2. proband has had prior pelvic irradiation
3. has an inability to communicate with ease in English
4. has an inability to give consent

Below are the proposed specific tasks to be accomplished in the context of this project:

Task 1 involved submitting the protocol for approval, and finalizing all study materials. We subdivided this task into the following sub-tasks:

- a. Submit Protocol to Institutional Review Boards (FCCC and DOD)
- b. Convene with Consultants
- c. Revise, Finalize and Partner Brochures
- d. Finalize Baseline and Follow-up Measures

Task 2 Interim Analyses

We subdivided this task into the following sub-tasks:

- a. Perform interim statistical analyses of data obtained from KN
- b. Prepare annual progress reports
- c. Convene with research team and consultants to discuss preliminary findings

Task 3 Final Analyses and Report Writing

We subdivided this task into the following sub-tasks:

- a. Conduct final data analyses
- b. Compose final progress report
- c. Prepare manuscript/professional presentations of results
- d. Discuss plans for dissemination of existing results and extension of study aims (e.g., to inner-city groups)

Currently, preparation of the proper documents for submission of the above-mentioned amendment to the FCCC IRB and DOD's IRB is underway.

KEY RESEARCH ACCOMPLISHMENTS

- Enrolled 2 dyads (PRAP participant and spouse/partner) into the study
- Submitted an amendment to the Fox Chase Cancer Center Institutional Review Board requesting approval to remove the Phase I Focus Groups. Approval from the FCCC IRB was received on 4/17/2007. Official approval from the DOD was received on 10/4/2007. The amendment was removed Co-investigator, Deborah Watkins-Bruner Ph.D., because she is no longer affiliated with this study and added Veda Giri, MD as a co-investigator.
- An on-going/continuous review was submitted on 10/14/2008. This review was revised and resubmitted on 11/3/2008. We are currently awaiting approval.
- Preparing the proper documents for submission of amendments to the Fox Chase Cancer Center's IRB to alter study protocol addressing the addition of the Knowledge Networks piece with the intention of enhancing study accrual.

REPORTABLE OUTCOMES

To date, there are no publications to report.

A poster presentation of this study was presented at the first annual Innovative Minds in Prostate Cancer Today (IMPACT) meeting hosted by the U.S. Army Medical Research and Material Command from September 5-8th, 2007.

CONCLUSION

Progress has been made toward reaching delineated study goals. However, in order to address adding the Knowledge Networks piece to enhance study accrual we are actively revising the study protocol. An amendment will be submitted to the Fox Chase IRB. Efforts are underway to bring this study up to date, as outlined earlier. Once amended changes have been approved, we anticipate no further obstacles in conducting the study

and foresee no further delays in the progress of this project. We expect that we will achieve our overall recruitment goals and successfully complete the study as outlined.

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