

Navigator-guided e-Psychoeducational Intervention for Prostate Cancer Patients and Their Caregivers

B. Lee Green, PhD¹, Brent J. Small, PhD², Jennifer Damonte, MA¹, Janelle Barrera Ikan, BS¹

¹ Moffitt Cancer Center, Tampa, FL

² University of South Florida, Tampa, FL

PCORI ID: CE-12-11-5285

HSRProj ID: 20142240

ClinicalTrials.gov ID: NCT02186444

To cite this document, please use: Green L, Small, B, Damonte J., et al. 2019. *Navigator Guided e-Psychoeducational Intervention for Prostate Cancer Patients and Their Caregivers*. Washington, DC: Patient-Centered Outcomes Research Institute (PCORI). <https://doi.org/10.25302/1.2019.CE.12115285>

Table of Contents

ABSTRACT	3
BACKGROUND	5
Participation of Patients and Other Stakeholders	13
SPECIFIC AIMS	14
METHODS	15
Study Design	15
Setting and Sample	15
Moderating Variables	16
Mediating Variables	17
Outcome Variables.....	18
Accrual	19
Baseline Assessment and Randomization.....	20
Experimental Conditions.....	20
Control Condition: Usual Care and Information Booklet.....	21
Intervention Period.	21
Follow-up Assessments.	22
Analytical and Statistical Approaches	22
Statistical Analysis.....	23
RESULTS	25
Demographic Characteristics	25
CONSORT Diagram	26
Aim 1. Longitudinal Changes in Patient and Caregiver Outcomes	28
Aim 2. Mediation Analyses of PHIN Intervention Effects	29
Aim 3. Moderation of PHIN Intervention Effects.....	30
Aim 4: Evaluate the Stakeholder Engagement and VOI Prioritization Process	34
DISCUSSION	31
Context for Study Results.....	31
Aim 1. Longitudinal Changes in Patient and Caregiver Outcomes	32
Aim 2. Mediation Analysis of PHIN Intervention Effects	33
Aim 3. Moderation of PHIN Intervention Effects.....	33
Generalizability of the Findings	33
Implementation of Study Results	33
Subpopulation Considerations.....	34
Study Limitations	34
CONCLUSION.....	35
REFERENCES	36

Abstract

Background. Newly diagnosed prostate cancer patients are often faced with choosing among a range of treatments. The treatments have a similar 10-year prognosis but with varying impacts on quality of life. Patients who are deciding among treatment options often do not have the amount of information they need. Relevant and appropriate information may be lacking to help men and their caregivers make the best decisions. This study was designed to address the gap in information. We developed a tablet-based interactive knowledge model of prostate cancer to provide personalized and patient-centered information on treatment and outcomes for patients and their caregivers.

Objectives. The 3 aims of this community-based randomized control trial were as follows:

- To evaluate the impacts of providing newly diagnosed prostate cancer patients and their caregivers with a tablet-based interactive application called the Prostate Health Information Navigator (PHIN™) delivered by a community navigator (CN) or providing a National Cancer Institute (NCI) information booklet delivered by a CN. We measured the impacts according to patient outcomes (decisional satisfaction, quality of life, knowledge, decisional self-efficacy, and decisional conflict) and shared decision-making practices (the patient's satisfaction with his preparation for treatment decision making and involvement in such decision making).
- To investigate the mechanism by which the PHIN affected patient and caregiver outcomes and shared decision making.
- To identify men who are most and least likely to benefit from the PHIN.

Methods. We enrolled 191 dyads, and 179 dyads were randomized to 1 of 2 conditions: (1) a tablet-based application (PHIN) delivered by a CN, or (2) an NCI information booklet delivered by a CN. The dyads were recruited from the Moffitt Cancer Center in Tampa, Florida, and from local clinics. Eligible dyads provided informed consent and completed a baseline interview that included the primary and secondary outcome measures as well as potential mediators and moderators. They were contacted for follow-up assessments at postintervention (6 weeks), post-medical consultation (if applicable), 6 months, and 12 months. We evaluated whether

variables such as educational attainment, income, race/ethnicity, and comorbidities score interacted with changes over time that could be attributed to the intervention.

Results. This study did not find any advantage to using the PHIN rather than the standard printed NCI prostate cancer information: Patient and caregiver outcomes were the same in both study arms. However, some findings were of interest. Overall, both patients and caregivers benefited from education, as evidenced by significant gains in Satisfaction with Decision Scale (SWDS) scores ($p < .05$). Caregivers learned more about prostate cancer with the PHIN than with the NCI booklet. Patients' prostate cancer knowledge was strongly correlated with their preparedness to make treatment decisions, and this preparedness was correlated with decisional satisfaction.

Conclusion. Compared with the baseline, caregivers (but not patients) showed statistically significant improvements in the Prostate Cancer Knowledge Questionnaire. Patients and caregivers both experienced significant gains in the SWDS. Neither group experienced significant improvements on the Preparation for Decision Making Scale, and there was no significant benefit from using the PHIN rather than the NCI information booklet.

Limitations. The study's main limitation was the lack of African American men among the participants.

Background

Prostate Cancer Treatment and Survival. At the time of the study, nearly 2.8 million men were living with a history of prostate cancer in the United States, and 161 360 additional diagnoses were projected for 2017.¹ More than 90% of all prostate cancers are discovered in the local or regional stages, for which the 5-year relative survival rate approaches 100%.¹ The 10-year and 15-year relative survival rates are 98% and 96%, respectively.¹ Treatment options vary depending on the stage and grade of the cancer as well as patient comorbidity, age, and personal preferences.¹ Data show similar survival rates for patients with early-stage disease who are treated with either radiation therapy or surgery.¹ Active surveillance is also a valid and commonly recommended approach, particularly for older men and those with less aggressive tumors or more serious comorbid conditions.¹ However, many of the treatments also present serious side effects. For example, surgery or radiation therapy can result in incontinence, erectile dysfunction, and bowel complications. Patients who receive hormonal treatment may experience loss of libido and menopausal-like symptoms such as hot flashes, sweats, irritability, and osteoporosis. In the long term, hormone therapy can also increase the risk of or exacerbate comorbid conditions such as diabetes, cardiovascular disease, and obesity.²

Impact of Prostate Cancer Treatment on Men and Their Caregivers. In addition to affecting patients' physical and emotional well-being, prostate cancer treatment can affect caregivers' psychological well-being. Factors associated with distress among caregivers of early-stage prostate cancer patients include poor marital quality,³ caregivers' use of avoidant coping,³ uncertainty about cancer,⁴ and perceived lack of social support.⁵⁻⁷ *Dyadic mutuality* (the interactive effect between the patient and the caregiver) occurs when the 2 display significantly similar distress; this can happen from diagnosis through treatment.⁸⁻¹⁰ Treatment decision making and symptom management can be adversely affected when both members of the dyad are experiencing distress.¹¹ Studies have found that caregivers who cope by seeking out information and using problem solving, open communication, and positive reappraisal experience less stress.¹²⁻¹⁴ But despite the disconcerting effects of a prostate cancer diagnosis, few personalized psychoeducational interventions are available to help partners manage

symptoms and maintain a reasonable quality of life (QOL).¹⁵⁻²⁰ (QOL is defined as general well-being, or a person's overall satisfaction with his or her life.)

Innovation and Potential for Improvement Through Research. Prostate cancer has many available treatment alternatives but very few certainties related to outcome.¹ No data are available from long-term randomized controlled trials comparing the efficacy of different treatment options. The lack of conclusive information and the complexity of choosing a treatment option can make the decision-making process extremely difficult and fraught with anxiety.

Decision Aids. Over the past decade, decision aids have been developed to help patients with the decision-making process. These aids aim to assist patients at different stages of the cancer care continuum, from screening to treatment. O'Brien and colleagues conducted a literature review that examined the efficacy of various decision aids; they found that, overall, the aids enhanced knowledge for cancer screening, prevention, and treatments.²¹

Feldman-Stewart and colleagues explored the treatment decision-making process among cancer patients using values clarification exercises.²² The exercises helped patients combine 2 of their values: fundamental judgments and preferences (the former are applied across different situations, while the latter are more situation-specific). The researchers studied the effects of the values clarification exercises by measuring patients' preparedness for decision making and regrets about the decisions they made. They found that the intervention exercise made patients feel better prepared to make decisions and resulted in fewer regrets about those decisions a year later.

Men with newly diagnosed prostate cancer and their caregivers want to be informed and involved with their physicians in the decision-making process,²³ but physicians' medical expertise and practice type can be contextual factors for treatment recommendations and shared decision making (SDM).²⁴ In SDM, the patient and the clinician work together to make treatment-related decisions. However, for example, urologists may tend to favor surgery for localized prostate cancer, while radiation oncologists may tend to favor radiation therapy.²⁴ In

addition, patients and health care providers often differ regarding the type and amount of information patients need to make decisions.

Recent studies have found that physicians continue to provide information using a standard approach developed through years of clinical practice, even though several studies suggest that an individualized approach is better.^{23,25} Meanwhile, patients have unmet information needs, and a significant proportion are not satisfied with their ability to communicate with their physicians about the diagnosis and how to choose a treatment.²⁵ This study aimed to inform the amount, type, and impact of information provided to patients and their caregivers. We hoped that this intervention would serve as a catalyst to enhance patient-centeredness among newly diagnosed patients and their caregivers, resulting in more shared decision making and better patient and caregiver outcomes.

To facilitate the SDM process, Berry and colleagues provided patients with basic education about localized prostate cancer management and customized information that addressed each patient's specific preferences and concerns. They also coached the patients on how to share these issues with their doctors.²⁶ The intervention was delivered over the internet and included texts and videos. The findings demonstrated the benefits of addressing decision uncertainty and helping patients choose a prostate cancer treatment consistent with their values and preferences.

This innovation in the present study is the use of a community navigator (CN) and mobile tablet technology in community-based settings. We used community-based navigation to increase access to relevant information and resources. The Prostate Health Information Navigator (PHIN), an interactive psychoeducational intervention, was delivered as a mobile application to patients and caregivers by the CN in nonclinical settings. Through the PHIN, patients and their caregivers had access to tailored, evidenced-based information and other supportive resources they needed to effectively participate in SDM. The PHIN was used to facilitate the exchange of information and the patient–physician partnership, enabling patients and their caregivers to make decisions that were consistent with their personal preferences. The CN was an iteration of the patient navigation model to eliminate barriers to timely cancer screening, diagnosis, treatment, and supportive care and increase the timely uptake of

information and services.²⁷

Development of the PROSPER Application for iPads. In the study titled Comparative Effectiveness Research for Eliminating Disparities (CERED), funded by the National Institute on Minority Health and Health Disparities (NIMHD), the principal investigators conducted a community-based, randomized control trial with a group of asymptomatic African American men aged 40-70. The CERED trial assessed the feasibility of using community health workers to deliver prostate cancer education via emerging technology. Components of the intervention were delivered through an iPad web application called PROSPER.

Creation of the PHIN Application. An evaluation of the PROSPER app confirmed the feasibility of using iPad technology and community health workers in community-based settings. The PHIN is a more robust version of the PROSPER app. The 3-phase development of the PHIN was guided by patient engagement through qualitative research studies and by the National Comprehensive Cancer Network Guidelines for Prostate Cancer Patients (see Table 1a). In the first phase, key findings from a literature review and 33 in-depth interviews with prostate cancer patients and their caregivers revealed a lack of knowledge and limited access to culturally appropriate information; lack of culturally appropriate coping strategies and problem-solving skills; and lack of effective communication strategies. Participants preferred a balance of evidenced-based information, including the pros and cons of available treatment options and associated side effects; use of physicians as credible spokespersons; and the ability to navigate to additional resources such as websites, national reports, seminal research papers, or a simulation of the treatment procedures. In 2 peer reviewed, published manuscripts,^{28, 29} we describe the findings of this formative research and provide details on how we used these data to inform an intervention strategy that fosters provision of the right information to the right patient at the right time.

We presented the PHIN to the NIMHD-funded (P20) Center of Excellence Community Advisory Board (CAB) for feedback. The CAB (whose membership includes caregivers)

Table 1a. Overview of PHIN Intervention Development Procedures

Phase I. Preproduction	Phase II. Production	Phase III. Postproduction
<ul style="list-style-type: none"> • Conducted literature review of research on unmet educational and psychosocial needs of patients, and interventions designed to provide education to newly diagnosed prostate cancer patients • Reviewed existing audiovisual and electronic tools for patients • Conducted 33 in-depth interviews with prostate cancer patients and their spouses • Conducted knowledge elicitation with a family physician and an urologist 	<ul style="list-style-type: none"> • Infused findings from phase I into initial drafts of the concept maps, using iterative and systematic processes • Modified drafts based on feedback from clinicians, content experts, and members of an interdisciplinary team • Refined content, graphics, resources, and intervention title based on feedback from the interdisciplinary team and community members • Generated 133 2- to 3-minute video clips, and produced final versions of the 28 concept maps 	<ul style="list-style-type: none"> • Obtained reactions to the final version of the Prostate Health Information Navigator from a Community Advisory Board and an interdisciplinary group in attendance at the annual Florida Prostate Cancer Research Symposium in terms of appeal, suitability, and acceptability • Identified and linked to additional resources, including videos, websites, PDFs, national reports, and seminal research findings

considered the format to be appropriate and agreed that it facilitated personal navigation to a wide breadth of information and resources. Many CAB members valued videos of treatment providers delivering information on the common educational and psychosocial needs of patients.

Content of the PHIN. The PHIN uses a concept map–based interface that enables users to easily navigate through various kinds of information. We have extended the use of concept maps (Cmaps) beyond knowledge representation to serve as the browsing interface to a domain of knowledge. Figures 5a through 5d show the Cmap-based browser for the PHIN on prostate

Figure 1a. Sample Pages of Prostate Health Information Navigator

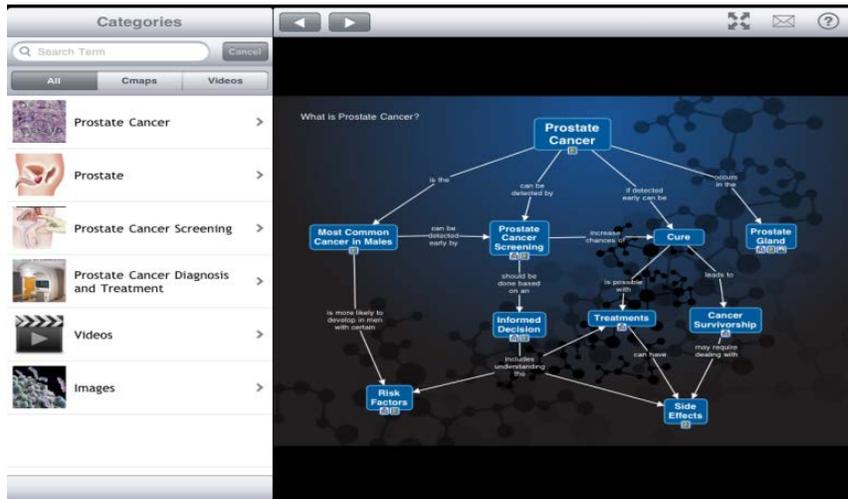


Figure 1b. Personal Health Information Navigator, Main Screen

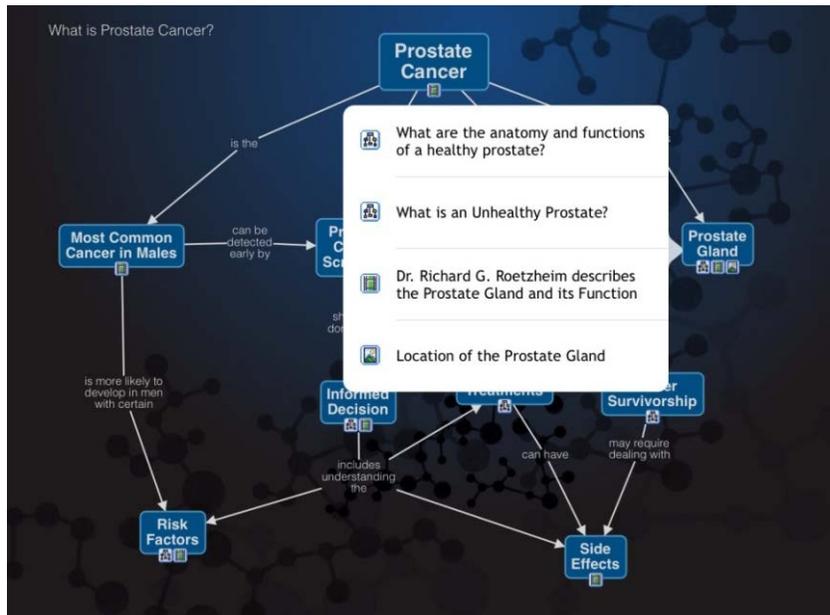


Figure 1c. Personal Health Information Navigator, Video Clip

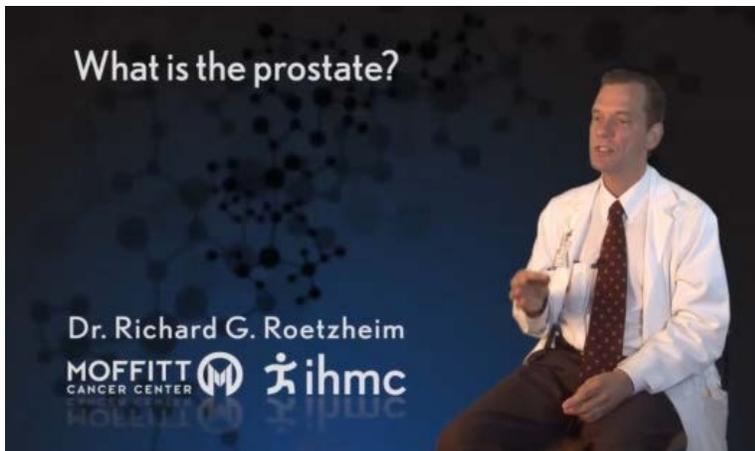
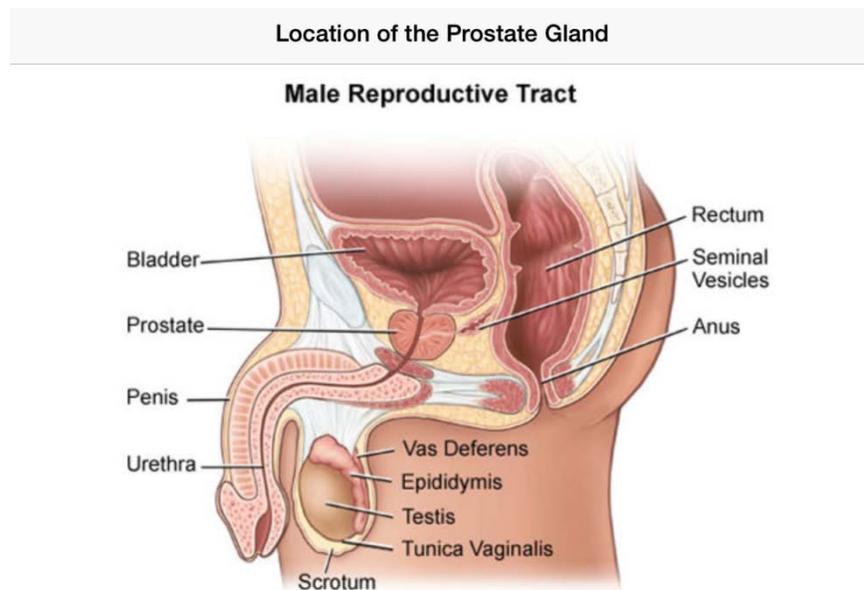


Figure 1d. Personal Health Information Navigator, Image



cancer, with icons that open to resources such as videos, images, and web pages. The app includes 28 Cmaps organized into 133 2- to 3-minute video clips (see Appendix B).

The content can be understood by users with fifth grade reading ability and is amenable to different users (patient, survivor, caregiver, etc.) with different interests. Learning is reinforced through a variety of media and resources. Users can “take the information with them”; they can go through it alone or with family, spend as much time on it as they need, and revisit the digital resources as often as they want. Users can email the URL to their health care providers and caregivers along with their own preferences, notes, and questions.

This study is the first robust test of the PHIN and its impact on patient and caregiver outcomes and participation in SDM. Because the PHIN intervention requires little training and can be delivered by CNs using iPads, it ensures the delivery of standardized, comprehensible, and culturally appropriate health messages. The use of iPads allows for real-time digital updates of health information and recommendations. In summary, we expected the PHIN to be an evidence-based intervention for men and their caregivers, ready for immediate and widespread dissemination and implementation to address a critical barrier to navigating a stressful and life-

changing event such as receiving a cancer diagnosis.

Impact on Health Care Performance. A key anticipated outcome of this study was improved efficiency in clinical decision making. Many organizations—including the American Cancer Society and the National Cancer Institute (NCI)—advocate for providing patient-centered cancer information to enhance clinical and nonclinical decision making and QOL (see Appendix B for the categories of informational needs). We anticipated 4 mediating outcomes of providing patient-centered information: (1) increased knowledge of treatment and disease; (2) improved self-efficacy; (3) participation in SDM; and (4) service utilization.^{30,31} Several studies have examined the efficacy of psychoeducational interventions with prostate cancer patients during diagnosis, treatment, and posttreatment.³²⁻³⁵ These interventions varied in design, length, method of delivery, and evaluation results.^{36,37} Psychoeducational interventions that provided information about the disease, treatment, and adverse effects were viewed positively by patients and often resulted in less disruption to daily life.^{33,34, 38-42} This study assesses whether the PHIN delivered by a CN is more effective than an NCI information booklet delivered by a CN. We describe the intervention as *psychoeducational* rather than *educational* because of the combined focus on knowledge and attitude change. The intervention has the potential to improve patient outcomes by decentralizing services that would otherwise burden the health care system, given the dynamic nature of the SDM process. The PHIN enables the patient and caregiver to arrive at the clinic with a clearer sense of options and tradeoffs, which is a key strategy to improve efficiency in clinical decision making.

Given the increasing complexity of information on prostate cancer and treatment options, the use of technology could help with the delivery of a consistent message and could reduce the variance often associated with interventions in community-based and nonclinical settings.

Relevance for Patients. Recent health care policies in the United States reflect the need for clinical consultations that include shared approaches to decision making. Such strategies ensure that health care decisions will combine health professionals' knowledge and expertise regarding care options and outcomes with the individual patient's personal experiences, values,

preferences, existing comorbidities, and life priorities.⁴³ Unlike the prevailing communication strategy between patients and their physicians, which has problems and limitations, SDM allows for discussion and negotiation of the treatment decision based on current evidence.⁴⁴

Congruent with PCORI's definition of patient-centeredness, this study addresses 3 questions:

1. Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?
2. What are my options, and what are the potential benefits and harms of those options?
3. What can I do to improve the outcomes that are most important to me?

Seeking information is the first, most basic, and most frequent method most people use to cope with a stressful life event about which information is limited. However, patients vary greatly in their approach to making a treatment decision,^{45,46} and these individual differences have been categorized by the extent to which people engage in *monitoring* or *blunting* during their diagnosis and treatment. Monitors actively seek information, while blunters actively avoid information that might be stressful or negative.^{45,46}

Participation of Patients and Other Stakeholders

Prostate Cancer Advisory Roundtable

We established a 2-member CAB for this study, using the principles of community-based participatory research. The Prostate Cancer Advisory Roundtable (PCAR) included 2 members of the targeted prostate community, whose role was to help define the essential characteristics of study participants, interventions, and outcomes; monitor study conduct and progress; formulate research questions; and disseminate research. We initially recruited 6 community members, but only 2 agreed to participate. One was a community health advocate for prostate cancer; the other was a prostate cancer survivor, who was also president of 100 Black Men of Tampa Bay. These 2 men reflected partnerships and relationships with local leaders from health advocacy associations, community health providers, public health entities, faith-based organizations, and the State of Florida Prostate Cancer Advisory Council. They provided insight on recruitment strategies as they were actively involved in the community and suggested

opportunities to discuss the study at community events. The 2 stakeholders reviewed and edited the intervention and revisions were made to accommodate a laymen term for the community. The PCAR members expressed concerns that the results need to be disseminated back into the community after study completion.

PCAR members were responsible for reviewing and editing both the intervention (PHIN), and the control (NCI booklet). The PCAR members found typos and grammatical errors that we revised before recruiting patients. They also suggested removing the prefix *psycho* in *psychoeducational* from the study title to avoid possible misunderstanding by potential recruits. Incorporating the perspective of the PCAR members in the study was essential to foster a system of care coordination outside the clinical setting and to enhance and expand the degree of trust between academic and clinical entities and underserved communities. One of the PCAR members earned his patient navigation certification, which enabled him to be the CN for participants recruited from the community.

Although the PCAR had only 2 members, they contributed a great deal. However, the small size of the CAB was a weakness when it came to patient and stakeholder engagement efforts. Midway through recruitment we discussed adding a third PCAR member, preferably a prostate cancer survivor who was interested in prostate cancer education and awareness, and open to discussing that concern. We contacted several prospects, but they all declined to participate. We continued to recruit but were not successful.

SPECIFIC AIMS

Specific Aim 1. To evaluate the impacts of providing newly diagnosed prostate cancer patients and their caregivers with a tablet-based interactive application called the Prostate Health Information Navigator™ delivered by a community navigator or providing a National Cancer Institute information booklet delivered by a CN. We measured the impacts according to patient outcomes (decisional satisfaction, quality of life, knowledge, decisional-self-efficacy, and decisional conflict) and shared decision-making practices (the patient's satisfaction with his preparation for treatment decision making and involvement in such decision making). On the

basis of previous research, we hypothesized that the group that received the PHIN would experience better outcomes and would engage more actively in shared decision making.

Specific Aim 2. To investigate the mechanism by which the PHIN affects patient and caregiver outcomes and shared decision making. On the basis of relevant theory and previous research, we hypothesized that patient and caregiver improvement in knowledge of prostate cancer, satisfaction with preparation for decision making, and self- efficacy would explain the expected beneficial effects of the PHIN on patient outcomes and shared decision making.

Specific Aim 3. To identify men who are most and least likely to benefit from the PHIN. On the basis of relevant theory and previous research, we hypothesized that, among newly diagnosed men and their caregivers who receive the PHIN, those of lower socioeconomic status (educational attainment, income) or of a minority group would benefit more.

METHODS

Study Design

This was a community-based randomized control trial providing educational materials (i.e., the Prostate Health Information Navigator or an NCI Information booklet) and a community navigator to newly diagnosed prostate cancer patients and their caregivers. Participants provided informed consent and completed baseline surveys. We conducted follow-up surveys after the intervention, after a medical consultation, at 6 months, and at 12 months. This design allowed researchers to assess and compare the quality, depth, and responsiveness to usual care plus CN-guided PHIN versus usual care plus CN-guided information booklet. (See section on content of the PHIN for more details.)

Setting and Sample

We recruited participants from the Moffitt Cancer Center (MCC) in Tampa, Florida, and other local clinics. Choosing MCC as a primary recruitment site allowed the research team to tap the Moffitt Clinical Research Network. The network includes community-based urologists

and primary care providers with patient populations of at least 40% African American men (compared with MCC's 10%), which ensured a representative sample of prostate cancer patients in the study. **Inclusion Criteria:** Patient requirements were as follows: (1) newly diagnosed (within 6 months) with a biopsy-confirmed case of prostate cancer; (2) 40-80 years of age; (3) able to speak and read English; (4) living within 120 miles of a health care treatment facility; (5) no documented or observable visual, auditory, psychiatric, or neurological disorders that would interfere with study participation (e.g., blindness, deafness, psychosis, dementia); (6) able to complete telephone interviews; (7) had not completed the first course of treatment; (8) had a family member or caregiver who was willing to participate; and (9) capable of providing written consent for study participation. Men diagnosed with early-stage, locally advanced, or metastatic disease or on active surveillance were eligible to participate in this study. Caregiver requirements were as follows: (1) aged 18 or older; (2) identified by patient as his caregiver (i.e., provider of emotional or physical care); and (3) had not been diagnosed with cancer in the previous year and was not receiving cancer treatment. Eligible participants were identified by either a nurse practitioner or a research coordinator from MCC at the Magnolia Campus and at International Plaza (Genitourinary Clinic, Radiation Oncology, and Radiology). The research coordinator and the community navigators met eligible patients at the clinic and enrolled those who were interested and who met all the eligibility criteria. Patients declined to participate for the following reasons: too busy, do not have caregivers, already have adequate information, unsure about the benefits of the study.

Instruments

Moderating Variables

Moderating variables are those that might have a positive or negative impact on the effectiveness of the intervention. The moderators identified here are not susceptible to change from the intervention but might affect the extent to which a person can benefit from the PHIN intervention.

Demographic factors. Ethnicity, age, marital status, education level, employment, income level, and health insurance status were ascertained during the baseline telephone interview. We used these data for descriptive purposes.

Clinical factors. We abstracted disease characteristics (i.e., PSA level at diagnosis, Gleason score); treatment information (i.e., expectant management, radical prostatectomy, radiation, hormonal therapy); and treatment completion date from medical records at study enrollment.

Charlson Comorbidity Index. Predicts the 10-year mortality for a patient who may have a range of comorbid conditions (a total of 22 conditions). Each condition is assigned a score of 1, 2, 3, or 6, depending on the risk of dying associated with that condition. The scores are summed to a total score that predicts mortality.⁴⁷

Information-seeking style. The Miller Behavioral Style Scale (MBSS) is a 32-item tool used to identify the information-seeking behaviors of individuals under threat. The items are marked as Monitoring (M) and Blunting (B). To obtain a total score, the total B score is subtracted from the total M score. The higher (more positive) the total score, the greater the monitoring (range is minus 16 to plus 16). In our study, the internal consistency of the M and B subscales of the MBSS was .72 and .75, respectively.⁴⁸

Mediating Variables

The mediating variables described below are those that might help explain the mechanism underlying the intervention effect for the outcome variables. For example, the PHIN intervention might increase the self-efficacy of patients or caregivers, and persons with increased self-efficacy might have more positive outcomes.

Prostate Cancer Knowledge Scale. This scale assesses prostate cancer knowledge using a 17-item test developed in 2001 by researchers from Robert H. Lurie Comprehensive Cancer Center, the VA Chicago Health System, and Northwestern University to assess the general knowledge of patients with prostate cancer following a didactic educational intervention. We computed a 0% to 100% score for each participant in our study, based on the number of questions answered correctly.⁴⁹

Decision Self-Efficacy Scale. This scale assesses confidence in one's ability to participate in decision making at a level personally desired. The 11 items require participants to reflect on how confident they felt about various aspects of the decision-making process. Responses are measured on a Likert scale that ranges from 0 (not at all confident) to 4 (very confident). Scores are summed, divided by 11, and multiplied by 25 to arrive at a score of self-efficacy that ranges from 0 (low self-efficacy) to 100 (high self-efficacy). This scale has demonstrated high reliability, with reported Cronbach's alpha coefficient values ranging from .84 to .89.⁵⁰

Preparation for Decision Making. This tool assesses participants' perceptions of all actions taken from the time of diagnosis while preparing for their treatment decision. The scale includes 10 items about decision preparation, each with 5-point Likert-type responses from 1 (not at all) to 5 (a great deal). Scores range from 0 to 100, with higher scores indicating greater perception of preparedness.⁵¹

Outcome Variables

Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP). We assessed prostate-specific symptoms through the EPIC-CP, a self-report instrument assessing function and bother related to urinary, sexual, bowel and hormonal symptoms in men with prostate cancer during the previous 4 weeks. Scores are rated on a Likert-type scale. Summative scores for each of the 4 symptom subscales are used (with a minimum symptom score of 0 and maximum symptom score of 12 in each domain), with lower scores indicating less bother and better function. In our study, internal consistency was high for the EPIC-CP (Cronbach's alpha values from 0.64 to 0.84).⁵²

Satisfaction with Decision Scale. This adapted 6-item scale is a measure of a patient's satisfaction with his decision regarding prostate cancer treatment. The response option uses a 5-point Likert scale ranging from strongly agree to strongly disagree.⁵³

Decisional Conflict Scale. We used this scale to assess uncertainty about decision making, the degree to which the patient felt informed, and the extent to which he believed he could make a decision that was consistent with his values. The scale has been found to distinguish between those who make a decision versus those who delay a decision. The 9-item survey uses a 4-level

Likert scale ranging from 1 (strongly agree) to 4 (strongly disagree). Zero represents no conflict, and 100 reflects the highest level of conflict. The scale has been used in a racially and ethnically diverse sample with adequate reliability (Cronbach's alpha value of .76).⁵⁴

Decision-making involvement. We used the Control Preferences Scale to assess preference for control in the decision-making process. Response options include the following: (1) I make the final decision on my own; (2) I make the decision after seriously considering my doctor's opinion; (3) My doctor and I share responsibility for the decision; (4) I prefer that the doctor make the decision after seriously considering my opinion; and (5) I prefer that the doctor make the decision. The responses are collapsed and categorized into 3 categories: active decision-making style (options 1 and 2); collaborative style (option 3); and passive style (options 4 and 5).⁵⁵

Procedures

The study was approved by the Scientific Review Committee of the Moffitt Cancer Center and the Institutional Review Board for the University of South Florida. Data collection began after written approval was received.

Accrual

Moffitt patients: The research coordinator or the community navigator approached patients in the outpatient clinics, and those who met the inclusion criteria were invited to participate in the study. The research coordinator or CN described the study and answered participants' questions. If the patient and caregiver agreed and signed the informed consent forms, a baseline assessment was conducted in a quiet, private location at Moffitt. Contact information was collected for the 6-week navigation and the follow-up assessments.

Non-Moffitt patients: The research coordinator contacted patients via telephone and described the study. If they patients interested in participating, their eligibility was assessed. The research coordinator or the CN set up meetings with eligible patients and caregivers in public places (e.g., a coffee shop) to obtain the consent and conduct baseline assessments.

The research team and the PCORI program officer discussed the fact that recruitment goals were not being met and agreed to reduce the number of questionnaires participants had to complete. Reducing the amount of time it would take for a patient or caregiver to fill out various forms made people more willing to participate, and we saw a significant increase in the number of patients and caregivers who agreed to participate. In consultation with the statistician on the project, we determined that we could still answer the key research questions outlined for the study.

Baseline Assessment and Randomization

Participants completed a battery of baseline assessment questionnaires. Participants who needed more time to complete the surveys were provided with prepaid return envelopes to mail them back. The baseline assessment included demographic information, clinical characteristics, Prostate Cancer Knowledge Questionnaire (PCKQ), Expanded Prostate Cancer Index Composite for Clinical Practice, Decision Self-Efficacy Scale, Preparation for Decision Making Scale (PDMS), Decisional Conflict Scale, Satisfaction With Decision Scale (SWDS), Charlson Comorbidity Index, Control Preference Scale, and Patient Treatment Decision. Following the baseline assessment, the research coordinator entered patient information into a centralized computer-generated randomization schedule to assign patients in equal numbers to the 2 study conditions. The randomization was blocked by race/ethnicity and information-seeking style to ensure comparable distributions in the intervention and control conditions. The schedule was prepared by the study biostatistician and maintained by the Moffitt Cancer Center Subject Registration and Randomization System. Access to randomization was limited to the research coordinator to avoid potential bias during the follow-up assessments.

Experimental Conditions

Experimental Condition: Usual Care and Personalized Health Information Navigator.

Patients randomized to the PHIN were assigned to a CN for 6 weeks. The CN provided navigation services and social support while the PHIN provided patient-centered education. The iPad, preloaded with the PHIN app, was delivered by the CN or by UPS within a week of

randomization. For local patients, the CN met with them and their caregivers at a location of their choice. At the initial meeting, the CN reviewed the study parameters and showed them how the PHIN worked. The CN observed the patients' level of comfort and control of the Apple iPad. For nonlocal patients, the iPad was delivered with detailed instructions and Q&A pamphlets. The patient kept the iPad for the 6-week duration of the study. The CN underscored the importance of using the PHIN app to address any educational or psychosocial needs. In a weekly telephone interview, the CN monitored the patients' use of the PHIN, including topics, which Cmaps were used most frequently, and which learning objects (i.e., Cmap, video, images) the patient accessed.

Control Condition: Usual Care and Information Booklet. Patients randomized to the information booklet were assigned to a CN for 6 weeks. The print materials were delivered by the CN or by UPS within a week of randomization. For local patients, the CN met with them and their caregivers at a location of their choice. At the initial meeting, the CN reviewed the study parameters and the print materials and emphasized the importance of reading carefully to help prepare for their discussion with their health care provider. For nonlocal patients, the education materials were delivered with Q&A pamphlets. The patient kept the print materials for the 6-week duration of the study (standard in previous studies). The information booklet was a compilation of the NCI brochures "What You Need to Know About Prostate Cancer," "Taking Time: Support for People With Cancer," and "Facing Forward, Life After Cancer Treatment." The booklet addressed prostate cancer treatment options, the late and long-term effects, follow-up care, and sources of support.

Intervention Period. Participants kept their intervention materials for up to 6 weeks. Each week, the CN conducted telephone interviews with the patients in both the PHIN and brochure groups and helped them address their information and resource needs. Using skills learned in the certified training, the CN assessed whether a patient was experiencing any financial, communication, psychosocial, coordination, or access to services barriers that required traditional navigation. Patients and their caregivers could contact the CN regarding any issues that arose between the weekly calls.

Follow-up Assessments. We conducted assessments at 5 points: baseline; postintervention (1 month); after the medical consultation (within 1 month, if applicable); at 6 months; and at 12 months. These assessments examined postbaseline levels of outcome variables. The same assessment time points have been used in previous studies.^{24,27} We anticipated that some men would be receiving treatment when they were contacted for follow-up interviews; therefore, all men were asked about treatment, including type of treatment and date of last treatment. To maximize the follow-up response rate, we reduced the number of surveys included in the 6- and 12-month assessments. In addition, the CNs offered to conduct the surveys over the phone.

Analytical and Statistical Approaches

Preliminary Analyses. Before conducting the primary analyses, we evaluated participants' demographic and clinical characteristics for possible differences across the 2 groups, using Wilcoxon or chi-square tests as appropriate. We adjusted for any significant variables at the $p < 0.10$ level in the multivariable analysis. All hypothesis testing used a 2-sided P value of 0.05 significance level unless otherwise stated. We adjusted P values for multiple comparisons using the Holm method.⁵⁶ We based analysis on all eligible patients who received their allocated intervention (i.e., intent-to-treatment analysis). We used the multiple imputation method to handle missing data.⁵⁷ In cases where the pattern of missing data might not have been random, we used auxiliary variables (e.g., race/ethnicity, education) to aid in the approximation of the missing at random assumption.⁵⁸

Power Analysis. Sample sizes for the current study were guided by considerations of statistical power.⁵⁹ In particular, because each of the aims uses random effects models, we based our power calculations on conventions outlined by Diggle and colleagues.⁶⁰ Specifically, they indicate that a beginning sample size of 300 would be sufficient to have 80% power to detect between-group differences, assuming an alpha of .05 (2-tailed), an intraclass correlation (ICC) of .50, and 5 measurement occasions. This corresponds to a medium-sized effect, which would be considered to be clinically relevant. This estimate of sample size is at the maximum for an ICC of .50; the sample size requirements decrease as the cross-time correlation coefficients go down.

Although we anticipated attrition longitudinally, the random effects models can include all participants in the analyses.

Statistical Analysis

Aim 1. To evaluate the impacts of providing newly diagnosed prostate cancer patients and their caregivers with a tablet-based interactive application called the Prostate Health Information Navigator™ delivered by a community navigator or providing an NCI information booklet delivered by a CN. We measured the impacts according to patient outcomes (decisional satisfaction, quality of life, knowledge, decisional self-efficacy, decisional conflict) and shared decision-making practices (the patient's satisfaction with his preparation for treatment decision making and involvement in such decision making).

The basic analytic strategy for this aim was to apply random effects models to the data using SAS Proc Mixed.⁶¹ The advantage of this method over traditional repeated analysis of variance measures is that all participants could be included in the analyses, not just those for whom we had complete data. The random effects method is more flexible in allowing for different time periods between assessments, and alternate covariance matrices can be applied to the data. The basic terms in this model included an intercept describing the outcome at the initial time of measurement, the effect of time that describes whether the outcome changes systematically over the follow-up period, and the group–time interaction. This last term is critical, as a statistically significant interaction indicates that the groups change at different rates over time. Follow-up analyses for this interaction included pairwise comparisons across groups to determine whether the PHIN group changed at a more rapid rate. In addition to the linear terms for the time effect, the richness of the data allowed us to model quadratic effects of time, which could indicate an acceleration or deceleration of change over time. We also planned to examine how the responses of patients and their caregivers related to the outcomes, using actor-partner models of dyadic analysis.⁶²

Aim 2. To investigate the mechanism by which PHIN improves patient and caregiver outcomes and shared decision making among men newly diagnosed with prostate cancer and their caregivers.

For this aim, we planned to conduct mediational analysis to examine whether the potential mediator variables explained (i.e., mediated) PHIN intervention effects on the patient outcome variables and shared decision making. We used the methods described by Bauer and colleagues⁶³ that extend the mediation analyses often reported for regression and are extended to the level of random effects.^{64,65} In these analyses, the intervention group was the independent variable and patient outcomes and SDM were the dependent variables. For the mediators, we first examined the mediating variables (e.g., self-efficacy, knowledge of prostate cancer, satisfaction with preparation for decision making) individually and then subjected all the mediators that were statistically significant to a multiple mediation analysis.

Aim 3. To identify men who are most and least likely to benefit from the PHIN.

We planned to apply the same basic statistical approach used in Aim 1 to evaluate whether comorbidities, socioeconomic status, and race/ethnicity moderated the impact of the intervention. In this case, we added the moderating terms as interactions to the effects of time in the random effects models. Specifically, we evaluated whether the moderating variables (e.g., educational attainment, income, race/ethnicity, comorbidities score) interacted with changes over time that were attributable to intervention group status. If the 3-way interactions (time–group–moderator) were statistically significant, we stratified by moderator group status to evaluate whether the group–time effects were comparable across levels using point estimates and 95% CI.

Table 1. Demographic Characteristics

	Patient		Caregiver	
	PHIN	PEG	PHIN	PEG
n	87	89	85	89
Age (years)	61.38 7.79	64.56 7.22	57.47 9.89	60.98 9.51
Gender (% female)	0.00	0.00	97.7	96.7
Race/ethnicity (% white)	86.52	86.67	87.36	81.11
Hispanic (%)	0.00	5.56	1.12	4.44
Education (% college)	66.67	55.17	56.98	65.91

RESULTS**Demographic Characteristics**

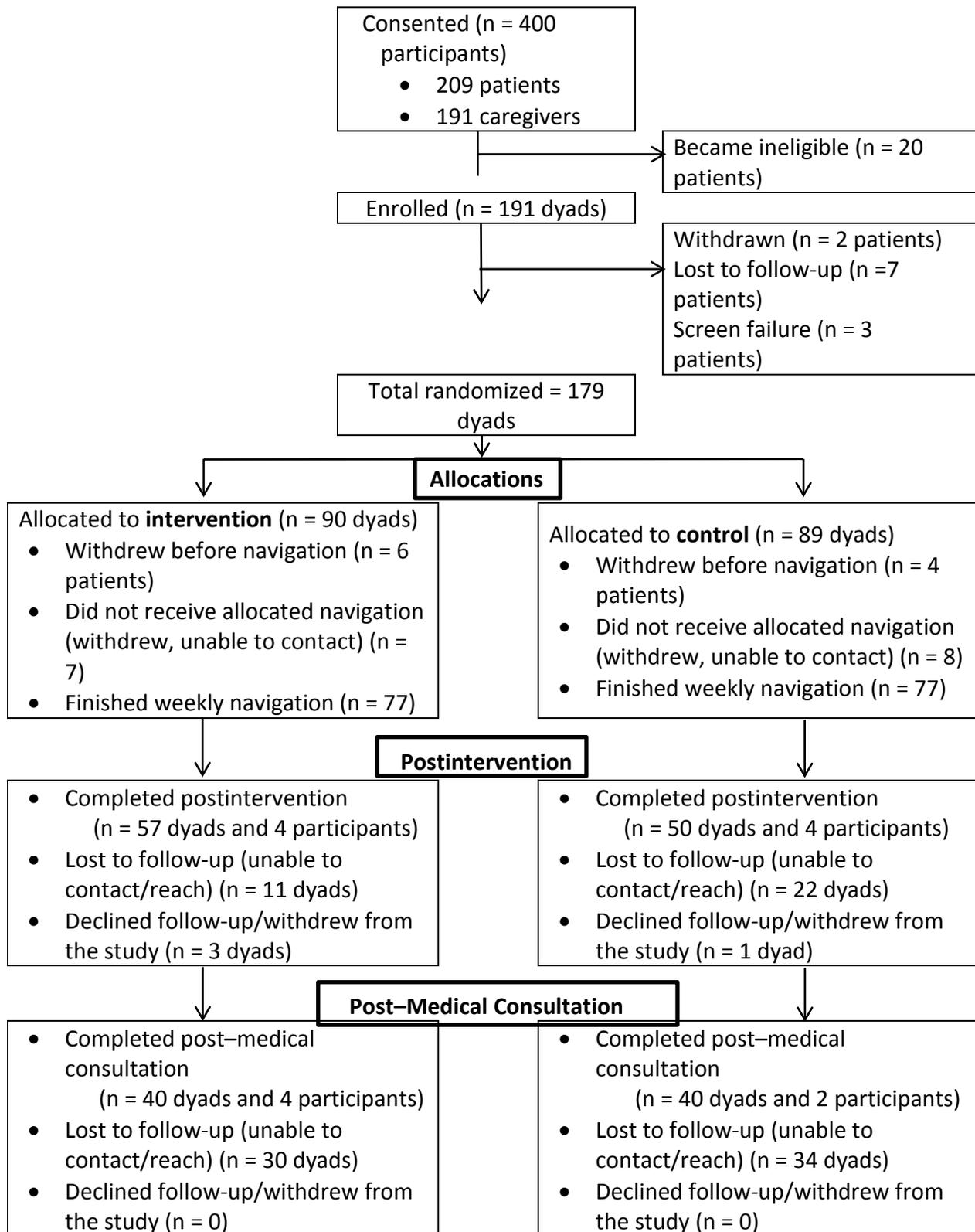
Table 1 shows the demographic characteristics of the patient and caregiver groups by group assignment. We compared the groups on several demographic characteristics as well as for differences between the intervention groups. The analyses indicated significant effects of age for the PCKQ, the SWDS, and the PDMS, with a significant patient type effect (patient type: $F(1, 346) = 16.34; p < .001$), suggesting that the caregivers were on average younger than the patients and the effect of intervention group (group: $F(1, 346) = 13.02; p < .001$), indicating that the PHIN group was on average slightly younger than the PEG group. The interaction between group and patient type was not statistically significant ($F[1, 346] = .03; p = .861$). Among caregivers, there were no statistically significant group differences in gender ($X^2[1] = 0.17; p = .678$); race/ethnicity ($X^2[1] = 1.29; p = .255$); or educational attainment ($X^2[1] = 2.37; p = .124$). Among the patients, the groups were comparable in terms of race/ethnicity ($X^2[1] = .001; p = .977$) and educational attainment ($X^2[1] = 1.466; p = .266$). In the analyses that follow, age is considered as a covariate.

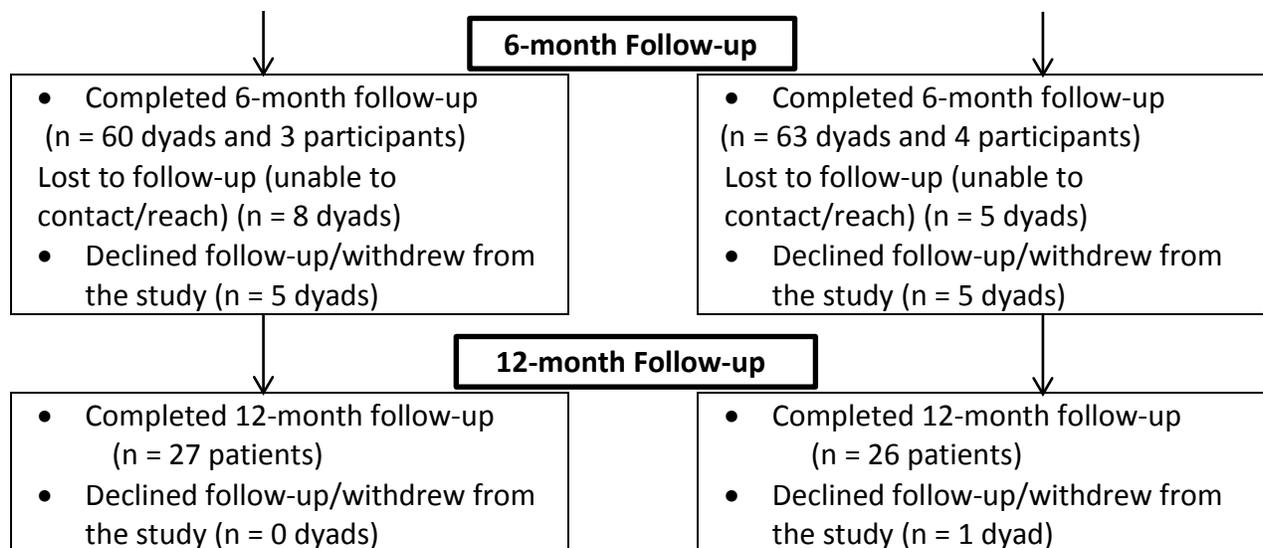
CONSORT Diagram

The CONSORT diagram (Figure 2) shows that 400 participants (209 patients and 191 caregivers) were consented. Twenty patients were ineligible because their caregivers were not willing to participate in the study, so 191 pairs (dyads) were enrolled in the study. Of these, 179 dyads were randomized: 90 to the intervention group and 89 to a control group. Seventy-seven dyads in each group completed the weekly navigations.

Among dyads that completed the weekly navigation, 57 dyads and 4 participants (118 participants) from the intervention group and 50 dyads and 4 participants (108 participants) from the control group completed postintervention surveys; 40 dyads and 4 participants (84 participants) from the intervention group and 40 dyads and 2 participants (82 participants) from the control group completed post–medical consultation surveys; and 60 dyads and 3 participants (123 participants) from the intervention group and 63 dyads and 4 participants (130 participants) from the control group completed the 6-month follow-up surveys. Finally, 27 participants from the intervention group and 26 participants from the control group completed the 12-month follow-up surveys. Despite extensive efforts to collect follow-up data, numerous participants were lost (we were unable to contact them) or withdrew from the study because they were busy or no longer interested.

Figure 2. CONSORT Diagram





* 12-month follow-up surveys for caregivers implemented on June 22, 2016.

Aim 1. Longitudinal Changes in Patient and Caregiver Outcomes

Table 2 presents the results of the random effects models across all time points for the 3 primary outcomes of interest among the prostate cancer patients. These include the PCKQ, the SWDS, and the PDMS. “Intercept” reflects the average score at the point of randomization. The effects of age and group reflect the influence of these variables on scores at baseline. The effect of time indicates whether statistically significant changes were present for the follow-up period. The effects of greatest interest here are the group–time and age–time–group parameters. Significance indicates that the groups change at different rates across the follow-up period. The absence of a group–time or age–group–time effect indicates that the groups experienced comparable changes across time. These trajectories are also shown in the figure. There was a significant effect of time for the SWDS scores (which indicated increasing scores across the follow-up period) but not for the PCKQ or PDMS outcomes.

Table 2. Parameter Estimates for the Patient Outcomes

Fixed Effects		PCKQ	SWDS	PDMS
Intercept	β	19.17***	3.39***	4.12***
	SE	1.97	.59	.58
Age	β	-.04	.01	.001
	SE	.03	.01	.001
Time	β	.15	1.01*	.21
	SE	1.35	.42	.52
Group	β	1.64	-0.09	-.10
	SE	3.94	1.19	1.15
Group-time	β	0.18	0.33	-0.86
	SE	2.71	0.85	1.03
Age-time	β	.02	-.01	-.002
	SE	.02	.01	.008
Age-group	β	-.03	.002	.01
	SE	.06	.02	.02
Age-time-group	β	-.005	-.006	.01
	SE	.04	.01	.01
Random Effects				
Intercept	β	5.07***	.45***	.25*
	SE	.95	.10	.11
Slope	β		.09*	.09
	SE		.05	.07
Correlation	β		-.94***	-.34
	SE		.09	.31
Residual	β	4.64***	.38***	.51***
	SE	.51	.06	.08

Note: * $p < .05$; ** $p < .01$; *** $p < .001$. The parameters in the table reflect average score at study outset (intercept) and whether age (age) or intervention group (group) or the interaction (age-group) were related to scores at baseline. We examined changes over the follow-up interval (time) as a function of age (age-time), intervention group (group-time) or their interaction (age-group-time) influenced these changes.

Table 3 presents the results of the random effects models for the 3 primary outcomes of interest among the caregivers. The absence of a group-time or age-group-time effect indicates that the groups experienced comparable changes across time. These trajectories are also shown in the figure. For each of the outcomes, there were significant effects of time for PCKQ and SWDS, with increases over the follow-up period. Age was associated with all scores at baseline, with 1 additional year of age being linked to higher scores at randomization.

Aim 2. Mediation Analyses of PHIN Intervention Effects

Because the analyses on the patient and caregiver outcomes were not significant, we conducted none of the planned mediational analyses. The goal of this set of analyses was to

describe the mechanism by which the patient navigator effects were observed, but since none of the effects were statistically significant, these analyses were not appropriate.

Aim 3. Moderation of PHIN Intervention Effects

For this analysis, we examined race (white/nonwhite), education (less than high school/high school or greater), and number of comorbid conditions (patients only) as potential moderators of the intervention group effect. For patients, white race ($\beta = 2.44$; $SE = .79$; $p = .003$) and greater than high school education ($\beta = 3.18$; $SE = .99$; $p = .002$) were associated with significantly greater PCKQ scores at baseline but were unrelated to changes over time or to the group–time interaction. The number of comorbid conditions was unrelated to the outcomes at baseline or changes over time. None of the predictors of SWDS or PDMS scores were statistically significant. Among the caregivers, greater than high school education was associated with higher PCKQ scores at baseline ($\beta = 3.89$; $SE = 1.36$; $p = .006$) but unrelated to changes over time. Race was not related to PCKQ, SWDS, or PDMS scores at baseline or to changes over time.

Table 3. Parameter Estimates for the Caregiver Outcomes

Fixed Effects		PCKQ	SWDS	PDMS
Intercept	β	12.16***	2.99***	3.20***
	SE	1.72	.43	.38
Age	β	.07*	.02*	.01*
	SE	.03	.01	.01
Time	β	4.24**	.95**	.56
	SE	1.47	.32	.35
Group	β	−1.53	−1.25	−1.73*
	SE	3.44	.85	.75
Group–time	β	1.47	0.72	1.33
	SE	2.94	0.65	0.69
Age–time	β	−.05*	−.01	−.01
	SE	.02	.01	.01
Age–group	β	−.02	.02	.03
	SE	.06	.01	.01
Age–time–group	β	−.02	−.01	−.02
	SE	.05	.01	.01
Random Effects				
Intercept	β	8.16***	.39***	.27***
	SE	1.67	.10	.08

Slope	β	2.55*	.11*	.14**
	SE	1.11	.05	.06
Correlation	β	-.50**	-.90***	-.58***
	SE	.14	.08	.14
Residual	β	5.58***	.38***	.35***
	SE	.91	.06	.05

Note: * $p < .05$; ** $p < .01$; *** $p < .001$. The parameters in the table reflect average score at study outset (intercept) and whether age (age) or intervention group (group) or the interaction (age–group) were related to scores at baseline. We examine changes over the follow-up interval (time) as a function of age (age–time), intervention group (group–time), or their interaction (age–group–time) influenced these changes.

DISCUSSION

Context for Study Results

Because many treatment options exist for prostate cancer, patients and providers may struggle with deciding on the right course of treatment. A primary question is how this decision-making process could be easier for the patient and the provider. More important, how can we ensure that the patient and caregiver feel confident and content about their ultimate decision? It is important to establish a practice strategy that makes it easier for patients, caregivers, and providers to collaborate during the decision-making process. The literature is very clear that patients and caregivers who receive appropriate information can help make better treatment decisions. Regarding prostate cancer specifically, the lack of conclusive information related to diagnosis and potential outcomes makes the decision-making process even more difficult.

Most of the literature agrees that decision aids enhance patient and caregiver knowledge about the disease, and men and their caregivers prefer to be active members of the team making decisions about care. Most physicians continue to use a standard approach to provide information to patients and caregivers.

This study examined the use of mobile technology through which patients and caregivers had access to the latest information related to prostate cancer that could be updated in real time. But simply providing patients with an iPad loaded with prostate cancer information would not be beneficial. We developed the Prostate Health Information Navigator to manage the information, and a community navigator walked patients and caregivers through

the information and answered their questions, in a setting that was comfortable for the patient and the caregiver. This patient-centered process can provide patients and caregivers with the information they want and need to make decisions about treatment.

Aim 1. Longitudinal Changes in Patient and Caregiver Outcomes

The primary goal of this study was to evaluate the impact of providing newly diagnosed prostate cancer patients and their caregivers with information delivered via mobile technology versus a standard information booklet provided by the National Cancer Institute. Both arms of the study involved the use of a community navigator, whose role was to help patients and caregivers access the information. The research team hypothesized that the patients and caregivers using the mobile technology would have better outcomes and would feel more comfortable about their treatment decision making. Overall, both patients and caregivers benefited from the prostate cancer education provided by the CN, regardless of the method of delivery. Caregivers were less knowledgeable about prostate cancer at baseline but had a greater increase in postintervention knowledge with the PHIN. Results also indicated that patients' prostate cancer knowledge was strongly correlated with their preparedness to make a treatment decision and that preparedness to make a treatment decision was correlated with decisional satisfaction.

We found no differences between the groups with regard to iPad delivery versus the NCI booklet. The research team believes that the introduction of a community navigator for both groups canceled out any differences that might have been observed if patients and caregivers had simply been given the information. It is also possible that older men might feel more comfortable with printed booklets and materials they can highlight than with technology. Some men found the PHIN format confusing—a lot of information is available in the program and navigating it can be difficult. A follow-up study could include 2 more groups without CNs, to determine whether the navigator affects the results.

In addition, simply providing patients with more information might not be the way to help them feel comfortable with their treatment decisions. Providing them with very targeted information might be more meaningful. With either the iPad delivery or the NCI booklet, patients and caregivers—as well as the CN—might have focused on the information that was

important to them. Perhaps it did not matter which method was used to provide that information.

Aim 2. Mediation Analysis of PHIN Intervention Effects

Aim 2 could not be confirmed, because the results in Aim 1 were nonsignificant. The goal was to determine the mechanism by which the patient navigator effects were observed. Since none of the effects were statistically significant, these analyses were not appropriate.

Aim 3. Moderation of PHIN Intervention Effects

There were no indications that some men were more or less likely than others to benefit from the PHIN application. None of the analyses were significantly different over time. The research team believed that a certain category of men, based on demographic factors (e.g., race, age, educational level), would benefit significantly more than other men from the PHIN, but we found this was the case. This result could be attributed to the fact that the sample was not diverse enough to identify differences in the impact of the PHIN. This aim would have to be tested with a more diverse sample.

Generalizability of the Findings

The study findings are not generalizable because of the lack of diversity among the patients and caregivers. The study fell short in recruitment of African American men, which resulted in a sample that was majority white men. Because prostate cancer incidence and mortality are higher in the African American population, it is important to have a representative sample of African Americans to determine the impact of this intervention on this population.

Implementation of Study Results

Because the study did not find that using the iPad intervention made a significant difference, we have no recommendations for implementation in a typical health care setting. We hypothesized that having information on an iPad that could be personalized to each patient would be beneficial to the patients and caregivers on key decisions about their care. However, this study did not find that the iPad intervention made a significant difference.

Subpopulation Considerations

Because an overwhelming majority of patients and caregivers in this study were white, no subpopulation considerations are required. There were not enough diverse patients to conduct any subpopulation analysis on the data.

Study Limitations

The study had a number of difficulties and limitations, primarily in recruiting. The sample was mostly white, owing to difficulties recruiting black or Hispanic men. The sample was also smaller than originally proposed, and it became increasingly difficult to enroll patients and caregivers. Despite an extensive effort to collect follow-up data, the researchers were unable to contact a number of participants, and some withdrew because they were busy or no longer interested. We also experienced difficulty recruiting patients and stakeholders for the Community Advisory Board. We recruited 2 people who were very engaged, but many attempts to recruit additional members met with little or no success. This situation certainly affected the amount of feedback we received from patients and stakeholders. Any future study should aim for a much larger advisory board to ensure sufficient engagement and a representative sample of participants who can provide guidance from a stakeholder perspective.

We also made a significant change in the study protocol. Owing to the difficulty of recruiting patients and caregivers who were willing to complete the follow-up questionnaires, we decided to shorten them by eliminating questions that would not affect the main research goals. This strategy worked, but it meant that we did not collect all the information we set out to gather. This was a definite limitation of the study.

Both the study coordinators and the community navigators recruited patients and conducted follow-up surveys. This division of labor might have influenced participants' responses, if they answered the way they thought their CN wanted them to answer. In future studies we recommend that the people who recruit patients are not involved in conducting the surveys.

CONCLUSIONS

The results of the study showed statistically significant improvements in the Prostate Cancer Knowledge Questionnaire and the Satisfaction with Decision Scale among caregivers and significant improvements in the SWDS for patients. However, these effects were the same in both intervention groups, indicating that improvements were not the result of format or content. We saw no significant improvements for either group in the Preparation for Decision Making Scale. We conclude that there was no significant benefit of using the PHIN application plus a navigator over using the usual NCI printed materials plus a navigator.

Although this study did not find that the PHIN was a more effective means of delivering information to patients and caregivers, a future study could explore this question further with a much larger, more diverse sample. A future study could also examine more closely the role of the navigator in the delivery of information.

REFERENCES

1. American Cancer Society. *Cancer Facts & Figures*. Atlanta, GA: American Cancer Society; 2017.
2. Kintzel PE, Chase SL, Schultz LM, O'Rourke TJ. Increased risk of metabolic syndrome, diabetes mellitus, and cardiovascular disease in men receiving androgen deprivation therapy for prostate cancer. *Pharmacotherapy*. 2008;28(12):1511-1522.
3. Bantia R, et al. The effects of dyadic strength and coping styles on psychological distress in couples faced with prostate cancer. *J Behav Med*. 2003;26(1):31-52.
4. Germino BB, et al. Uncertainty in prostate cancer. ethnic and family patterns. *Cancer Pract*. 1998;6(2):107-113.
5. Ptacek J, et al. Social support in spouse of cancer patients: what do they get and to what end? *Pers Relatsh*. 1997;(4):431-449.
6. Demark-Wahnefried W, et al. Riding the crest of the teachable moment: promoting long-term health after the diagnosis of cancer. *J Clin Oncol*. 2005;23(24):5814-5830.
7. Demark-Wahnefried W, et al. Current health behaviors and readiness to pursue life-style changes among men and women diagnosed with early stage prostate and breast carcinomas. *Cancer*. 2000;88(3):674-684.
8. Howlader N, et al. *SEER Cancer Statistics Review, 1975-2009*. Bethesda, MD: National Cancer Institute; 2012.
9. American Cancer Society. *Cancer Facts & Figures for African Americans, 2011-2012*. Atlanta, GA: American Cancer Society; 2011.
10. Brawley OW. Prostate cancer epidemiology in the United States. *World J Urol*. 2012;(30):195-200.
11. Chornokur G, et al. Disparities at presentation, diagnosis, treatment, and survival in African American men affected by prostate cancer. *Prostate*. 2011;71(9):985-997.
12. Maliski SL, Heilemann MV, McCorkle R. From "death sentence" to "good cancer": couples' transformation of a prostate cancer diagnosis. *Nurs Res*. 2002;51(6):391-397.
13. Malcarne VL, et al. Problem-solving skills and emotional distress in spouses of men with prostate cancer. *J Cancer Educ*. 2002;17(3):150-154.

14. Lavery JF, Carke VA. Prostate cancer: patients' and spouses' coping and marital adjustment. *Psychol Health Med*. 1999;(4):289-302.
15. Manne S, et al. Buffering effects of family and friend support on associations between partner unsupportive behaviors and coping among women with breast cancer. *J Soc Pers Relat*. 2003;20(6):771-792.
16. Manne S, et al. Couples' support-related communication, psychological distress, and relationship satisfaction among women with early stage breast cancer. *J Consult Clin Psychol*. 2004;72(4):660-670.
17. Manne SL, et al. Couple-focused group intervention for women with early stage breast cancer. *J Consult Clin Psychol*. 2005;73(4):634-646.
18. Manne SL, et al. Coping and communication-enhancing intervention versus supportive counseling for women diagnosed with gynecological cancers. *J Consult Clin Psychol*. 2007;75(4):615-628.
19. Northouse L, et al. Effects of a family intervention on the quality of life of women with recurrent breast cancer and their family caregivers. *Psychooncology*. 2005;14(6):478-491.
20. Northouse LL, et al. A family-based program of care for women with recurrent breast cancer and their family members. *Oncol Nurs Forum*. 2002;29(10):1411-1419.
21. O'Brien MA, et al. Are cancer-related decision aids effective? a systematic review and meta-analysis. *J Clin Oncol*. 2009;27(6):974-985.
22. Feldman-Stewart D, et al. The impact of explicit values clarification exercises in a patient decision aid emerges after the decision is actually made: evidence from a randomized controlled trial. *Med Decis Making*. 2012; 32(4):616-626.
23. Arora NK. Interacting with cancer patients: the significance of physicians' communication behavior. *Soc Sci Med*. 2003;57(5):791-806.
24. Fowler FJ, McNaughton Collins M, Albertsen PC, et al. Comparisons of recommendations by urologists and radiation oncologists for treatment of clinically localized prostate cancer. *JAMA*. 2000;(283):3217-3222.
25. Hewitt M, Greenfield S, Stovall E. *From Cancer Patient to Cancer Survivor: Lost in Transition*. Washington, DC: The National Academies Press; 2006. Institute of Medicine, ed.

26. Berry DL, et al. The personal patient profile-prostate decision support for men with localized prostate cancer: a multi-center randomized trial. *Urol Oncol*. 2013;31(7):1012-1021.
27. Wells KJ, et al. Patient navigation: state of the art, or is it science? *Cancer*. 2008; 113(8):1999-2000.
28. Rivers BM, et al. Psychosocial issues related to sexual functioning among African-American prostate cancer survivors and their spouses. *Psychooncology*. 2011;20(1):106-110.
29. Rivers BM, August EM, Quinn GP, et al. Understanding the Psychosocial Issues of African American Couples Surviving Prostate Cancer. *Journal of cancer education: the official journal of the American Association for Cancer Education*. 2012;27(3):546-558. doi:10.1007/s13187-012-0360-1.
30. Campbell L, Keefe FJ, Scipio C, et al. Facilitating research participation and improving quality of life for African American prostate cancer survivors and their intimate partners. *Cancer (suppl)*. 2007;109(2):414-424.
31. Hewitt M, Greenfield S, Stovall E. *From Cancer Patient to Cancer Survivor: Lost in Transition*. Washington, DC: The National Academies Press; 2006. Institute of Medicine, ed.
32. Berglund G, et al. Between men: patient perceptions and priorities in a rehabilitation program for men with prostate cancer. *Patient Educ Couns*. 2003;(49):285-292.
33. Mishel M, et al. Helping patients with localized prostate carcinoma manage uncertainty and treatment side effects. *Cancer*. 2002;(6):1854-1866.
34. Mishel M, et al. Moderators of an uncertainty management intervention for men with localized prostate cancer. *Nurs Res*. 2003;53(2):89-97.
35. Weber B, et al. The effect of dyadic intervention on self-efficacy, social support, and depression for men with prostate cancer. *Psychooncology*. 2004;(13):47-60.
36. Campbell L, et al. Facilitating research participation and improving quality of life for African American prostate cancer survivors and their intimate partners. *Cancer(suppl)*. 2007;109(2):414-424.
37. Badr H, Krebs P. A systematic review and meta-analysis of psychosocial interventions for couples coping with cancer. *Psychooncology*. 2013;22(8):1688-1704.

38. Davison B, et al. Comparing a generic and individualized information decision support intervention for men newly diagnosed with localized prostate cancer. *Cancer Nurs.* 2007;30(5):e7-e15.
39. Hack T, et al. Impact of providing audiotapes of primary treatment consultations to men with prostate cancer: a multi-site, randomized, controlled trial. *Psychooncology.* 2007;(16):543-552.
40. Kim Y, Roscoe JA, Morrow GR. The effects of information and negative affect on severity of side effects from radiation therapy for prostate cancer. *Support Care Cancer.* 2002;(10):416-421.
41. Manne S, et al. Couples' support-related communication, psychological distress, and relationship satisfaction among women with early stage breast cancer. *J Consult Clin Psychol.* 2004;72(4):660-670.
42. Thornton AA, Perez MA, Meyerowitz BE. Patient and partner quality of life and psychosocial adjustment following radical prostatectomy. *J Clin Psychol Med Settings.* 2004;11(1):15-30.
43. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least 2 to tango). *Soc Sci Med.* 1997;44(5):681-692.
44. Hovey RB, et al. Partners in our care: patient safety from a patient perspective. *Qual Saf Health Care.* 2010;19(6):e59. doi: 10.1371/journal.pone.0122499
45. Feldman-Stewart D, et al. What prostate cancer patients should know: variation in professionals' opinions. *Radiother Oncol.* 1998;49(2):111-123.
46. Feldman-Stewart D, et al. The information required by patients with early-stage prostate cancer in choosing their treatment. *BJU Int.* 2001;87(3):218-223.
47. Charlson ME, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.
48. Miller SM. Monitoring and blunting: validation of a questionnaire to assess styles of information seeking under threat. *J Pers Soc Psychol.* 1987;52(2):345-353.
49. Volk RJ, Spann SJ. A randomized controlled trial of shared decision making for prostate cancer screening. *Arch Fam Med.* 1999;(8):333-340.
50. Bunn H, O'Connor A. A validation of client decision-making instruments in the context of psychiatry. *Can J Nurs Res.* 1996;28(3):13-27.

51. Bennett C, Graham ID, Kristjansson E, et al. Validation of a preparation for decision making scale. *Patient Educ Couns*. 2010;(78):130-133.
52. Chang P, Szymanski KM, Dunn RL, et al. Expanded prostate cancer index composite for clinical practice: development and validation of a practical health related quality of life instrument for use in the routine clinical care of patients with prostate cancer. *J Urol*. 2011;186(3):865-872.
53. Holmes-Rovner M, et al. Patient satisfaction with health care decision: the satisfaction with decision scale. *Med Decis Making*. 1996;(16):58-64.
54. O'Connor A, et al. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25-30.
55. Degner LF, Sloan JA, Venkatesh P. The control preferences scale. *Can J Nurs Res*. 1997;29(3):21-43.
56. Holm S. A simple sequentially rejective multiple test procedure. *Scand Stat Theory Appl*. 1979;(6):65-70.
57. Enders CK. *Applies Missing Data Analysis*. New York, NY: The Guildford Press; 2010.
58. Graham JW. Missing data analysis: making it work in the real world. *Annu Rev Psychol*. 2009;60(1):549-576.
59. Brasher PM, Brant RF. Sample size calculations in randomized trials: common pitfalls. *Can J Anaesth*. 2007;(54):103-106.
60. Diggle PJ, Heagerty P, Liang K-Y, Zeger SL. *Analysis of Longitudinal Data*. New York, NY: Oxford University Press; 2002.
61. Littell RC, et al. *SAS for Mixed Models*. 2nd ed. Cary, NC: SAS Press; 2006.
62. Kenny DA. Models of non-independence in dyadic research. *J Soc Pers Relat*. 1996;13(2):279-294.
63. Bauer DJ, Preacher KJ, Gil KM. Conceptualizing and testing random indirect effects and moderated mediation in multilevel models: new procedures and recommendations. *Psychol Methods*. 2006;(11):142-163.
64. Bauer DJ. Evaluating individual differences in psychological processes. *Curr Dir Psychol Sci*. 2011;20(2):115-118.

65. Hayes AF. Beyond Baron and Kenny: statistical mediation analysis in the new millennium. *Commun Monogr.* 2009;76(4):408-420.

Copyright© 2019. H. Lee Moffitt Cancer Center & Research Institute Hospital, Inc. All Rights Reserved.

Disclaimer:

The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Acknowledgement:

Research reported in this report was [partially] funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (CE-12-11-5285). Further information available at: <https://www.pcori.org/research-results/2013/treatment-decision-support-men-prostate-cancer-and-their-caregivers>