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PRINCIPAL INVESTIGATOR: James R. Hebert, MSPH, Sc.D.

CONTRACTING ORGANIZATION: University of South Carolina
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James R. Hebert, MSPH, Sc.D.

E-Mail: mckenziw@gwm.sc.edu

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14. ABSTRACT:
Following surgery or radiation of primary early-stage prostate cancer (PrCA), one in three patients will experience an elevation in serum prostate antigen (PSA) within 10 years. This rises to one in two at 15 years. After such evidence of recurrence, the most common treatment is androgen ablation. We hypothesize that the host-PrCA balance in asymptomatic men with biochemically recurrent PrCA, as reflected by the PSA rise, is favorably affected by an intensive, vegetable-based diet, plus physical activity and mindfulness-based stress reduction. This randomized trial will enroll 60 men with rising PSA levels along with a partner of their choice, half of whom will be randomized to the intervention and half to usual care. The intervention will continue for 3 months, followed by monthly booster sessions for 3 months. Data will be collected on main study outcomes, protocol compliance and adherence, and potential effect modifiers, mediators, and confounders of treatment effect.

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A Diet, Physical Activity, and Meditation Intervention in Men with Rising Prostate-Specific Antigen (PSA)

Annual Report:

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Introduction:

Prostate cancer (PrCA) is the most commonly occurring cancer, excluding skin cancer, in Western male populations (1). South Carolina, an area of high prostate cancer incidence, has the highest mortality rate of the disease in the world (2, 3). Generally, patients who present with prostate cancer are treated with either radical prostatectomy or radiation therapy. However, biochemically defined recurrence, marked by a rise in prostate-specific antigen (PSA), and the development of metastatic disease is common. No curative therapy exists for metastatic prostate cancer (4). Androgen ablation, the most commonly used management strategy, produces side effects whose severity has motivated a search for new strategies that could retard tumor progression and postpone the use of such therapy (5-7). Epidemiologic and laboratory studies suggest that environmental influences may be the most important modifiable PrCA-related risk factors. A more complete discussion of these issues can be found in the complete study protocol.

This randomized trial will evaluate the effects of such environmental influences on PSA rise, quality of life, and circadian organization. The focus will be on the effects of a vegetable-based diet, circadian-timed physical activity, and mindfulness stress reduction. Previous studies suggest these factors promote favorable outcomes in the host-prostate cancer balance. Asymptomatic men with rising PSA values following primary PrCA treatment along with a partner of choice are being recruited from the Palmetto Health system and the greater Columbia, SC area. Results from this study will add to our body of knowledge of the modifiable risk factors associated with the progression of prostate cancer.

Specific Aims:

Previous studies with both animal and human models suggest diet, physical activity, and stress reduction produce favorable results within the host-prostate cancer balance in asymptomatic men with rising concentrations of prostate-specific antigen (PSA) following primary PrCA treatment. This study will evaluate how the host-PrCA balance, as reflected by PSA rise, the span until symptom appearance, the robustness of circadian activity/sleep and melatonin patterns, and quality of life, is affected by an intervention consisting of:

- a whole-grain diet rich in soy products, other beans, and vegetables;
- a physical activity regimen aimed at increasing fitness and general well-being and establishing and maintaining the circadian coordination of the subject's sleep/activity cycle; and
- a mindfulness-based stress reduction aimed at increasing the coping resources of participants in dealing with difficult emotional reactions to a PrCA recurrence and related physical symptoms, and to increase compliance with other components of the intervention (i.e. to use meditation and other stress reduction techniques to increase self efficacy or the belief in the subject's own ability to change his other health-related behaviors for the better).

The purpose of this study is to test the effect on PSA levels of an intensive intervention combining diet, physical activity, and mindfulness-based stress reduction in prostatectomized (by either surgery or radiation or both) men after biochemical recurrence of prostate cancer. In order to assess the effect of the intervention on PSA rates of change and doubling times from the pre-recruitment period to the end of the intervention, subjects will be compared to age-matched controls randomized to usual care.

Body:

The approved Statement of Work (see Appendix 1) categorized the work objectives for the project into 5 distinct tasks, each with indications for the months from the study timeline in which these tasks will be accomplished. Due to unforeseen delays in getting Human Subjects approval from the Institutional Review Boards of the three bodies governing this research (i.e., U.S. Army, University of South Carolina, and Palmetto Health), the original study timeline was revised. The original timeline started in May 2003 (month 1) and participant recruitment was scheduled to begin in August 2003 (month 5). Final approval from all three institutions was not obtained until late March 2004, with recruitment for the first wave of participants beginning immediately after.

With the start of recruitment, data became available on the number of men contacted, the number of responses received from contacts, the number of ineligibles and the number of eligibles. We had promising results in the beginning of recruitment with the referrals from urologists. But currently, we have to explore other avenues in order to recruit participants. We have been focusing our recruitment efforts on advertisements and health fairs, along with expanding our efforts to the surrounding Midlands areas. We also have been focusing our efforts on recruitment of the African-American population through various publications widely read in that population.

In the following sections, each individual sub-task outlined in the Statement of Work is indicated in bold text and by an alphabetic indicator (e.g., a, b, c,…). Our work to accomplish these sub-tasks follows in bulleted form. Where applicable, problems encountered in completing tasks are described and our plans for overcoming these barriers are outlined.

Task 1: Run-in Phase, Months 1-4:

a. Inventory and finalize all assessment instruments and data collection protocols.

- Accelerometers were purchased from MTI Actigraph. Analysis programs were provided by Dr. Chuck Matthews to analyze the Actigraph data for physical activity at baseline and six months. Instruction sheets for the proper use and return of the Actigraphs was prepared for participants. To ensure that we received the Actigraphs in a timely fashion, half of the participants brought their Actigraphs to us, while the other half of the group had their Actigraphs picked up by a courier service. The instruction letters were provided in Appendix 2.
- The collection of 24-hour recall data at baseline and six months was added to the protocol and approved in March 2004. The protocol for this data collection is based on similar recalls done in previous studies by members of the study team (Appendix 3).
- All questionnaires and data collection protocols are housed in the study's Procedures Manual.

b. Review baseline questionnaires for completeness and for content validity.

- A baseline questionnaire packet was reviewed and compiled. All questionnaires were submitted to the Department of Defense on November 14, 2003. The packet includes the following sections:
    - Demographics
    - Food Frequency Questionnaire
    - The Community Health Activities Model Program for Seniors (CHAMPS)
    - Medical/Family History

- Personal Reaction Inventory (also known as the Marlowe Crowne Social Desirability Scale)
- Martin-Larsen Approval Motivation scale (to measure social approval)
- Perceived Stress Scale
- Anger Expression Scale

- The Perceived Stress Scale was approved to be added the baseline questionnaire packet. This questionnaire allows for better assessment of how individuals react to stress, versus simply listing the number of potentially stressful events to which they have been exposed.

c. Revise baseline questionnaire to assess demographic, health history, and family health history, as necessary.

- Questionnaires were reviewed by Dr. Wilcox and Dr. Heiney to assess for readability in this population.
- On their recommendation, the font of all questionnaires was changed to Times New Roman, type size 14.

d. Hire and train the Project Coordinator, Research Nurse, and other project staff.

- A Project Coordinator trained in nutrition and exercise science was hired in August 2003. In the fall of 2004, the role of Project Coordinator was divided into two part-time positions. The original project coordinator transitioned into the role of class instructor for the intervention group and a new project coordinator was hired to handle the everyday operations of the study. The coordinator's biosketch is attached as Appendix 4.
- Due to HIPAA compliance, the Nurse Navigator system at Palmetto Health is being used instead of a Research Nurse. The Nurse Navigator system uses a nurse trained in patient education, who is also an employee of the Palmetto Health system, to act as liaison between the urologist/oncologist offices, possible participants and study staff. This system has been of limited use in recruitment and we have found going straight through the urologist's office has produced better results.
- A chef trained in vegetarian cooking was hired in October 2003 in order to develop recipes and a cookbook for the intervention group. This individual completed study-related duties in 2004.
- An instructor trained in mindfulness-based stress reduction was hired in January 2004 to prepare class materials and teach the meditation portion of the intervention classes. The meditation instructor has trained the class instructor on mindfulness-based stress reduction and now serves as a consultant. Trained phlebotomists have been hired to perform blood draws at each clinic and handle the preparation and shipment of biological samples collected.
- Two Benedict College students (a Historically Black College here in Columbia) and one graduate assistant from the University of South Carolina have been hired to aid in data entry and other study duties.

e. Develop the study data management systems.

- Under the supervision of Dr. Sue Heiney and Mr. Tom Hurley, Microsoft Access databases have been created for recruitment; i.e., in order to track eligibility/ineligibility statistics as well as source of referral.

- A tracking database also has been established to track participants' study compliance.

f. Develop the tracking database based on our experience with other intervention studies in the Department of Epidemiology and Biostatistics.

- Tom Hurley, biostatistian in the Statewide Cancer Prevention and Control Program and USC the Department of Epidemiology and Biostatistics with extensive experience in creating and managing Access databases, oversaw the development of the tracking database used by the study.

g. Train staff in all data-related and clinic-based procedures.

- Training sessions are held periodically to train Phlebotomists for the study's clinic.
- All other study personnel involved with data-related and clinic-based procedures are trained upon hire. Periodic updates and reviews are provided in bimonthly study team meetings. We continue to have bi-monthly study meetings to update and train staff.

h. Develop and finalize all laboratory procedures to be used in the trial.

- Dr. Shuk Mei Ho at the University of Massachusetts and Dr. Blask with the Bassett Research Institute have provided protocols for the collection and shipment of the specimens they will analyze, i.e., blood and urine, respectively.
- A clinic routine, with directions for team members assisting in the clinic appointments, has been established and is on file. The clinic routine and script are maintained in the study's procedures manual. These have been updated as needed.

i. Finalize all biological sample collection and storage procedures to be used in the study.

- A blood collection, processing and shipping protocol along with a urine collection, processing and shipping protocol were developed and are housed in the study's procedures manual (on file).

j. Establish recruitment procedures for men entering the study.

- A bulleted recruitment outline was provided to Department of Defense contact Donna Ferrandino on March 10, 2004. The outline is attached as Appendix 7.

k. Establish retention procedures.

- The following retention procedures were outlined in the protocol:
    - Establish a project identity. The study identity EASE – Eating, Activity, and Stress Education was created along with a logo to support the identity. The logo was submitted in March 2003 to Donna Ferrandino.
    - Multiple contacts leading up to consent. The bulleted outline on file details the multiple contacts the study team makes with the potential participant before the individual consents. These contacts include mailings as well as phone calls.
    - Provision of meaningful incentives. $10 gas coupons as well as other incentives have been, and will continue to be, provided to participants each week they are enrolled in the study. The list of incentives participants will receive was provided previously and is on file.

- Provision of clear communications and expectations. A brochure was created as a tool for providing clear communications to prospective study participants. Participants also are provided with an overview of the intervention from section D.10. of the protocol, as suggested by Donna Ferrandino, and a more detailed description of the intervention diet (on file). Projected dates of the intervention and clinic appointments are provided during recruitment and are finalized in the welcome call and reminder letter to the participants. The welcome call script and reminder letter were submitted in March 2004 to Donna Ferrandino.
- Maintenance of between-assessment and intervention contacts. This maintenance includes weekly incentives to both intervention and control participants, thank you notes included with each incentive, and phone calls to remind them of clinic appointments.

l. Finalize the intervention protocol.

- An intervention manual was created with an outline, handouts, menu and recipes for each intervention class. A copy of the manual's table of contents was submitted in March 2004 to Donna Ferrandino.
- Personnel to run the intervention were hired (dietitian trained in exercise science, instructor trained in mindfulness-based stress reduction) and a chef trained in specialized vegetarian cooking.

Task 2: Recruitment, Months 5-18:

a. Identify men who could be eligible for the study from the tumor registry and patient records at the collaborating urology practices in Columbia, SC.

- The tumor registry is not being utilized at this point.
- As of 30 April 2006, fifty three patients who were eligible and willing to participate have been referred to the study by collaborating urologists in the Columbia, SC area.
- Dr. Heiney also sent a general mailing to the 430 PrCA patients with whom she works at Palmetto Health Richland. Mailings were also sent to patients of Lexington Urology Associates and Orangeburg Urology Associates this year in order to recruit patients. Some patients were recruited from the Prostate Cancer Survey mailed by the South Carolina Central Cancer Registry to prostate cancer patients who were diagnosed in the eight-country area around Columbia.
- The University of South Carolina's public relations department provided, and IRB approved, Public Service Announcements to area radio stations and newspapers (on file).
- In addition to the above recruitment efforts, various cancer advocates around the state have been given the study brochure and are distributing them at area events and doctor's offices. Brochures were provided at the South Carolina Cancer Alliance (SCCA) annual meeting, cancer presentations in Greenville, South Carolina, area members of the American Urological Association (AUA), and Dr. Thomas Keane's (Chief of Urology) office at the Medical University of South Carolina (MUSC). Dr. Keane asked specifically to be able to refer eligible patients and distribute the study brochure to interested patients in his practice.
- We also began utilizing the South Carolina Central Cancer Registry in the Summer of 2005 with letters being mailed to potentially eligible participants and surveys being returned indicating their potential interest in the study.

- We have also focused recruitment efforts on health fairs, conferences, minority populations via publications targeted for their communities.

b. Among those who say they are willing to participate, confirm eligibility using the criteria listed in section D.2. of the proposal.

- To aid in confirming eligibility of participants. Dr. Heiney and Lynne Bridges developed a checklist, which is mailed to participants. Ms. Bridges then calls potential participants and reviews the checklist with them. All checklists and phone scripts were submitted to Donna Ferrandino on March 2, 2004.

c. Enroll 60 eligible men.

- Currently, we have a database of 533 men who have been diagnosed with prostate cancer and have been in contact with either by phone or by mail. Of those, 53 men were eligible, agreed to participate, and were able to participate in the study.

d. Establish baseline PSA levels through repeat measures taken before subjects are randomized to intervention.

- Due to HIPAA regulations, previously obtained PSA levels recorded in patient medical records, which would establish a baseline PSA level, cannot be obtained until written permission is obtained from the patient. This permission will be collected during the participant's first clinic visit. After gaining his written consent, we will obtain previous PSA levels recorded in his medical charts as well as collect a blood sample during our baseline clinic for PSA testing by Quest diagnostics.

e. Collect data on diet, physical activity, other aspects of lifestyle, demographic, and health (family and personal history), and other factors as outlined in D.4.

- Data collection began on June 9, 2004 and we continue to collect the baseline data from each group enrolled.

f. Schedule the first clinic appointment for the purposes of collecting all of the blood and urine specimens and taking the anthropometric measurements.

- The first group recruited into the study had their first clinic on 9 June 2004.
- These participants were contacted via phone and through letters. The Welcome Call script and letter were submitted to Donna Ferrandino in March 2003.

{Task 2, items g and h, and Tasks 3-4 have not been reached at this time; delays in Institutional Review Board/ Human Use Committee reviews and revisions are the underlying cause of the delays}

g. Abstract medical records for relevant health history and pathology data. This activity is on-going and will continue to be conducted.

h. Randomize half of study participants to the intervention condition and half to control by SAS program. Block randomization is done so that cases and controls are matched on age (within 5 years). When randomized to the intervention group, the participants are scheduled to have an

individual and group sessions with the interventionist. Currently, all 53 men in the study have been randomized.

Task 3: Intervention / Passive Follow Up in the Controls, Months 8-30:

a. Ensure that the intervention is delivered according to the protocol. This is being done by conducting 24 hour recalls and the recalls being reviewed by a member of the staff.
b. Schedule incentives. Incentives have been scheduled and we continue to provide incentives on a regular basis to encourage men who are randomized to intervention and their significant other to attend group sessions and other intervention methods.
c. Establish a schedule of reminders to participants regarding the intervention. This is done on a regular basis. We use a reminder call script which is on file.
d. Stay in contact with the control group to assure compliance with the follow-up measures. We continue to maintain contact with the control group, including reminding them of the opportunity to select the intervention in the next available cycle.
e. Schedule clinic visits for the blood, urine, and anthropometric data collection. We continue to be up to date in the collection of all study-related data.
f. Assure that all self-assessments are completed at follow up. A regular check of database and a clinic check list is done in order to ensure that all data needed has been collected.

Task 4: Data Entry, Verification and Interim Analyses, Months 6-31:

a. Assure that all data are immediately read into the tracking and analytic databases. All data are immediately entered into the appropriate data systems.
b. Flag all outlier and illogical responses. All out-of-range or otherwise suspect data are identified.
c. Verify all outlier and illogical responses, re-contacting participants, if necessary. All out-of-range or otherwise suspect data are checked and reconciled.
d. Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics). This activity has been on-going since wave C.

Task 5: Final Data Analyses, Months 30-36:

a. Perform all exploratory analyses to test for adherence to model assumptions. We are in the process of conducting formal analyses using all data collected through Wave E.
b. Perform all necessary data manipulations (e.g., log transforming all non-normal and heteroschedastic data). This is done as a matter of course in conducting formal analyses of data collected through Wave E.
c. Test study hypotheses. This will not occur until Wave F is completed (in the late fall of 2006).
d. Conduct post-hoc analyses of study data. This will not occur until the formal intention-to-treat analyses of Wave A to F is completed (in the late fall of 2006).
e. Prepare manuscripts. This will not occur until Wave F is completed (in the late fall of 2006).
f. Archive datasets for future analyses and future patient follow-up. This will occur as part of study shut-down.
f. Plan for future studies. Although discussions have begun, this will not begin in earnest until the summer of 2006.

Key Research Accomplishments:

In our first year of funding, we have created an intervention manual with twelve weeks of lessons combining instruction in nutrition, mindfulness-based stress reduction (MBSR), physical activity, and behavior change methods. To aid in at-home compliance with the intervention, study personnel have created a cookbook and an instructional MBSR audio CD set. Additional accomplishments include the study and procedure manuals, the study's questionnaire packet and study databases. We began our 6th (F) wave of participants in April 2006. We are also utilizing the South Carolina Central Cancer Registry and building a database of PrCA patients. This has aided in the recruitment of participants for this study and will aid in the recruitment of future participants to other studies, providing the general population with opportunities heretofore unavailable to men in South Carolina..

We have offered intervention classes for the controls who have completed the study and wish to learn about the intervention. And at the request of the participants, we have held a reunion for those who have completed the study and have requests to do hold another reunion in the future (which is currently planned for June 2006).

Reportable Outcomes:

Study products: The study's intervention manual and procedures manual have been completed. The study efforts thus far have also produced a vegetarian cookbook and MBSR instructional CD set. Recruitment efforts have aided participating doctor's offices with establishing databases capable of tracking their patients.

Funding applied for and received based on this award: Study biostatistian, Tom Hurley, was awarded a grant by the South Carolina Research Authority and the South Carolina Nutrition Consortium entitled "Self-Reporting of Dietary Data: Influence of Bias and Imprecision on Intervention Effect Estimates." This will allow us to conduct three 24-hour dietary recall interviews for each of the study periods. This provides a huge advantage for the study, as this is the deluxe method of dietary assessment (8-10) and is provided at no cost.

Training opportunities: So far, Four interns have worked with the study. These have included three dietetic interns from Winthrop University completing part of their community nutrition rotation by working with the study intervention manual and 24-hour recall set-up, and a masters student in the Health, Promotion, Education and Behavior department at the Arnold School of Public Health completing his degree's practicum requirement. Collaborative efforts have begun with Benedict College, a HBCU here in Columbia, SC with the hiring of two students. These efforts include accepting their students as research assistants to aid the study in our recruitment efforts within the state's minority population. Also, we have provided training opportunities for two additional Winthrop University dietician interns.

Conclusions:

At this point in the timeline, the study team has recruited the 6th and final wave of participants and anticipates the completion of this wave by the end of October 2006. The previous 5 waves have completed. We will offer one additional intervention class at the completion of the 6th wave so that

the individuals assigned to the control group will have the opportunity to attend the intervention classes. We continue to utilize the procedures an materials that were put in place for baseline testing and the intervention classes. Current recruitment data shows that we have exhausted our efforts with the Midlands urologists and we have moved out side of the midlands in order to recruit. To continue a strong recruitment effort and reach as many potentially eligible men as possible, the study team is strengthening and creating collaborative efforts statewide. We will continue to build our database of prostate cancer patients through our collaboration with the South Carolina Cancer registry.

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