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Award Number: W81 XWH-04-1-0179

TITLE: Evaluating an Interactive, Multimedia Education and Decision Program for Early-Stage Prostate Cancer Patients in a Randomized Controlled Trial

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REPORT DATE: February 2006

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE 01-02-2006		2. REPORT TYPE Annual		3. DATES COVERED 15 Jan 2005 – 14 Jan 2006	
4. TITLE AND SUBTITLE Evaluating an Interactive, Multimedia Education and Decision Program for Early-Stage Prostate Cancer Patients in a Randomized Controlled Trial				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-04-1-0179	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Michael A. Diefenbach, Ph.D.				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Mount Sinai School of Medicine New York, NY 10029-6574				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES Original contains colored plates: ALL DTIC reproductions will be in black and white.					
14. ABSTRACT This 3-arm randomized controlled trial evaluates the efficacy of a CD-ROM based multimedia prostate cancer education system (PIES). PIES is an educational software that provides patients with information about prostate cancer and its treatment through an intuitive interface, using video, animation, text, and voice-over text. All text is tailored to a person's information seeking preference. Participants (N = 312) are patients diagnosed with localized prostate cancer who will be randomized into three experimental conditions: a) Standard care, involving the provision of standard NCI print material about prostate cancer, Group 1; b) PIES software without tailoring component, Group 2; c) and PIES software with tailoring component, Group 3. Assessments will be taken prior to exploring the software/brochures, immediately after completing the software/brochure, and 6-weeks post baseline. The study design allows for the evaluation of the efficacy of the multimedia intervention against traditional care; the influence of tailoring versus not tailoring information within a multimedia context; and for an evaluation of the moderating effect of monitoring on the efficacy of the groups.					
15. SUBJECT TERMS Prostate Cancer, Treatment Decision Making, Multimedia, Randomized controlled Trial, Intervention.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	8	19b. TELEPHONE NUMBER (include area code)

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PI: Michael A. Diefenbach, Ph.D.

Abstract

This 3-arm randomized controlled trial evaluates the efficacy of a CD-ROM based multimedia prostate cancer education system (PIES) developed by our research group. PIES is an educational software that provides patients with information about prostate cancer and its treatment through an intuitive interface, using video, animation, text, and voice-over text. All text is tailored to a person's information seeking preference (i.e., high versus low monitors). Participants (N = 312) are patients diagnosed with localized prostate cancer who will be randomized into three experimental conditions: a) Standard care, involving the provision of standard NCI print material about prostate cancer (Group 1); b) PIES software without tailoring component (Group 2); c) and PIES software with tailoring component (Group 3). Assessments will be taken prior to exploring the software/brochures, immediately after completing the software/brochure, and 6-weeks post baseline. The study design allows for three main comparisons: it evaluates the efficacy of the multimedia intervention against traditional print materials or standard care; it evaluates the influence of tailoring versus not tailoring information within a multimedia context; and, it allows for an evaluation of the moderating effect of monitoring on the efficacy of the intervention groups.

W81XWH-04-1-0179: Evaluating an interactive, multimedia education and decision program for early-stage prostate cancer patients in a randomized controlled trial.

PI: Michael A. Diefenbach, Ph.D.

Introduction: Despite advances in treatment, uniform treatment recommendations for localized prostate cancer have yet to emerge. Consequently, men with this diagnosis are faced with a complex set of disease information and treatment challenges as they select a treatment option (Diefenbach, et al., 2002). To educate patients about prostate cancer and its treatment and to ease their decisional burden, we have developed an innovative CD-ROM based multimedia prostate cancer interactive education system (PIES; <http://www.temple.edu/imits/pies.htm>). The development of the software has been guided by our cognitive-affective, self-regulation theoretical framework (Diefenbach & Leventhal, 1996; Miller & Diefenbach, 1998). PIES uses the metaphor of a health center. Patients can explore various rooms to interactively obtain treatment and disease information. PIES goes beyond the inclusion of text, video, audio, and animation, by providing a unique intelligent expert system that tailors text information to the patient's information seeking preferences (high vs. low monitoring; Miller, 1996; Miller & Diefenbach, 1998). Research has identified high monitors as information seeking and being more distressed compared to low monitors, who are classified as information distracting and being less distressed.

This 3-arm randomized controlled trial evaluates the efficacy of PIES. Participants are patients diagnosed with localized prostate cancer who will be randomized into three experimental conditions: a) Standard care, involving the provision of standard NCI print material about prostate cancer (Group 1); b) PIES software without tailoring component (Group 2); c) and PIES software with tailoring component (Group 3). Assessments will be taken prior to exploring the software/brochures, immediately after completing the software/brochure, and 6-weeks post baseline. The study design allows for three main comparisons: it evaluates the efficacy of the multimedia intervention against traditional print materials or standard care; it evaluates the influence of tailoring versus not tailoring information within a multimedia context; and, it allows for an evaluation of the moderating effect of monitoring on the efficacy of the intervention groups.

Body: While we were in the process of obtaining IRB approval from MSSM, we enhanced and updated the content of the PIES program. A new version of PIES was created consisting of video tapes of MSSM faculty and staff addressing commonly asked questions by prostate cancer patients and adding new books to the virtual library focusing on "Trimodal Therapy" for prostate cancer and "Laparoscopic and Robotic Surgery". These books provide an overview of the treatment procedures and explain the pros and cons of each option.

After obtaining IRB approval from MSSM recruitment began and to date, we have accrued 39 patients into the study. To expand and speed up accrual we have initiated expansion of PIES to a new study site, Queens Hospital Center, an affiliate of Mount Sinai School of Medicine. Queens Hospital is served by Mount Sinai faculty and therefore it represents a natural expansion. MSSM IRB approval for this expansion was obtained in June 2005, however, the DOD approval is still pending.

To boost awareness of the clinical trial and to increase enrollment, we initiated the following steps:

- We met with MSSM's public relation office and initiated the approval process to list the study on MSSM's clinical trials web-page.
- In conjunction with MSSM's public relation office and an advertising specialist who volunteered her time for the Dean Prostate Health and Research Center, we initiated a major press release for New York City newspapers about the clinical trial.
- Launched an advertising campaign in three morning papers in Manhattan, that are free to the public. These free publications (Metro, am-NY and Daily News) have a combined readership of over 1 million readers. The advertisements (approximately \$6,500) were paid by the Deane Prostate Health and Research Center
- Outreach to Support groups. Dr. Diefenbach (PI) gave several talks to local support groups such as the local "Man to Man" chapter.

We have created SPSS databases for managing all data that is collected throughout the study. Databases have been created for all questionnaires: Baseline, Post group1, Post group2/3, and 6 Week Follow-up.

To date, we have enrolled 39 patients into the RCT. Eligible patients were randomized into the Control Group (N=9), Intervention Group with tailoring (N=16), and Intervention without tailoring (N=14). Patients were on average 63.5 years old (SD: 1.48), 55% reported being retired, 79% are married, 52.8% completed high school or below and 47.3% had a college or post graduate degree. The minority population is 37% (5% Hispanic Origin; 31.6% African American); 52.6% of patients are Caucasian/Non-Hispanic.

Preliminary analyses of the baseline dataset focused on the assessment of the main outcome variables "decisional conflict." The decisional conflict total score and its subscale scores are scored to range from 0-100. At baseline, prior to a treatment decision, the average total decisional conflict score is M: 55.14 (SD: 8.3), indicating a moderate to high decisional conflict. Among the sub-scales decisional uncertainty was particularly high (M: 65.7 (SD:27.07)). Men were moderately uncertain that they could make an effective decision (M: 57.8 (SD:14.8)0, and needed assistance in sorting out what was important for them (value clarification M: 55.5 (SD: 8.3)). Patients felt moderately informed about prostate cancer (M: 54.2 (SD: 8.9)0, and had fairly well to moderately well developed decisional support (M: 47.2 (SD:15.0)). At baseline we did not expect to find any differences by group for these scales and we did not find any.

These results indicate a clear need for patient education and decisional support in line with what PIES offers to patients. Future analyses will focus on the immediate and long-term effect of PIES on decisional conflict and distress compared to standard care, as well as the unique contribution of the tailoring component on these variables.

Key Research Accomplishments:

- 1) We have obtained IRB approval from MSSM and have been recruiting patients.
- 2) We had a major press release in New York City, advertising PIES and the clinical trial in 3 morning newspapers.
- 3) We can be found on the web on the Mount Sinai Clinical Trials website.
- 4) Outreach to local support groups in New York City to increase awareness.

- 3) We have to date enrolled N=39 study patients from MSSM. Although recruitment was slow during the summer months we have been accruing an average of 3 patients per month since the fall.
- 4) We enhanced the content of the PIES program by adding “Trimodal” and “Robotic Surgery” books to the library that provide an overview of these treatment procedures including a discussion of the pros and cons of each of these treatment options. Different versions of these books appropriate for high and low monitor information seeking styles were created.
- 5) We further enhanced PIES by creating a new version using all MSSM faculty and staff and updating all written materials incorporating the latest literature. The video footage includes segments by Urologists, Radiation Oncologists, a Nurse, a Research Scientist, and Radiation Technicians. This involved creating new scripts, video taping, editing footage, and integrating it into the previously established PIES format. Footage covered: Trimodal Therapy, 3-D Radiation, Seed Implants, Hormone Therapy, Erectile Dysfunction, what to expect during Pre and Post Operation, what to expect duration radiation therapy, and “What is a clinical trial?”.
- 6) We developed databases in SPSS and entered data.
- 7) We have expanded the study to an affiliate hospital under the MSSM network. Queens Hospital is in the process of being added to the study protocol to expand recruitment opportunities. We are awaiting final approval from USAMRMC to begin recruitment.
- 8) We made copies of the new version of the PIES CD-ROM to adequately supply each patient work station.

Key Research Accomplishments:

- Refinement of Baseline Questionnaire
- Enrollment of 39 study participants
- Obtained IRB approval MSSM
- Process of expansion of study to an affiliate institution
- Created databases for all questionnaires to manage subject data
- Filmed a new version of PIES with MSSM staff
- Added new books to the PIES library
- Press release of PIES in New York City
- Advertisements in three morning newspapers.

Reportable Outcomes: Not Applicable.

Conclusions: Despite difficulties with recruitment we have taken steps to remedy the slow subject recruitment by including Queens Hospital Center (QHC) as an additional recruitment site. It is expected that the inclusion of QHC, with an average 6 prostate cancer patient diagnosed per month, will enhance recruitment to meet the accrual goals of this RCT.

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Appendices: NONE

Supporting Data: NONE