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**W81 XWH-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.

**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:** To expand and speed up accrual we have expanded PIES to a new study site, Queens Hospital Center (QHC), an affiliate of Mount Sinai School of Medicine (MSSM). 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. DOD approval was obtained in June, 2006 and recruitment from Queens Hospital Center began in July, 2006. To date, a total of six patients have been enrolled from Queens for a total of 80 patients from both sites.

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

- We can be found on the Mount Sinai Clinical Trials website.
- Monthly meetings with the head of marketing and outreach for the Barbara and Maurice Deane Prostate Health and Research Center have been established to continue to increase enrollment and community awareness of PIES.
- Outreach to Support groups. Dr. Diefenbach (PI) has continued his relationship with local support groups such as the local “Man to Man” chapter.
- We have attended prostate cancer awareness and fund raiser gatherings to expose PIES within the community.
- Distribution of several hundred informational materials advocating PIES at a free prostate cancer screening sponsored by The Daily News at Mount Sinai Hospital.

Milestones:

- We have obtained GCO continuation approval for one year (1/15/2007-1/14/2008) under a No Cost Extension.
- The research is approved with the MSSM IRB through 6/15/2007 a continuation will be submitted to extend this project 5/15/2007.
- We have extended recruitment to Queens Hospital Center (QHC), an affiliate of Mount Sinai School of Medicine, and have successfully been recruiting since July 2006. To ensure a seamless transition we met with colleagues from QHC to inform them about the PIES program
- Enrollment has nearly doubled since the last annual report. To date we have enrolled N=80 study patients from MSSM and QHC. We continue to work very hard to recruit patients and have maintained an average accrual of 3 patients per month.
- To disseminate our findings we have submitted an abstract of our analyses to the annual meeting of the Society for Shared Decision Making in May 2007.
- We will also submit our findings at the “IMPACT: Innovative Minds in Prostate Cancer Today” meeting hosted by the Department of Defense (DoD) Prostate Cancer Research Program in September 2007.
- All questionnaires are being entered in SPSS databases as they are received. All data entry is double checked for accuracy.

### **Narrative of Results:**

Eligible patients were randomized into the Control Group (N = 20), Intervention Group with tailoring (N= 34), and Intervention without tailoring (N= 26), resulting into N = 80 patients. Patients were on average 61.9 years old (SD: 8.5); 38.5% reported being retired; 71.3% were married, 33.3% completed high school and 57% had a college or post graduate degree. The proportion of minority participants is 43% (14.6% Hispanic Origin; 27.3% African American); 57% of patients are Caucasian/Non-Hispanic.

Participants were evaluated at baseline and immediately after viewing PIES or the Brochures (Control Group). Among the participants who viewed the PIES program, 91% reported that PIES is well organized & easy to follow. An overwhelming majority (82%) believed the graphics were clear and easy to understand, and 79% reported that using PIES was like visiting a health center. Participants felt that information was easy to understand (77%), anatomical and biological information was clearly presented (64%), and 66% reported that using PIES helped them with their treatment decision.

The following analyses combined the two PIES groups into one and compared it against the Control Group. Preliminary analysis of the data indicate that participants who viewed the PIES program felt significantly more confident in their treatment decision ( $p < .033$ ) than patients in the control condition. Patients also believed that the information presented was more effective in calming their nerves ( $p < .04$ ) and was significantly more helpful for learning about prostate cancer treatments ( $p < .000$ ). In contrast, participants in the control group felt significantly more anxious about having to make a treatment decision ( $p < .047$ ), felt they were presented with too much information ( $p < .00$ ) and would prefer to have more time and information in order to make a treatment decision ( $p < .03$  and  $.034$ , respectively).

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  $M: 49.42$  ( $SD: 16$ ), indicating a moderate to high decisional conflict. Among the sub-scales men were moderately uncertain that they could make an effective decision ( $M: 53.7$  ( $SD: 19$ )), and needed assistance in sorting out what was important for them (value clarification  $M: 50.1$  ( $SD: 21$ )). Patients felt moderately informed about prostate cancer ( $M: 44.1$  ( $SD: 17$ )), and had fairly well to moderately well developed decisional support ( $M: 52.7$  ( $SD: 20.4$ )). At baseline (i.e., after randomization) there were no differences among these scales by study group.

Participants were asked to evaluate decisional conflict again six weeks after participating in the study. Preliminary analysis found that among the participants who viewed the PIES program, overall decisional conflict was significantly reduced ( $M: 36.3$ ;  $p < .00$ ). Significant decreases were also noted on the decisional conflict subscales. Men felt that they were better able to make an informed decision ( $p < .007$ ), they were better able to clarify their values ( $p < .001$ ), had more developed decisional support ( $p > 0 .01$ ) and believed that they could make a more informed decision ( $p < .00$ ). Among patients in the control condition, there was a secular trend for an improvement in overall decisional conflict ( $M: 42.36$ ;  $p < .048$ ), however, subscales values were not significantly different from baseline values.

These results indicate that PIES is well accepted by patients. It is well organized, easy to use, informative, and presents clear and accurate graphics. Two thirds of patients indicated that it is helpful with decision making. Patients who used PIES were significantly more confident about their decision and significantly less anxious about their decision. Decisional conflict was reduced from Baseline to 6 weeks among PIES patients on 5 of the 6 scales including overall decisional conflict.

### **Key Research Accomplishments:**

- Patients randomized into the PIES condition overwhelmingly indicated that the program was easy to use; the information was easy to understand and clearly presented. Most importantly two-thirds of the patients indicated that the PIES program helped with their treatment decision making.
- Patients across study conditions exhibited elevated levels of decisional conflict (total score) as well as elevated levels in the various subscales.
- Six weeks later these positive and significant results were maintained as patients randomized into the PIES condition exhibited a lower total decisional conflict score as well as lower decisional conflict subscales
- PIES is well accepted by all patients, is easy to use and contains helpful information, including graphics and animations.

**Reportable Outcomes:** Not Applicable.

**Conclusions:** Our preliminary results are extremely promising and point to the efficacy of the PIES program as an educational tool and a decision aid.

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**Appendices:** NONE

**Supporting Data:** NONE