

AD _____

Award Number: W81XWH-11-1-0604

TITLE: An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy

PRINCIPAL INVESTIGATOR: Michael A. Diefenbach, Ph.D.

CONTRACTING ORGANIZATION: Mount Sinai School of Medicine
New York, NY 10029

REPORT DATE: August 2013

TYPE OF REPORT: Annual Report

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE August 2013			2. REPORT TYPE Annual		3. DATES COVERED 15 July 2012 – 14 July 2013	
4. TITLE AND SUBTITLE An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy					5a. CONTRACT NUMBER W81XWH-11-1-0604	
					5b. GRANT NUMBER W81XWH-11-1-0604	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Michael A. Diefenbach E-Mail: michael.diefenbach@mountsinai.org					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Mount Sinai School of Medicine One Gustave Levy Place New York, NY 10029					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						
14. ABSTRACT Our study team has made considerable progress during the second year of the award. During the past 12 months, we held a focus group with prostate cancer patients to test the usability of the program, and minor revisions were made to the application based on the participants' feedback. Multiple research team meetings were held to discuss recruitment procedures and study protocol and we have added two additional physicians to the study to aid our recruitment efforts. We have successfully enrolled n=10 eligible patients and are continuing to actively enroll participants into the study. During the extension period, we plan to complete recruitment and all expected follow-up assessments. We will also begin analyzing data and writing up the results for publication and presentation at national meetings.						
15. SUBJECT TERMS User testing, vasomotor symptom intervention, software development, feasibility study						
16. SECURITY CLASSIFICATION OF:				17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	19b. TELEPHONE NUMBER (include area code)			
				UU	6	

Table of Contents

	<u>Page</u>
Introduction.....	1
Key Research Accomplishments.....	1
Conduct Beta Test and Revision of VSI.....	1
Participant Recruitment.....	2
Interim/Final Analyses.....	2
Additional Physicians.....	2
References.....	3

Project title: An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy

Principle Investigator: **Michael A. Diefenbach**

Grant Number: **PC101229**

Date: 08/14/2013

I. Introduction

Hormone therapy, or androgen deprivation therapy (ADT), is considered first-line treatment for prostate cancer patients who experience a rising PSA level after definitive treatment (i.e., surgery and radiation). While ADT is effective in slowing the rise in PSA, 70-80% of men receiving this treatment experience vasomotor symptoms (VS), also known as hot flashes.¹ These symptoms often negatively impact patients' mental health, sleep, fatigue, and quality of life.² While there are pharmacological treatments available to manage hot flashes, many patients choose not to take them due to the increased risk of additional side effects.³⁻⁵ Thus, in response to the need of a non-pharmacological approach to manage hot flash symptoms, the aims of this study were to develop a behavioral intervention to reduce hot flashes. Specifically, we aim to (1) develop a breathing exercise application for the iPod touch platform; and (2) assess the feasibility and acceptability of this intervention among advanced prostate cancer survivors on hormone therapy. To reach these goals, we have developed an application, titled "2Breathe," for Apple's iPod Touch platform to help men apply the breathing techniques and we are currently evaluating its feasibility and acceptability.

II. Key Research Accomplishments

Our study team, led by Michael A. Diefenbach, PhD, has made considerable progress in the second year of the project entitled "An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy." During the past 12 months, we 1) had a group of 6 men testing 2Breathe and 2Play programs on the iPod Touch for its usability; 2) refined recruitment strategies with our collaborators at the VA; 3) successfully enrolled n=10 eligible patients into the study; 4) added Dr. Seth Blacksborg, MD and Dr. George Dawson, MD, both radiation oncologists at Icahn School of Medicine at Mount Sinai and the James J. Peters VA Medical Center, respectively, to the study team to increase our pool of potential participants. Further detail about our progress is described below.

Conduct Beta Test and Revision of VSI (Statement of Work, Task 7)

As per Task 7 of the Statement of Work, in October of 2012 we conducted usability testing with a group of men (N=6) who are experiencing hot flashes as a result of hormone therapy. During this session, the PI demonstrated the use of the 2Breathe (intervention) and 2Play (attention-control) software and the use of the iTouch, along with the breathing exercise. Participants then had a chance to try out the software. Participants had no difficulties operating the iTouch, calling up the software, and entering the necessary data. Overall, participants displayed great interest in the software and reviewed it positively.

Participant recruitment and baseline and follow-up data collection of the feasibility study
(Statement of Work, Task 8)

As per Task 8 of the Statement of Work, we have begun recruitment as well as baseline and follow-up data collection of the feasibility study. As of August 2013, we have successfully enrolled a total of n=10 eligible patients into the study. Participants have been recruited from the Icahn School of Medicine at Mount Sinai and the James J. Peters VA Medical Center. Participants have been available for all follow-up assessments (at 3-, 6-, and 9-weeks). A database was created for all participant-generated data, consisting of their usage of the 2Breathe and 2Play applications and the responses to the questionnaires.

Interim Analyses/Final Analyses and Report Writing (Statement of Work, Tasks 9 & 10)

We have not reached our accrual goal due to delays in study approval through the VA, software development, and slower than anticipated accrual. However, we believe that based on our current rate of accrual of approximately 5-6 participants a month, we should be able to achieve our overall accrual goal of N = 66 in the remaining study period.

Additional Physicians

During Y2 of the award, we included two additional physicians to the study to aid recruitment efforts. Dr. Seth Blacksborg, MD is a radiation oncologist at the Icahn School of Medicine at Mount Sinai and Dr. George Dawson, MD is a radiation oncologist at the James J. Peters VA Medical Center. Each physician has confirmed that he sees approximately n=3 eligible patients per month. Additionally, Dr. Simon Hall, MD in the Department of Urology at Icahn School of Medicine at Mount Sinai and Dr. Glen McWilliams, MD in the Department of Urology at the James J. Peters VA Medical Center confirmed that they see approximately n=8 eligible patients each month, combined. Anticipating an average recruitment of n=5 patients per month, we expect to reach our goal of n=66 patients by April 2014. This will give us sufficient time to conduct the 9-week follow up assessments and complete the final data analyses.

References

1. Engstrom CA. Hot Flashes in Prostate Cancer: State of the Science. *American Journal of Men's Health*. June 1, 2008 2008;2(2):122-132.
2. Kattan MW. Measuring hot flashes in men treated with hormone ablation therapy: an unmet need. *Urol Nurs*. 2006;26(1):13-18.
3. Atala A, Amin M, Harty JI. Diethylstilbestrol in treatment of postorchiectomy vasomotor symptoms and its relationship with serum follicle-stimulating hormone, luteinizing hormone, and testosterone. *Urology*. 1992;39(2):108-110.
4. Steinfeld AD, Reinhardt C. Male climacteric after orchiectomy in patient with prostatic cancer. *Urology*. 1980;16(6):620-622.
5. Miller JI, Ahmann FR. Treatment of castration-induced menopausal symptoms with low dose diethylstilbestrol in men with advanced prostate cancer. *Urology*. 1992;40(6):499-502.