Award Number: W81XWH-11-2-0178

TITLE: ARCPEP 2 Continuation Project (Seton Hill University)

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CONTRACTING ORGANIZATION: The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.

Bethesda, MD 20817

REPORT DATE: October 2014

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT:

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1. REPORT DATE (DD	D-MM-YYYY)	2. REPORT TYPE		3.	DATES COVERED (From - To)	
October 2014	1	ANNUAL			26 Sep 2013 - 25 Sep 2014	
4. TITLE AND SUBTIT	LE			5a.	CONTRACT NUMBER	
ARCPEP 2 Cont	inuation Proiect (S	Seton Hill Universit	ill University)			
			,		GRANT NUMBER	
					1XWH-11-2-0178 PROGRAM ELEMENT NUMBER	
				50.	PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)				5d.	PROJECT NUMBER	
COL(Ret) Marina Vernalis, DO, FACC						
Janice Sandrick, Ph.D.				5e.	TASK NUMBER	
email:marina.vernalis@us.army.mil				51.	WORK UNIT NUMBER	
7. PERFORMING ORG	ANIZATION NAME(S)	AND ADDRESS(ES)		8. F	PERFORMING ORGANIZATION REPORT	
	(0)				NUMBER	
The Henry M. Jackson	Foundation					
For the Advancement of	of Military Medicine, Inc.					
6720 A Rockledge Driv	e Suite 100					
Bethesda, MD 20817						
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command				10.	SPONSOR/MONITOR'S ACRONYM(S)	
U.S. Army Medical R	esearch and Materiel	Command	. ,			
Fort Detrick, Marylan	d 21702-5012					
					SPONSOR/MONITOR'S REPORT	
					NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT						
Approved of Public Release statement: distribution unlimited.						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT						
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It is widely acknowledged that cardiovascular disease prevention requires intervention as early in the human lifespan as practical. A window of opportunity presents in early adulthood when students gain independence as young adults attending university. In a						
three-phase investigation, this study will evaluate the behavioral patterns of university students in the domains of diet, exercise,						
stress management, smoking and sleep (phase 1). Informed with information from phase 1, a pilot study (phase 2) will test the						
feasibility of performing an intervention in university students consisting of an 8-week period during which the students will receive						
three text messages (by phone or iPad) per week, tailored to address the behavioral issues that the student has identified as						
needing improvement and for which the student has indicated a desire to make change. Using lessons learned in phase 2, a						
randomized, controlled trial the 8 week intervention (phase 3) will be performed with the plan to compare the outcomes of						
behavior change, measures of anthropomorphic data, and serum markers of cardiovascular risk to test the impact of the						
15. SUBJECT TERMS						
Lifestyle; Cardiac Prevention; Behavior; Cardiovascular Disease (CVD); Diet ;Exercise; Stress						
TO. SECURITY CLASS	DIFICATION OF:		17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON	
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					Standard Form 298 (Rev. 8-98)	

Prescribed by ANSI Std. Z39.18

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ARCPEP 2 Continuation Project (Seton Hill University) Annual Report Dates: 9-27-13 to 9-26-14

Executive Summary

The collaborative relationship between Walter Reed and Seton Hill University has been dynamic, to include the ICHP team conducting a successful day long Healthy Engagement Coaching Workshop for Seton Hill University students at Walter Reed. SHUPEP has been very successful to date. The technology application was successfully built and launched during phase 2 of the project. Phase 1 of this proposal is an observational study and began in January 2013. Phase 2 was successful launched. Four poster presentations were successfully delivered at the American College Health Association in May 2014. Data from Phase 1 and 2 is being used to inform Phase 3 which will launch in FY2015.

Introduction

This study aims to study the issues of health behaviors in the domains of nutrition, exercise, stress, sleep and smoking. We aim to improve health behaviors in these domains by evaluating lifestyle choices, learning styles, and communication preferences with a three-phase investigation.

Phase I has the specific objective of lifestyle assessment. Phase 2 constitutes a pilot study in a limited number of university students to determine the feasibility of causing healthy behavior change by health coaching and the use of electronic messaging via a prototype technologic application to university students. Phase 3 will measure improvements in the lifestyle behaviors of students as a result of health coaching and electronic feedback messages.

Body

Walter Reed location:

- 1. Continued oversight, research and data management coaching via weekly telephonic conference calls and emails.
- 2. Provided direct "hands-on" teaching with statistical methods using summary statistics, analysis of variance and correlation analysis.
- 3. Wrote, edited, rewrote and coached on writing abstracts.

- In collaboration with the Scientific Team, developed a schedule of academic conferences with abstract due dates and meeting dates and locations.
- 5. Reviewed and updated database from Phase 1 data, performed quality checks on data entries and requested corrections from original completed questionnaires.
- 6. Data from Phase 1, resulting from prior enrollment of 180 students, was analyzed with particular topical areas of interest. This produced four abstracts which were submitted to and accepted for presentation at the annual international meeting of the American College Health Association. These abstracts were successfully taken to San Antonio TX as poster presentations in June 2014 garnering substantial interest from meeting attendees. Abstract citations:
 - Bowman T, Sandrick J, Tracy D, Roth A, Harouse-Bell K, Kashani M, Vernalis M, Eliasson A. Associations Between Anthropometric Measures of College Students and Campus Dining Options. American College Health Association May 2014; San Antonio, TX, poster presentation
 - Harouse-Bell K, Sandrick J, Tracy D, Bowman T, Roth A, Kashani M, Vernalis M, Eliasson A. Vegetarian-style Eating in College Students--Diet Survey Analysis and BMI. American College Health Association May 2014; San Antonio, TX, poster presentation
 - Roth A, Sandrick J, Tracy D, Bowman T, Harouse-Bell K, Kashani M, Vernalis M, Eliasson A. Vitamin D Deficiency in College Students—Prevalence and Implications. American College Health Association May 2014; San Antonio, TX, poster presentation
 - Sandrick J, Eliasson A, Tracy D, Harouse-Bell K, Bowman T, Roth A, Kashani M, Vernalis M. Sleep Quality, not Sleep Quantity, Correlates with Academic Performance. American College Health Association May 2014; San Antonio, TX, poster presentation

For Phase 2 of the SHUPEP protocol, participants were aggressively recruited in the Spring of 2014. After recruiting 85 potential participants with an additional 20 potential subjects on a waiting list for possible participation, 50 subjects were screened and a planned 36 participants were enrolled in the protocol. Of these 36 enrolled subjects, 34 completed all data collection in May 2014.

- 7. Data analysis for Phase 2 is underway.
- For Phase 3, aggressive recruitment was begun in August 2014 in order to find 70 qualified participants for a planned start-up date of Phase 3 in January 2015. To date, 43 subjects have been screened with several more screening dates scheduled in the coming weeks.

Seton Hill location:

The following deliverables was completed in the year from 27 September 2013 to 26 September 2014:

- SHUPEP team submitted revised local IRB approved protocol that included addition of focus groups to HRPO and ORP for approval on 18 October 2013
- On 4 November 2013 HRPO and ORP acknowledged submission as a minor amendment which will be recorded at continuing review
- SHUPEP team submitted revisions to local IRB approved protocol that included conversion of original demographic survey into a pre and post participant survey, a document containing behavioral assessment questions, an increase of sample size in Phases 2 and 3 and updated phase 2 methods to SHU IRB for approval on 29 January 2014
- On 12 February 2014, SHU IRB approved revision of protocol
- SHUPEP team submitted SHUPEP Annual Update and Request for Continuation of Approval to SHU IRB on 28 February 2014
- On 18 March 2014, SHU IRB approved Request for Continuation of Approval
- SHUPEP team submitted Continuing Review Documents for SHUPEP to HRPO on April 22, 2014 after local IRB approval.
- Acknowledgement of HRPO receipt of Continuing Review documents was received on April 29, 2014. No further action related to this continuing review was needed.
- SHUPEP team members presented four poster sessions highlighting specific aspects of Phase 1 data at American College Health Association Annual Meeting on May 29-30, 2014.
- SHUPEP team submitted revisions to local IRB approved protocol that included information about focus groups to be conducted after Phase 2 as well as revisions to consent form for focus group participants and consent form for phase 3 participants; and additions to Participant Survey Pre-Intervention and Health Assessment forms on 31 July 2014
- On 8 August 2014 Seton Hill University Institutional Review Board approved protocol and document revisions

In addition the following tasks were completed at Seton Hill from 27 September 2013 to 26 December 2013:

- Participated in weekly conference calls with ICHP.
- Completed CITI Training Renewal of HIPS/HIPAA certifications
- Completed data collection for Phase 1
- With IT consultant, created SHUPEP website which will serve as portal for participants in Phase 2

- Planned and implemented presentation of SHUPEP at Groundbreaking Ceremony for new Health Sciences Building on 14 October 2013
- Coordinated efforts of five SHUPEP student research assistants
- Launched recruitment efforts for focus groups
- Arranged and hosted three focus groups on 11 November, 13 November, and 14 November 2013 to obtain input on messages
- Transcribed and coded audio files from focus groups.
- Developed and revised messages for Phase 2 based in part on feedback from focus groups
- Developed behavioral assessments related to nutrition for the application to be used in Phase 2
- Initiated email blasts to faculty members and coaches for Phase 2 recruitment
- Recruited for Phase 2, visiting seventeen classrooms and hosting information booth
- Recruited 52 potential participants for Phase 2, 16 of whom have been waitlisted until screening is conducted
- Revised SHUPEP Demographic Survey for Phase 2 and renamed it Participant Survey
- Identified subscores for Rate Your Plate survey by combining responses to questions on related topics to help Health Coaches uncover areas for possible goal development for Phase 2 participants
- Supervised research hours of junior and senior dietetics students who assisted with message revision, focus group activities, identification of content for website, and creation of iMovies on SHUPEP procedures to serve as website content and/or for training purposes for dietetics students

The following tasks were completed at Seton Hill from 27 December 2013 to 26 March 2014

- Hosted five sessions to screen participants recruited for Phase 2 in fall 2013
- Screened participants according to eligibility criteria and completed study documents including Informed Consent, HIPAA Authorization for Release of Information, and W-9 tax form
- Enrolled Phase 2 participants in patient portal website to take surveys
- Assisted participants in downloading study mobile application on Apple iPad and iPhone devices
- Scheduled participants for two data collection appointments and one goal setting appointment
- Completed body composition analysis using BodPod and Bioimpedance
- Scheduled Excela Health nurses to perform laboratory blood work
- Performed anthropometric measurements on participants

- Performed blood pressure measurements
- Charged, dispensed, and retrieved data from Sensewear arm bands
- Completed comprehensive evaluation of all data collection results in preparation for goal setting appointments with participants
- Conducted goal setting appointments with all participants
- Discussed plans for a possible phase 4 of SHUPEP
- Developed budgets for no-cost extension and possible phase 4 of SHUPEP
- Conducted literature search to determine if anything could be found to indicate that research strategies were inappropriate or dangerous in preparation for submission of Continuing Review Documents to HRPO
- Disseminated weekly text messages to participants
- Reviewed goal development, text message selection, and acceptance of text messages by participants
- Prepared Performance Appraisal Documents for Clinical Research Coordinator and Health Coaches for initial approval by Subaward PI's Senior Supervisor and Human Resource Program Administrator
- Participated in weekly SHUPEP team meetings

The following tasks were completed at Seton Hill from 27 March 2014 to 26 June 2014:

- Participated in numerous conference calls with ICHP and MDM Technology
- Participated in regularly scheduled SHUPEP staff meetings
- Continued to send individualized test messages three times per week to phase 2 study participants
- Reviewed responses of behavioral assessments received by and completed once a week by study participants. Health coaches used information when selecting messages to send to participants the following week.
- Sent survey link to participants and followed-up for completion compliance
- Calibrated BodPod before assessments were performed
- Completed body composition analysis using BodPod and Bioimpedance
- Performed anthropometric measurements
- Performed blood pressure measurements
- Scheduled Excela Health phlebotomists to perform laboratory blood work
- Charged, dispensed, and retrieved data from Sensewear armbands
- Managed study participant data in patient portal
- Completed exit interviews with Phase 2 participants to obtain feedback on their experience as subjects
- Processed incentive payments for participants who completed follow-up data collection

- Restocked study supplies
- Completed performance appraisals of Clinical Research Coordinator and Health Coaches and submitted documents to Human Resources
- Met with Human Resources concerning family Medical Leave arrangements
- Managed study research assistants
- Supervised student research hours for junior and senior dietetics majors
- Scheduled and met with COSMED representative for annual BodPod certification and training
- Presented information about SHUPEP to incoming freshmen and their parents at two Setonian Days
- Earned various continuing education credits for maintenance of credentials and health coach certifications
- Recruited consultant statistician to assist with data analysis
- Developed initial data analysis plan for Phase 1 data
- Participated in calls with consultant statistician
- Created four posters highlighting various findings from Phase 1 data for ACHA Conference
- Four SHUPEP staff members attended ACHA Annual Meeting from May 27 to May 31, 2014 and presented poster sessions
- Reviewed weekly abstracts from NCBI
- Revised budgets and justifications for no-cost extension and possible phase 4 of SHUPEP
- Conducted initial review of phase 1 frequencies and descriptive statistics in preparation for meeting with statistician
- Confirmed session at ICHP in October 2014 for dietetics students and SHUPEP team
- Reviewed theoretical frameworks
- Coded Phase 2 data export
- Completed troubleshooting of various data export issues with MDM Technology

The following tasks were completed at Seton Hill from 27 June 2014 to 26 September 2014.

- Developed procedure for focus groups to gain insight into participants' experience and perception of the goal setting process, heath coach interactions, and the impact of health based text messages delivered electronically over the eight week intervention
- Amended protocol to include focus groups conducted with Phase 2 participants, revised consent forms for focus group participants and Phase 3 participants, and revised Health Assessment forms

- Revised Participant Survey—Pre Intervention to include questions on vegetarianism and cell phone use. These questions were added based on feedback obtained during conference poster session presentations
- Submitted updated study documents to SHU IRB for approval
- Coded qualitative data from Phases 1 and 2
- Met with consultant statistician to discuss Phase 1 data analysis plans, results of analysis and interpretation. Rate Your Plate sub scores created earlier by combining responses to questions on related topics in the survey did not correlate so that method will be abandoned in favor of looking at responses to individual questions
- Co-Principal Investigator provided brief informational presentations to incoming freshmen and their parents about SHUPEP at two Setonian Days
- Developed Phase 2 focus group script, recruited participants, reserved rooms and ordered food. About 10% of participants volunteered for focus groups but despite reminders, actual attendance was poor. Team members completed interview with participant.
- Principal Investigator completed CITI HIPAA module
- Health coaches completed continuing education required for recertification
- Interviewed, hired, and trained one new SHUPEP student research assistant and retained two others
- Requested permission to have email blast sent to faculty concerning recruitment for Phase 3 in classrooms
- Planned and presented SHUPEP research workshops for junior and senior students
- Review of articles relevant to research
- Consultant statistician provided workshop on the use of SPSS for SHUPEP team and senior dietetics students
- Health coaches provided training for junior dietetics students on equipment used in SHUPEP research
- Supervised dietetic students in SHUPEP activities
- Scheduled dates for Phase 3 recruitment booths
- Co-Principal Investigator arranged travel and hotel accommodations for trip to ICHP
- Consulted with MDM on Phase 3 preparations
- Development and revision of list of CRC duties that will need to be fulfilled by replacement worker for 10 weeks from January until April when CRC is on Family and Medical Leave
- Discussion of personnel needs with Human Resources and prospective candidates
- Meeting of CRC and Principal Investigator with prospective replacement

• Revision of deliverables schedule and budget for budget period 4

V. Key Research Accomplishments:

- Data collection for phase 1 was completed on 4 October 2013.
- Thirty-four participants completed data collection for SHUPEP Phase 2 on 13 May 2014.
- Initial analysis of Phase 1 data was completed in August 2014, but interpretation and application is ongoing.
- The technology application was successfully built, implemented and functional.

VI. <u>Reportable Outcomes</u>: The titles of the four poster sessions presented at the American College Health Association Annual Meeting on 29 May 2014 are shown below. Complete abstracts can be found in the Appendices.

- Associations Between Anthropometric Measures of College Students and Campus
 Dining Options
- Sleep Quality, not Sleep Quantity, Correlates with Academic Performance
- Vegetarian-style Eating in College Students: Diet Survey Analysis and BMI
- Vitamin D Deficiency in College Students: Prevalence and Implications

VII. <u>Conclusions</u>: Results of focus group and participant input and comments during poster session presentations have informed Phase 3. Results of data analysis on Phase 1 data are being interpreted, and team is planning for publication and the launch of Phase 3.

VIII. References: N/A

IX. <u>Appendices:</u> Abstracts of the posters presented at the American College Health Association Annual Meeting on 29 May 2014 meeting can be found below:

Associations Between Anthropometric Measures of College
Poster
Students and Campus Dining Options
Title

Authors Bowman, T., Sandrick, J., Tracy, D., Roth, A., Harouse-Bell, K., Kashani, M., Vernalis, M., Eliasson, A.

Purpose The purpose of this poster session is to understand the impact of various campus-dining options on body fat, BMI and weight among college students.

Abstract
 University students (n=161; female 72.6%, Caucasian 82%, mean age 19.8yr) were surveyed for meal plans and measured for percent body fat (%BF) and body mass index (BMI). Students with on-campus meal plans had similar %BF (p=0.84) and BMI (p=0.90) compared to students with no meal plans. However, on-campus diners with flex dollars had higher %BF (29% vs 22%, p<0.0005) and BMI (25 vs 24kg/m2, p=0.04). Flexible spending, not specific dining plans, is associated with increased weight.

Overweight and obesity are pandemics that include college-aged students. Students commonly struggle with increased percent body fat and high BMIs despite a personal desire to achieve fitness.

- Practice Universities are responding to the problem of overweight by offering
 Gap more diverse dining plan options than ever before. However, the impact of these various campus dining options is not well understood. There is a lack of data about campus dining choices and maintenance of a healthy weight.
 - **Poster** Sleep Quality, not Sleep Quantity, Correlates with Academic **Title** Performance
- Authors Sandrick, J., Eliasson, A., Tracy, D., Harouse-Bell, K., Bowman, T., Roth, A., Kashani, M., & Vernalis, M.

The purpose of this activity is to provide college health

Purpose professionals with information to allow more useful and accurate guidance to college students who are experiencing daytime fatigue

and poor academic performance.

Sleep is essential for learning. However, little evidence validates this theory outside laboratory settings. University students (n=157; female 72%, Caucasian 82%, mean age 20.0±1.9yrs) showed no difference in total sleep time between students with GPA≥ median
 Abstract and those <median (p=0.34). However, high-GPA students reported

Abstract and those <median (p=0.34). However, high-GPA students reported better sleep quality (p=0.001), shorter sleep latency (p=0.035), less early AM awakening (p=0.029) and less daytime fatigue (p=0.001). Parameters of sleep quality correlate more strongly with academic performance than total sleep time.

In their role to promote student health and improve student performance, college health practitioners and student counselors would benefit from the knowledge that sleep quantity (total sleep time) is not the primary goal to improve sleep behaviors among college students. These health professionals should emphasize improving sleep quality with the aim of decreasing time to fall asleep, difficulty staying asleep and resolving the symptom of daytime fatigue.

- **Poster** Vegetarian-style Eating in College Students: Diet Survey Analysis **Title** and BMI
- Authors Harouse-Bell, K., Sandrick, J., Tracy, D., Bowman, T., Roth, A., Kashani, M., Vernalis, M., & Eliasson, A.
- **Purpose** The purpose of this poster session is to illuminate the early benefits of vegetarian style eating in a subsample of college students.

In a health assessment, university students (n=161, mean age 19.8yrs) completed Rate-Your-Plate (RYP) questionnaires.

Abstract Compared to meat-eaters (n=86), vegetarian-style-eaters (n=20) had healthier RYP scores (68.7±5.5 vs 54.6±6.5, p=0.003) and lower BMI (22.2±3.4 vs 24.8±4.1 kg/m2, p=0.01). These differences were not due to eating behaviors such as portion control (p=0.46),

skipped meals (p=0.19), or stress eating (p=0.39). These results extend prior findings to a younger age than previously described, supporting initiatives for health promotion in college-aged adults.

Improved health is one of the many reasons people choose to adopt a vegetarian-style diet. Research has found many health benefits with this type of diet. A vegetarian diet started earlier in life **Practice** might avert significant risks to health and may be positively

Gap associated with the development of certain chronic diseases. Vegetarian style diet choices are usually limited in the collegiate setting, but could be incorporated into more dining options and health education in this population given the benefits documented.

Poster Vitamin D Deficiency in College Students: Prevalence and **Title** Implications.

Authors Roth, A., Sandrick, J., Tracy, D., Bowman, T., Harouse-Bell, K., Kashani, M., Vernalis, M., & Eliasson, A.

The purpose of this poster session is to illuminate the alarmingPurpose rates of Vitamin D deficiency in a subsample of college students and discuss the factors associated with deficiency.

A health assessment of university students (n=161; female 72.6%, Caucasian 82%; mean age 19.8) was conducted in spring. Laboratory including 25-hydroxyvitamin (25-OH) D levels were obtained. Participants completed Rate Your Plate (RYP) survey,

Abstract which scores dietary quality based on frequency of consumption of 27 food categories. 73.2% of participants had Vitamin D, (25-OH) D deficiency (<20 ng/mL). Participants with normal Vitamin D levels had a more healthful diet by RYP score, compared to those with insufficiency (p<0.05).

Vitamin D deficiency has garnered attention from researchers given
 the substantial rates of prevalence, especially in geographic regions
 with less sun exposure and with minority populations. Vitamin D
 deficiency poses significant risks to health and may be negatively
 associated with the development of certain chronic diseases.

Vitamin D is not commonly tested in the collegiate setting, but could be incorporated into health assessments given the severity of prevalence documented.