

Award Number: W81XWH-18-1-0180

TITLE: Investigating Self-acupressure for Fatigued Ovarian Cancer Survivors

PRINCIPAL INVESTIGATOR: Suzanna Zick, ND

CONTRACTING ORGANIZATION: The Regents of the University of Michigan
Ann Arbor, MI 48109

REPORT DATE: June 2019

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;
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 PAGEForm 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 June 2019		2. REPORT TYPE Annual		3. DATES COVERED 1 Jun 2018 - 31 May 2019	
4. TITLE AND SUBTITLE: Investigating Self-Acupressure for Fatigued Ovarian Cancer Survivors				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-18-1-0180	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Suzanna Zick, ND E-Mail: szick@med.umich.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Regents of The University of Michigan Kathryn Dewitt 503 Thompson Street Ann Arbor, MI 48109-1340				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 It has been significant accomplishment to have finalized the AcuWand design, had a logo competition for the AcuWand and have achieved approval by the University of Michigan Regents to release the funds to Arbor Medical Innovations to manufacture the AcuWands. The first ten AcuWands have been manufactured and we are now doing quality control testing on them to ensure durability as well as accuracy and repeatability of downloaded data. We have also hired an engineering student to write a MathLab program to allow a user and investigator friendly interface.					
15. SUBJECT TERMS AcuWand					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 10	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

Table of Contents

Page

Distribution Statement	1
SF 298 Unlimited Distribution	2
Table of Contents	3
1. Introduction	4
2. Keywords	4
3. Accomplishments	4-7
4. Impact.....	7
5. Changes/Problems.....	7
6. Products.....	7-8
7. Participants & Other Collaborating Organizations.....	8-9
8. Special Reporting Requirements.....	10
9. Appendices.....	10

1. **INTRODUCTION:**

Long-term fatigue is a common and burdensome problem for many women with ovarian cancer even many years after the end of cancer treatments. Women who have fatigue tend to have higher levels of chronic pain, poorer sleep, lower quality of life, and have a tendency to not join as frequently in self-care activities such as physical activity. Despite the challenges experienced by women with persistent fatigue, there are very few attempts to identify self-care-focused treatments. One possible self-care technique for fatigue is self-administered acupressure. Acupressure comes from Traditional Chinese Medicine and is a technique where physical pressure is applied by the finger, thumb, or with devices to acupoints found throughout the body to treat illness or its symptoms. In this study we plan to test if self-acupressure administered via the MeTime Acupressure app and used along with a device the AcuWand--daily for 6 weeks--can decrease long-term fatigue, improve sleep and quality of life in chronically tired ovarian cancer survivors when compared to a sham or a “false” set of acupressure points also delivered using the MeTime Acupressure app and the AcuWand or to no treatment. We hypothesize that fatigued ovarian cancer survivors will experience improvements in fatigue, sleep and quality of life as well as other common symptoms often found along with fatigue such as pain, depression, sexual issues, poor memory or problems concentrating from using relaxing as compared to sham acupressure or no treatment. Also, that improvements in fatigue, sleep, and quality of life and other common symptoms will continue even after women are no longer doing self-administered acupressure.

2. **KEYWORDS:** Acupressure, fatigue, sleep, quality of life, ovarian cancer, cancer survivorship, mobile app, AcuWand, and MeTime Acupressure

3. **ACCOMPLISHMENTS:**

- o **What were the major goals of the project?**

Statement of Work (SOW)

	Timeline	Completion Status
Major Task 1: Prepare Regulatory Documents and Research Protocol	Months	
Refine eligibility criteria, exclusion criteria, screening protocol	1-3	100% Completed
Finalize consent form & human subjects protocol	1-3	100% Completed
Coordinate with MDHHS for IRB protocol submission	1-3	100% Completed
Coordinate with MDHHS for U of M IRB review	1-6	100% Completed
Submit amendments, adverse events and protocol deviations as needed	As Needed	100% Completed
Coordinate with MDHHS for annual IRB report for continuing review	Annually	100% Completed
<i>Milestone Achieved: Local IRB approval at U of M</i>	6	100% Completed. Local IRB obtained in July 2018, Documents submitted to DOD shortly thereafter.

<i>Milestone Achieved: MDDHS IRB approval</i>	6	100% Completed. MDHHS IRB approved April 12, 2019 (this included an amendment requested by the MDDHS).
Major Task 2: Hiring and Training of Study Staff		
Create and post job descriptions	1-4	100% Completed
Advertise and interview for project related staff	4-8	100% Completed
Coordinate for space allocation for new staff	1-7	100% Completed
<i>Milestone Achieved: Research staff trained</i>	8-11	100% Completed
Major Task 3: Create Study Intervention/ Device		
Subtask 1: Create sham acupuncture mobile app	1-6	100% Completed
Create script and film video of sham points	1-6	100% Completed
Create graphics/illustrations for app	1-6	100% Completed
Create “No Treatment” message/instructions	1-6	100% Completed
<i>Milestone Achieved: Sham acupuncture mobile app developed</i>	1-6	100% Completed
Subtask 2: Create AcuWands	1-6	100% Completed. First ten prototype AcuWands are made and quality control testing is being completed before all AcuWands are ordered.
Supplies ordered	1-6	
Molds completed	1-6	
<i>Milestone Achieved: AcuWands manufactured</i>	1-6	
Major Task 4: Order and Configure Study Supplies		
Identify best computer tablets	1-3	100% Completed
Investigate best mailing options for tablets and wands	1-3	100% Completed pending manufacture of AcuWand.
<i>Milestone Achieved: Computer tablets received by study staff</i>	1-3	100% Completed
<i>Milestone Achieved: Mailing supplies received by study staff</i>	1-3	100% Completed pending manufacture of AcuWand.
Install acupuncture mobile app, sham, relaxing, or no treatment message on computer tablet	6	100% Completed
<i>Milestone Achieved: Computer tablets configured and ready to be mailed to participants</i>	6	100% Completed
Major Task 5: Participant Recruitment, Therapy, Participant Evaluation		

Coordinate with study staff for flow chart for all study steps, Qualtrics web data collection and Redcap database requirements	4-6	100% Completed
Finalize assessment measurements and program in Redcap	1-4	100% Completed
Begin subject recruitment	7-30	Started
Send out letters through the Michigan Tumor Registry	7-22	First letters went out 5/31/2019 to Institutions to obtain physician names
Screen potential participants using eligibility screener and consent (N=160)	7-24	Anticipated by July 15 th , 2019
Evaluate and assign participants to one of the three randomized groups	7-24	NA
<i>Milestone Achieved: 1st participant consented, screened and enrolled</i>	7	NA
Participants complete assigned acupuncture treatment over 6 weeks N=160	7-30	NA
Assess all participants at the baseline, 3, 6, 12, and 24 week timeframe	10-33	NA
<i>Milestone Achieved: Complete participant recruitment</i>	33	NA
Major Task 6: Data Analysis		
Perform all analyses according to specifications, share output and finding with all investigators	33-36	NA
Work with other investigators to disseminate study findings (abstracts, presentation, publications, DOD)	33-36	NA
<i>Milestone Achieved: Report results from data analyses</i>	33-36	NA
<i>Milestone Achieved: Report findings from study</i>	33-36	NA

○ **What was accomplished under these goals?**

Our major activities this year have been focused on study start-up and regulatory activities. All study materials including protocol, informed consent, and recruitment materials have been completed and submitted to the Local IRB, the DOD, and the Michigan Department of Health and Human Services (MDHHS) IRB. We have received approval from all three IRBs.

We have hired and trained our study coordinator Ms. Sara Snyder and our research assistant Kellie Chin. We have completed creation of both the sham mobile application (app) and modified the “true” study app such that participants will be blinded to study assignment. We have purchased Kindles for the study and tested the true and sham apps on the devices. We have also finalized the AcuWand design, had a logo competition for the AcuWand and have achieved approval by the University of Michigan Regents to release the funds to Arbor Medical Innovations to manufacture the AcuWands. The first ten AcuWands have been manufactured and we are now doing quality control testing on them to ensure durability as well as accuracy and repeatability of downloaded data. We have also hired an engineering student to write a MathLab program to allow a user and investigator friendly interface

We are completing the building and testing of all study questionnaires and case report forms in Redcap.

Letters have gone out to all institutions in the State of Michigan who care for women with ovarian cancer as of 5/31/2019 from the Michigan Department of Health and Human Services (MDHHS) Tumor Registry. They anticipate that we will be receiving consents to be contacted from women with ovarian cancer by mid-July 2019.

- **What opportunities for training and professional development has the project provided?**
 - *Nothing to Report."*
- **How were the results disseminated to communities of interest?**
 - *Nothing to Report."*
- **What do you plan to do during the next reporting period to accomplish the goals?**
 - During the next reporting period we will complete the manufacture of all 150 AcuWands and the MathLab program to allow for easy interpretation of downloaded data from the devices. We will also be actively enrolling women into the study and conducting study visits (via the phone). We anticipate that we will recruit half of our participants (approximately 75 to 80 women) in the next reporting cycle. We also anticipate writing two to three manuscripts in the next year: one on the development of the MeTime app, the AcuWand and the quality control results for the AcuWand testing and another on the study protocol/design.

We also, intend to submit several abstracts about the AcuWand and mobile app focus group and quality control to Society for Integrative Oncology (SIO) and American Society for Clinical Oncology (ASCO).

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**
 - *Nothing to Report*
- **What was the impact on other disciplines?**
 - *Nothing to Report*
- **What was the impact on technology transfer?**
 - *Nothing to Report."*
- **What was the impact on society beyond science and technology?**
 - *Nothing to Report*

5. **CHANGES/PROBLEMS:** *Nothing to Report*

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**
 - **Journal publications.** *Nothing to Report*
 - **Books or other non-periodical, one-time publications.** *Nothing to Report*
 - **Other publications, conference papers, and presentations.** *Nothing to Report*
- **Website(s) or other Internet site(s)**
Nothing to Report
- **Technologies or techniques**
Nothing to Report
- **Inventions, patent applications, and/or licenses**
Nothing to Report
- **Other Products**
Nothing to Report:

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

<i>Name:</i>	<i>Sara Snyder</i>
<i>Project Role:</i>	<i>Project Coordinator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>2</i>
<i>Contribution to Project:</i>	<i>Ms. Snyder has performed work related to regulatory and ethics approval for the study.</i>
<i>Name:</i>	<i>Kellie Chin</i>
<i>Project Role:</i>	<i>Research Assistant</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>3</i>
<i>Contribution to Project:</i>	<i>Ms. Chin has performed work related to setting up the Redcap web-based data capture system.</i>
<i>Name:</i>	<i>Josh Budde</i>
<i>Project Role:</i>	<i>IT Support</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	<i>1</i>
<i>Contribution to Project:</i>	<i>Mr. Budde has performed work to identify and purchase study tablets, installed study mobile applications, and trained study team on their use.</i>
<i>Name:</i>	<i>Stephanie O'Malley</i>
<i>Project Role:</i>	<i>Mobile application designer</i>

<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	3
<i>Contribution to Project:</i>	<i>Ms. O'Malley has designed and completed the sham and true acupuncture study applications..</i>
<i>Name:</i>	<i>Celeste Leigh Pearce</i>
<i>Project Role:</i>	<i>Co-investigator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	1
<i>Contribution to Project:</i>	<i>Dr. Pearce has performed work related to expertise in ovarian cancer and liaison to Michigan Department of Health and Human Services.</i>
<i>Name:</i>	<i>Richard E. Harris</i>
<i>Project Role:</i>	<i>Co-investigator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	1
<i>Contribution to Project:</i>	<i>Dr. Harris has performed work related to expertise in acupuncture and assistance in the design of the sham application.</i>
<i>Name:</i>	<i>Ananda Sen</i>
<i>Project Role:</i>	<i>Co-investigator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	1
<i>Contribution to Project:</i>	<i>Dr. Sen has performed work related to expertise in statistical analysis and study design.</i>
<i>Name:</i>	<i>Suzanna M. Zick</i>
<i>Project Role:</i>	<i>Principal investigator</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	4
<i>Contribution to Project:</i>	<i>Dr. Zick has performed work related to study oversight, acupuncture app creation and training of study staff.</i>
<i>Name:</i>	<i>Grant Kruger</i>
<i>Project Role:</i>	<i>Engineer and owner Arbor Medical Innovations</i>
<i>Researcher Identifier (e.g. ORCID ID):</i>	
<i>Nearest person month worked:</i>	1
<i>Contribution to Project:</i>	<i>Dr. Kruger has performed work related to design and creation of the AcuWand.</i>

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
 - *Nothing to Report*
- **What other organizations were involved as partners?**
 - *Nothing to Report*

8. SPECIAL REPORTING REQUIREMENTS

- **COLLABORATIVE AWARDS:** *Not Applicable*

- **QUAD CHARTS:** *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

9. **APPENDICES:** *Not Applicable*

ADDITIONAL NOTES:

MARKING OF PROPRIETARY INFORMATION: Data that was developed partially or exclusively at private expense shall be marked as "Proprietary Data" and Distribution Statement B included on the cover page of the report. Federal government approval is required before including Distribution Statement B. The recipient/PI shall coordinate with the COR/GOR to obtain approval. **REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE.** It is the responsibility of the Principal Investigator to advise the COR/GOR when restricted limitation assigned to a document can be downgraded to "Approved for Public Release." **DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS. DO NOT USE WATERMARKS WHEN MARKING DOCUMENTS.**