

AWARD NUMBER: W81XWH-14-2-0005

TITLE: Interventions for sustainable weight loss in military families

PRINCIPAL INVESTIGATOR: Susan B. Roberts

CONTRACTING ORGANIZATION: Tufts University
Boston, MA 2111

REPORT DATE: May 2017

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 is 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 May 2017		2. REPORT TYPE Annual		3. DATES COVERED 15 APR 2016 - 14 APR 2017	
4. TITLE AND SUBTITLE Interventions for sustainable weight loss in military families				5a. CONTRACT NUMBER n/a	
				5b. GRANT NUMBER W81XWH-14-2-0005	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Susan B. Roberts E-Mail: susan.roberts@tufts.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Tufts University Gerald Wodehouse 136 Harrison Ave Boston, MA 02111-1817				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 We have implemented our alternative plans to expand our recruiting pool by incorporating additional military bases as well as allowing dependents of retired active duty military personnel members to join the study. In the past reporting year, we have received approval for and begun recruitment/enrollment at three additional Military Installations. This includes: Fort Campbell, Kentucky; Fort Carson, Colorado; and New London Naval Sub Base, Connecticut. These new installations are in addition to our continuous recruitment efforts at Hanscom Air Force Base, Fort Drum, Natick Soldier Systems Center, U.S. Coast Guard First District, Navy Recruitment District New England, and U.S. Coast Guard Cape Cod. Since the submission of our previous Annual Report in 2016, we have enrolled 93 dependent adult family members of Active Duty military personnel and 26 Active Duty / Retired Active Duty members themselves. One challenge facing program attendance for outcome events has been the originally unanticipated high rate of permanent change of stations (PCS). Approximately 15 percent of our study population has experienced a PCS since being enrolled in the study. To account for this situation; we have received IRB approval and implemented an alternative option for participants to obtain and submit their outcome results once a PCS has occurred. We have termed this process Remote Outcomes in our protocol. This allows participants to utilize their healthcare providers to obtain their physical results which would otherwise be obtained in person by the members of our study team. Participants then gather the results from their healthcare provider and submit to our study team. It is our intention to recruit and enroll the remaining amount of participants to reach our target study population within the next reporting period. On April 11 th , 2017; our study team participated in the MOMRP IRP at Fort Detrick, MD.					
15. SUBJECT TERMS Military dependents, recruiting, military bases, obesity					
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
Unclassified	Unclassified	Unclassified	Unclassified	12	19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Accomplishments.....	4
4. Impact.....	6
5. Changes/Problems.....	6
6. Products.....	7
7. Participants & Other Collaborating Organizations.....	7
8. Special Reporting Requirements.....	10
9. Appendices.....	10

1. INTRODUCTION:

Obesity and overweight are at epidemic levels in American Warfighters and their family members, and impact health, health care costs, absenteeism and physical performance. This study will test an innovative behavioral intervention in a clinical trial of overweight and obese adult dependents of active duty military personnel (ADMP) and retired ADMP to determine: a) whether the new intervention, called Healthy Weight for Living (HWL), results in more sustainable weight loss and health benefits over 2 years when compared to current best practices (CBP), and b) whether there is a “ripple effect” of program benefits to the obese and overweight ADMP or retirees who live with program participants. Our central hypothesis is that weight management interventions comprised of multiple strategies focused on hunger suppression are particularly effective for sustainable weight loss and benefit not only the immediate recipient but also family members including ADMP or retirees. This hypothesis has been formulated on the basis of strong preliminary data and will be tested in a 2-year randomized trial comparing the HWL intervention to CBP. Outcomes will include change in weight in adult dependents and ADMP as well cardiometabolic risk factors and quality of life. This study is innovative and timely because there is widespread recognition that effective approaches to weight control are urgently needed for American Warfighters and their families. Successful results will constitute a major breakthrough in a field where advances are much needed, and due to the racial, socioeconomic and regional diversity of ADMP will be readily translatable to the general population.

2. KEYWORDS:

- Obesity
- Weight loss
- Military dependents
- Active duty military personnel
- Recruitment
- Military bases
- Behavioral weight loss program

3. ACCOMPLISHMENTS:

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

Year 1 Goals

- Obtain IRB approval to conduct the study and the approval of base commanders to conduct the study at bases (Projected Completion: Year 1; Actual Completion: Year 1)
- Complete Manual of Procedures and study materials for conduct of study (Projected Completion: Year 1; Actual Completion: Year 1)
- Start recruitment of subject population in the study (Projected Completion: Year 1; Actual Completion: Year 1)

- Conduct baseline assessments in recruited population, randomize them to the different interventions and start intervention (Projected Completion: Year 1; Actual Completion: Year 2)
- Start data entry for baseline data (Projected Completion: Year 1; Actual Completion: Year 2)
- Complete all necessary sponsor reports (Projected Completion: Year 1; Actual Completion: Year 1)

Year 2 Goals

- Expand to additional military bases in order to increase our recruiting pool (Projected Completion: Year 2; Completion in Progress)
- Expand study inclusion criteria to include dependents of retired Active Duty Military Personnel (Projected Completion: Year 2, Actual Completion: Year 2)
- Implement the videoconferencing system to deliver the group counseling session to participants while continuing to conduct screening and outcomes testing in-person at the military bases (Projected Completion: Year 2; Actual Completion: Year 2)
- Conduct baseline assessments in recruited population, begin to randomize them to the different interventions and start intervention (Projected Completion: Year 1, Actual Completion: Year 2)
- Start data entry for baseline data (Projected Completion: Year 1; Actual Completion: Year 2)
- Recruit the entire study population, completing baseline assessments, randomizing the entire study population, and starting the intervention: (Projected Completion: Year 3; Completion in Progress)
- Complete all necessary sponsor reports (Projected Completion: Year 2; Actual Completion: Year 2)
-

Year 3 Goals

- Complete recruitment for the entire study population, complete baseline assessments, randomize the entire study population, and start the intervention for the entire targeted population. (Projected Completion: Year 3; Completion in progress, projected for Year 4)
- Receive approval for additional military installations in order to increase recruitment pool in an effort to reach our target enrollment: (Project Completion: Year 3; Actual Completion: Year 3)
- Receive IRB approval to incorporate strategy which we have termed Remote Outcomes in order to accommodate participants who relocate after enrollment in the study: (Projected Completion: Year 3; Actual Completion: Year 3)
- Complete data entry for all scheduled outcome events: (Projected Completion: Completion ongoing, all data has been entered for outcome assessment events that have occurred thus far)

- Complete all necessary sponsor reports (Projected Completion: Year 3; Actual Completion: Year 3)

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

During this reporting period, major activities include; increasing the study recruiting pool by expanding study locations to include Fort Carson, Fort Campbell, and New London Naval Sub Base. In addition to the new installations, we have continued recruitment efforts at: Fort Drum, Hanscom Air Force Base, Natick Soldier Systems Center, Navy Recruiting District New England and US Coast Guard First District. Participants recruited from these installations have started to enroll, complete baseline assessments, and start intervention sessions via the group counseling sessions. Data entry for baseline assessment has been completed for those participants who have completed the baseline event thus far.

Marketing strategies at each of the sites continued in order to increase our recruitment. We did not accomplish the outlined goal above of recruiting and enrolling the entire study population during this reporting period. Our intention is to recruit and enroll the remaining amount of participants needed to reach our target study population over the next recruitment period (Year 4). The addition of three new locations has shown promise in return for our marketing efforts and we will continue to utilize our strategies that have been shown to be successful at all approved study sites.

Permanent changes of stations have continued to occur at rates higher than previously expected. Although the online delivery of the intervention has allowed participants to continue the intervention as normal; the relocation inhibits participants from attending semi-annual/annual outcome measurement events to have data collected by our study team. To accommodate absenteeism at outcome events, we have received IRB approval to instill a new option to submit outcome data which we have termed Remote Outcomes. This process is voluntary but had been previously requested by participants who have relocated. If interested, participants may utilize their healthcare provider at the time of their outcome event to obtain their physical measurements such as body weight, blood pressure, and blood draws. Once obtained, participants can submit their data to our study team to be recorded. The alternative allows participants to submit our main outcome of body weight by using the body weight scale provided to them after first enrolling in the study.

All Technical Reports have been completed and submitted for this reporting period.

- **What opportunities for training and professional development has the project provided?**

- Interventionist, Amy Taetzsch completed training for the Current Best Practice Program
- Associate Investigator, LTC Asma Bukhari, transitioned to Walter Reed National Military Medical Center as the Chief of Education and Research within the Nutrition Services Department

- Tufts University has provided the opportunity for various Co-Op positions on the Healthy Families Healthy Forces study team for college students to gain exposure to the clinical research process.

- **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?**

- The goals for year 4 include: complete recruiting the entire study population, completing baseline assessments, randomizing the entire study population, and starting the intervention for the entire targeted population.
- We will continue to utilize recruitment strategies that have shown success at all of our approved military installations. Additionally, we will explore new avenues and opportunities in both a broad approach as well as specific to each location in order to increase our recruitment pool.
- We will continue to offer the IRB approved Remote Outcomes process in order to accommodate participants who are to relocate after initially being enrolled in the study.
- Data entry will be completed for all outcome events that occur within the study period.

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:

- **Changes in approach and reasons for change**

- Due to limited number of individuals signing up for screening at initial bases, we initiated our contingency plans which include expanding the project to additional bases of larger stature. Previously, this contingency plan has been carried out at Fort Drum in New York and has shown success. During this reporting period, we have expanded the project to similar installations in both Fort Carson, Colorado and Fort Campbell, Kentucky. We have also extended the project to New London Naval Sub Base in Connecticut.
- Due to the high PCS rate, participants now have the option to submit outcome data obtained by their healthcare provider during the time of outcome assessment events after relocating from the military installation where they first enrolled in the study.
- **Actual or anticipated problems or delays and actions or plans to resolve them**
 - Although recruitment has increased with the addition of three military installations, recruitment numbers remain below the targeted enrollment. In order to meet recruitment targets, we are planning to explore new marketing opportunities in both a broad nature as well as specific opportunities at each location.
 - A significant number of participants have experienced or are anticipating a Permanent Change of Station (PCS) making it impractical for them to be present for outcome measurements at the 6 month/12 month/ 24 month in-person events. For these participants, we have offered an option termed Remote Outcomes which will allow participants to utilize their healthcare provider in order to obtain and submit results. Alternatively, participants may also submit their body weight using their scales provided at enrollment and complete the online questionnaires and dietary recalls. These relocated participants may still participate in the group counseling sessions via the videoconferencing system.
- **Changes that had a significant impact on expenditures**
 - The expansion to new locations and increased enrollment, have caused expenses to increase due to travel for screening and outcome events.
 - Due to the initial slow recruitment, we have extended the period in which we expect to recruit our target population in its entirety. With this extension, we expect an increase in projected expenses due to personnel and travel costs.
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
 - There were no significant changes in the use or care of human subjects during this reporting period.

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)**

ClinicalTrials.gov Website: This website contains information about the study to the general public. When results are available, this website will be updated to include the

major results from this project.

<https://clinicaltrials.gov/ct2/show/NCT02348853?term=Healthy+Families+Healthy+Forces&rank=1>

- **Technologies or techniques:** Nothing to Report
- **Inventions, patent applications, and/or licenses:** Nothing to Report
- **Other Products**
 - We have fully developed the ScienceTrax database for data collection in this study. The database is a sophisticated combination of data entry portals for researchers and also for participants (for those pieces of data that are self-entered). The database also allows for tracking of intervention progress using predefined adherence measures created by the team.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

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

Name: Roberts, Susan

Project Role: PD/PI

Researcher Identifier:

Nearest person month worked: 2.4

Contribution to project: Dr. Roberts is responsible for overall oversight of the study and oversight of the weight loss interventions

Funding Support: n/a

Name: Das, Sai Krupa

Project Role: Outcome Chair

Researcher Identifier:

Nearest person month worked: 2.4

Contribution to project: Dr. Das will be scientifically responsible for outcomes assessments, quality control, and data management oversight for all aims of the proposed project plan.

Funding Support: n/a

Name: Pittas, Anastassios

Project Role: Diabetes Outcomes

Researcher Identifier:

Nearest person month worked: 0.2

Contribution to project: Dr. Pittas provides expertise on diabetes outcomes, analyses, and interpretation

Funding Support: n/a

Name: Saltzman, Edward

Project Role: Study physician

Researcher Identifier:

Nearest person month worked: 0.2

Contribution to project: Dr. Saltzman is responsible for safety oversight of the study including oversight of adverse events and monitoring and preparing reports on serious adverse events for the Tufts IRB

Funding Support: n/a

Name: Lichtenstein, Alice

Project Role: Cardiovascular Outcomes

Researcher Identifier:

Nearest person month worked: 0.2

Contribution to project: Dr. Lichtenstein provides expertise on cardiovascular outcomes, evaluation, and analysis.

Funding Support: n/a

Name: Gilhooly, Cheryl

Project Role: Co-Investigator

Researcher Identifier:

Nearest person month worked: 0.6

Contribution to project: Working with Dr. Roberts, Dr. Gilhooly is responsible for training the intervention components common to both interventions and for supervising the interventionists (psychologists/nutritionists) involved in delivery of the current best practice arm of the intervention.

Funding Support: n/a

Name: Martin, Edward

Project Role: Study Coordinator

Researcher Identifier:

Nearest person month worked: 11

Contribution to project: Responsible for operational logistics, tracking of study schedules, outcome assessments, data collection, and data entry for non-electronic forms, and will aid in responses to queries.

Funding Support: n/a

Name: Taetzsch, Amy

Project Role: Interventionist

Researcher Identifier:

Nearest person month worked: 11

Contribution to project: Responsible for delivering the group sessions for the Current Best Practice intervention.

Funding Support: n/a

Name: Krauss, Amy

Project Role: Interventionist

Researcher Identifier:

Nearest person month worked: 11

Contribution to project: Responsible for delivering the group sessions for the Healthy Weight for Life intervention.

Funding Support: n/a

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
 - Adrienne Hatch has replaced LTC Asma Bukhari as the responsible Investigator for the USARIEM
 - LTC Asma Bukhari's affiliation has changed to Walter Reed National Military Medical Center
- **What other organizations were involved as partners?**
 - **Organization Name:** US Army Research Institute of Environmental Medicine
 - **Location of Organization:** Natick, MA
 - **Partner's contribution to the project**
 - Facilities and Resources
 - Collaboration

8. SPECIAL REPORTING REQUIREMENTS:

- **QUAD CHARTS:** Enclosed

9. APPENDICES: None

Interventions for sustainable weight loss in military families

ERMS 5793 Log Number 13035001 Yr3 Annual Report
W81XWH-14-2-005



PI: Susan B. Roberts

Org: Tufts University

Award Amount: \$3,001,102.00

Study/Product Aim(s)

- Obesity and overweight are widespread in military families - effective weight control interventions are urgently needed. The objective of this study is to demonstrate effective, sustainable weight loss program in adult dependents of ADMP, and evaluate anticipated *ripple effect* benefits to ADMP themselves.

Approach

- Conduct a 2-year randomized controlled trial of the two interventions. Outcomes include changes in weight and cardiometabolic risk factors.
- Program recipients are adult dependents of active duty military personnel (ADMP) or retired ADMP. Effects will be evaluated in both program participants and their ADMP, anticipating a ripple effect of benefits to family members.
- Anticipated study outcomes: Sustainable weight loss and improved health in both ADMP and their adult dependents.



Accomplishments: During this reporting period, major activities include; increasing the study recruiting pool by expanding study locations to include Fort Carson, Fort Campbell, and New London Naval Sub Base. In addition to the new installations, we have continued recruitment efforts at: Fort Drum, Hanscom Air Force Base, Natick Soldier Systems Center, Navy Recruiting District New England and US Coast Guard First District. We have received IRB approval to allow participants to send results obtained from their healthcare provider at the time of outcome events after they are to relocate.

Timeline and Cost

Activities	CY	1	2	3	4	5
Recruitment, baseline testing and randomization						
2 year intervention with outcomes in intervention participants and their ADMP						
Complete data entry and data cleaning, lab and statistical analyses, publication of results						
Estimated Budget (\$K)		\$600	\$758	\$750	\$487	\$259

Goals/Milestones

Objective 1 –

- ✓ Obtain IRB amendment approval,

Objective 2 –

Ongoing- Recruit participants

Objective 3 –

Ongoing- Intervention, outcomes, data entry, locking baseline data, submit papers on baseline data

Objective 4–

- ☐ Data cleaning, locking, analyses

Objective 5-

- ☐ Write and submit intervention papers

Comments/Challenges/Issues/Concerns

- Recruitment continues at the approved military installations which is anticipated to yield the remaining number of participants needed to reach target study population
- Projected Expenditure: \$2,108,961
- Actual Expenditure: \$1,482,216.59

Updated: 15-April-2017