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TITLE: Interventions for sustainable weight loss in military families

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Fort Detrick, Maryland 21702-5012

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**6. AUTHOR(S)**
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**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

Trustees of Tufts College
Gerald Wodehouse
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U.S. Army Medical Research and Materiel Command
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**14. ABSTRACT**

Through the reporting period, we continued to collect outcomes data at all study approved military instillations, in an effort to complete the study data collection by Dec 2018 as projected in our revised SOW. Our revised SOW included: 1) completing our enrollment at 238 adult family members of ADMP's participants; 2) continuing the intervention for the one-year or two year support period for participants who were covered by their informed consent forms 3) moving the primary objective of the study to a 12 month change in weight from the originally intended 24 month timepoint; 4) Switching the occurrence of the final blood draw to the 12 month milestone from the 24 month mark in those participants who had not completed 12 months in the study as of January 1st, 2018. These procedures were carried out with participants per the revised SOW since the date of approval and all intervention and outcome data collection events have occurred as scheduled and were completed by December, 2018.

We have begun data cleaning as of January 2019 and data analysis as of April 2019. Research findings are planned to be presented and published during the course of 2019.

| 15. SUBJECT TERMS<br>Military dependents, recruiting, military bases, obesity | | | | | |
|---|---|---|---|---|---|
| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON<br>USAMRMC |
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**Standard Form 298 (Rev. 8-98)**
**Prescribed by ANSI Std. Z39.18**

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## 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 adult dependents of active duty military personnel (ADMP) and retired ADMP adults with overweight and obesity to determine: a) whether the new intervention, called Healthy Weight for Living (HWL), results in more sustainable weight loss and health benefits over one year when compared to current best practices (CBP), and b) whether there is a "ripple effect" of program benefits in ADMP with overweight and obesity 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 1-year randomized trial comparing the HWL intervention to CBP. Additional analyses will be conducted for between group effects on body weight in a subgroup of participants for whom 2-year follow-up data is available. 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 instillations 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)

Year 4 Goals

- Explore new avenues and opportunities in both a broad approach as well as specific to each location in order to increase our recruitment pool (Projected Completion: Year 3; Actual Completion: Year 4)
- Complete recruiting the entire study population (Projected Completion: Year 3; Actual Completion: Year 4)
- Completing baseline assessments and randomizing the entire study population (Projected Completion: Year 3; Actual Completion: Year 4)
- Start the intervention for the entire targeted population. (Projected Completion: Year 3; Actual Completion: Year 4)
- 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. (Projected Completion: Year 4; Actual Completion: Year 5)
- Data entry will be completed for all outcome events that occur within the study period. (Projected Completion: Year 4; Actual Completion: Year 5)

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

During this reporting period, we completed the final round of outcomes measures at the 12 or 24 month windows of assessment that was relevant for each participant. The primary outcome of the study was moved to a one-year change in weight opposed to the originally intended two.

Subjects continued to complete their participation in the group weight-loss intervention and outcome data collection events as scheduled:

At Hanscom Air Force Base: the last three groups enrolled in the study completed their final outcome events. The fourth group of participants completed their 24-month milestone in September of 2018, while the fifth and sixth completed their outcome events (24 and 12 months, respectively) in November 2018.

At Fort Drum: the last three groups enrolled in the study at this site completed their final outcome measurements. Due to limited staffing, the decision was made to have all three groups complete remote outcomes. The fourth, fifth, and sixth groups of participants completed their final remote outcomes (24-, 24- and 12-months, respectively) by December 2018.

Fort Carson: both groups enrolled at this site completed their final outcome events. The first group completed their 24-month milestone and the second group completed their 12-month milestone in July 2018.

Fort Campbell: All three groups enrolled at this site completed their final outcome events. The first and second groups completed their 24-month event, and the third group completed their 12-month outcome event in July 2018.

New London Navy Submarine Base: Both enrolled groups have finished their final outcome events. The first group completed their 24-month event and the second group completed their 12-month event in November 2018.

Data entry has been completed for all intervention and outcome events and data cleaning and analysis are underway.

For participants who relocated during their enrollment in the study and were no longer able to attend in-person outcome data collection events; they participated in the intervention as normal and we have carried out our remote outcomes procedures in opposition to collecting the measurements in-person at a given study milestone.

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

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

    - 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 and data cleaning process.
    - Tufts University study team members have completed the Good Clinical Practice in Research course through the Collaborative Institutional Training Initiative

- **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 plan to:

    - Complete the cleaning of all data
    - Develop Statistical Models and Prepare Manuscripts
    - Attend meetings to provide results
    - Complete all necessary sponsor reports
    - Seek opportunities to further explore and expand the best program practices for a wider reach within the military families including the ADMP and retirees.

**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 the high PCS rate, participants had the option to submit outcome data obtained by their healthcare provider during the time of outcome assessment events after relocating from the military instillation where they first enrolled in the study and we continued to collect such data in the last year and for the last group at Ft. Drum this was the only option as there were only 2 participants willing to be available in person.
- **Actual or anticipated problems or delays and actions or plans to resolve them**
  - The unanticipated departure of the key study coordinator and one of the interventionists during the latter half of 2018 resulted in additional work and redistribution of the roles and responsibilities and a slight revision to the timeline.
  - To accommodate this loss in staffing and the additional planning required due tot the complexity of the study design and statistical handling of the one and two year datasets a no-cost-extension (NCE) was requested. We are highly appreciative of the DOD's understanding in granting this extension from April to Dec 2019.
- **Changes that had a significant impact on expenditures**
  - The revised SOW and staffing loss did not impact expenditure but required a reallocation of funds to accommodate the change in efforts for some staff and increased data and statistical analysis needs which were more complex since the originally proposed study design.
- **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. Taetzsch A,** Gilhooly CH, Bukari A, Das SK, Martin E, Hatch AM, Silver RE, Montain SJ, Roberts SB. Development of a videoconference-adapted

version of the Community Diabetes Prevention Program, and comparison with in-person program delivery over 12 weeks. *Military Medicine*, usz069, https://doi.org/10.1093/milmed/usz069

- **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?** ? is the FTE from MAY 2018 to April 2019

**Name:** Roberts, Susan
**Project Role:** PD/PI
**Researcher Identifier:**
**Nearest person month worked:** 5.86
**Contribution to project**: N/A

**Name:** Das, Sai Krupa
**Project Role:** Outcome Chair
**Researcher Identifier:**
**Nearest person month worked:** 5.86

**Contribution to project:** N/A
**Funding Support:** n/a

**Name:** Pittas, Anastassios
**Project Role:** Diabetes Outcomes
**Researcher Identifier:**
**Nearest person month worked:** 0.16
**Contribution to project:** Dr. Pittas provides expertise on diabetes outcomes, analyses, and interpretation
**Funding Support:** n/a

**Name:** **Lisa Ceglia, M.D.**
**Project Role:** Study physician
**Researcher Identifier:**
**Nearest person month worked:** 0.24 (MAY 2018 to present)
**Contribution to project:**
**Funding Support:** n/a

**Name:** Lichtenstein, Alice
**Project Role:** Cardiovascular Outcomes
**Researcher Identifier:**
**Nearest person month worked:** 0.24
**Contribution to project:** N/A

**Name:** Gilhooly, Cheryl
**Project Role:** Co-Investigator
**Researcher Identifier:**
**Nearest person month worked:** 0.96
**Contribution to project:** N/A
**Funding Support:** n/a

**Name:** Martin, Edward
**Project Role:** Study Coordinator
**Researcher Identifier:**
**Nearest person month worked:** 7 (May 2018 to November 2018)
**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:** 4 (Jan 2019 to present)

**Contribution to project:** As of January 1st, 2018 Amy Taetzsch contribution to the project has been increased to 12 calendar months.
**Funding Support:** n/a

**Name:** Krauss, Amy
**Project Role:** Interventionist
**Researcher Identifier:**
**Nearest person month worked:** 4 (May 2018 to September 2018)
**Contribution to project:** Responsible for delivering the group sessions for the Healthy Weight for Life intervention.
**Funding Support:** n/a

**Name:** Taylor, Salima
**Project Role:** Research Assistant
**Researcher Identifier:**
**Nearest person month worked:** 3
**Contribution to project:**
**Funding Support:** n/a

**Name:** Rogers, Gail
**Project Role:** Statistician
**Researcher Identifier:**
**Nearest person month worked:** 0.29
**Contribution to project:**
**Funding Support:** n/a

**Name:** Livingston, Kara
**Project Role:** Data Manager
**Researcher Identifier:**
**Nearest person month worked:** 0.17
**Contribution to project:**
**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?**
  - N/A
- **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 projec**t
    - 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 Yr4 Annual Report
W81XWH-14-2-0005

**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.

Healthy Families | Healthy Forces

**Accomplishments: During this reporting period, major activities include: 4 groups of participants completed the study in its entirety at the 18-24 month milestone. 2 groups of participants completed the study in its entirety at the 12 month milestone. Two groups of participants completes the primary objective milestone of 12 months and will be followed up again at the 18-24 month period in November, 2018. The process of data cleaning and analysis has been initiated for all baseline data.**

## 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)** | **$601** | **$756** | **$750** | **$487** | **$406** |

**Updated:** 15-April-2018

## Goals/Milestones

**Objective 1** –
✓ Obtain IRB amendment approval,
**Objective 2** –
✓ Recruit participants
**Objective 3 –**
*Ongoing*- Intervention, outcomes, data entry, locking baseline data, submit papers on baseline data
**Objective 4–**
*Ongoing*- Data cleaning, locking, analyses
**Objective 5-**
❑ Write and submit intervention papers

**Comments/Challenges/Issues/Concerns**

- During this report period we have continued with the procedures approved in the revised SOW to change the primary outcome in the study from a 2 year change in weight to one. Baseline data cleaned and analysis has inititated.
- Projected Expenditure to-date: $2,876,004.93
- Actual Expenditure to-date: $2,778,323.43