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TITLE: Interventions for sustainable weight loss in military families

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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. On May 19 th , 2015 the first group of participants completed baseline testing at Hanscom Airforce Base. The first group of participants from Fort Drum were enrolled and completed baseline on July 27 th , 2015. Since the submission of the previous annual report, submitted May 14 th 2015, 150 participants have been enrolled in the study. On September 30 th , 2015 the study received IRB approval to move the delivery method of the intervention to an online group counseling system, opposed to the direct in-person delivery onsite at the military bases. This has allowed for a more efficient delivery of the intervention arms in terms of logistics, travel costs, and group attendance. We currently have enrolled participants divided into 5 groups participating in the online group counseling programs. Our alternative plans have yielded an increase in recruitment and we will continue to look to increase the recruiting pool by expanding to additional military bases.									
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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 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 2; Completion in Progress)

- **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 Drum in addition to Hanscom Air Force Base, Natick Soldier Systems Center, Fort Devens and US Coast Guard First District. We have also allowed dependents of retired Active Duty Military Personnel to enroll in the study along with their sponsors. These strategies to increase the recruiting pool have been made possible due to the IRB approval by Tufts University, the USARIEM, and the Human Research Protection Office, which allows group counseling sessions to be completed online through a videoconferencing system as opposed to in-person meetings. Participants 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.

During the reporting period, we expanded our study locations to include Fort Drum, NY in response to the slow initial recruitment. This expansion has yielded an increase in our recruitment. However, it will be listed that the actual completion for our enrollment goal

as in progress, as we continue our expansion efforts to new military base locations until our enrollment is completed. Nevertheless, recruitment has increased with the addition of Fort Drum and we will continue to look for opportunities at additional Military Bases to reach our target enrollment with a projected completion in year 3.

- **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?**

- The goals for year 3 include: recruiting the entire study population, completing baseline assessments, randomizing the entire study population, and starting the intervention for the entire targeted population.
- As the addition of a larger Military Base in Fort Drum has caused a significant increase in recruiting pools, we will continue to look for opportunities to add additional Military Bases who may be interested in participating in order to reach our target enrollment.
- We will continue to utilize the videoconferencing system to support the expansion in geographical locations as well as to support those participants who have received a permanent change of station.

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. During this reporting period, this contingency plan has been carried out at Fort Drum in New York. We will continue to look at opportunities to expand for bases that may be interested.
 - In an additional effort to increase the recruiting pool, we have received approval to recruit dependents of retired active duty military personnel.
- **Actual or anticipated problems or delays and actions or plans to resolve them**
 - Although recruitment has increased with the addition of Fort Drum, recruitment numbers remain below the desired quantity. In order to meet recruitment targets, we are planning to expand the project to be offered at additional bases which are larger in size than the initial locations where recruitment took place.
 - A significant number of participants have experienced or are anticipating a Permanent Change of Station (PCS) which will relocate the participant to a geographical location 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 will initiate our current remote outcome procedures to obtain the possible diet outcome variables including; weight, the completion of questionnaires, diet and physical activity recalls, and the analyses of supermarket receipts. These relocated participants may still participate in the group counseling sessions via the videoconferencing system.
- **Changes that had a significant impact on expenditures**
 - Due to the conversion of the diet interventions from in-person group meetings, into the online videoconferencing group counseling sessions, travel expenses were less than anticipated for this reporting period. As we expand to new locations and increase our recruitment population, we expect for these expenses to increase.
- **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: 3
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: Rogers, Gail
Project Role: Lead Statistician
Researcher Identifier:
Nearest person month worked: 1
Contribution to project: Provides expertise in ensuring that the main study is reasonably powered and that randomization and other data methodology are sound
Funding Support: n/a

Name: Das, Sai Krupa
Project Role: Outcome Chair
Researcher Identifier:
Nearest person month worked: 3
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: 1
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: 1
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: 1
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: 1
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: 10
Contribution to project: Responsible for operational logistics, tracking of study schedules, outcome assessments, data collection, 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: 9
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: 9

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?**
 - 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 project**
 - Facilities
 - Collaboration

8. SPECIAL REPORTING REQUIREMENTS:

- **QUAD CHARTS:** Enclosed

9. APPENDICES: None

Interventions for sustainable weight loss in military families

ERMS 5793 Log Number 13035001 Yr2 Annual Progress Report
W81XWH-14-2-005



PI: Susan B. Roberts

Org: Tufts University

Award Amount: \$2,854,179.00

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). 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:

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	\$497	\$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

- We have expanded recruitment efforts to dependents of retired military personnel to improve recruitment. We have also added Fort Drum and will look to continue expansion efforts to new bases.

Budget Expenditure To Date

Projected Expenditure: \$ 750,550 Actual Expenditure: \$441,555.02

Updated: 15-April-2016