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TITLE: Interventions for sustainable weight loss in military families

PRINCIPAL INVESTIGATOR: Susan B. Roberts

RECIPIENT: Tufts University
Boston, MA 02111

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14. ABSTRACT We started study recruitment in January 2015 and enrolled 11 participants between April 29-30th 2015. Despite overwhelming interest and need for weight loss programs as suggested by surveys and focus groups, recruitment for a 2 year program has been challenging in the Hanscom Air Force Base study location. This may be due to multiple constraints that are both unique to military families and particular to this base which is not typical of the larger, more traditional bases where a large active duty military dependent population exists. We have carefully monitored this challenge and have deployed our alternative plans that anticipated this problem. This includes expanding our recruitment pool to include more bases and opening up the online group counseling option. We hope to be well on our way with recruitment and participant enrollment with this plan in place.						
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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) 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 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. 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?**
 - 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; Completion in Progress)
 - Start data entry for baseline data (Projected Completion: Year 1; Completion in Progress)

- Complete all necessary sponsor reports (Projected Completion: Year 1; Actual Completion: Year 1)
- **What was accomplished under these goals?**

During this reporting period, major activities included obtaining IRB approval from Tufts University, U.S Army Research Institute of Environmental Medicine and HRPO, completing the Manual of Procedures and study materials, beginning recruitment of the subject population, and completing all required sponsor reports. Recruitment has begun at Hanscom Air Force Base, Natick Soldier Systems Center, Fort Devens and US Coast Guard First District.

During this reporting period, we did not achieve the stated goals of conducting baseline assessments in the recruited population and beginning data entry for baseline data. This is due to delays in the IRB approval process and slow initial recruitment. However, we were able to obtain all permissions in January 2015, and recruitment is now underway. We are extending our recruitment to Ft. Drum as an additional measure to increase enrollment. We have currently planned the first baseline assessments and start of the intervention to occur in the beginning of Year 2.

- **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 2 include recruiting the entire study population, completing baseline assessments, randomizing the entire study population, and starting the intervention.
- Based on recruiting efforts to date within the Greater Boston area we have determined that we are unlikely to recruit all necessary participants for this research program from within the planned New England military installations. Therefore have therefore activated our contingency plan to expand our reach and have been in contact with other military bases who may be interested in participating. Our first additional base will be Fort Drum, and active recruitment there is about to start. Collaborator LTC Dr Asma Bukhari is also investigating other military bases for partnership in this study, should Fort Drum not have sufficient eligible individuals who wish to participate.
- In preparation for the expanded geographical location we have made preparations to deliver the program via videoconferencing. We have made plans to conduct screening and outcomes testing live at the sites, and then have requested IRB permission for either live or videoconference weight loss group delivery to add flexibility.

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 involve expanding the project to additional larger bases.
- **Actual or anticipated problems or delays and actions or plans to resolve them**
 - There were delays in hiring the interventionists, as well as the retirement of the initially named statistician. However, these delays did not impact the study timeline, which was determined by IRB approval steps. All study staff have now been hired, and a replacement for the statistician has been identified and has begun work on the project.
 - Due to the complex nature of the IRB approval process in which we needed to seek approval from both Tufts University and the U.S Army Research Institute of Environmental Medicine prior to requesting approval from HRPO, the start of recruitment was delayed.
 - Recruitment has been slow at the initial research locations/base. We are planning to expand the project to be offered at additional larger bases in order to meet recruitment targets.
- **Changes that had a significant impact on expenditures**
 - Due to delays in hiring staff, expenditures on salary support were slightly less than anticipated.
 - Due to slow recruitment, travel expenditures were minimal during this reporting period (this money will be used later when recruitment is at target). In addition, due to the slow recruitment and start of the program, there were minimal intervention expenses (babysitting, materials & supplies, consultant services)

during this reporting period, and again this money will be used when recruitment is at target.

- **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: Dallal, Gerard
Project Role: Lead Statistician
Researcher Identifier:
Nearest person month worked: 1
Contribution to project: Provided expertise in ensuring that the main study is reasonably powered and that randomization and other data methodology are sound
Funding Support: n/a

Name: Schleicher, Molly
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?**
 - Susan Roberts
 - Tufts Collaborates (Roberts)- previously active- now closed
 - General Mills- previously active- now closed
 - NIH/NCI (U01 CA15004-02)- previously active- now closed
 - NIH/NIDDK (R01 DK099500)- previously pending, now active
 - FFE-657-2012/043-00 (Roberts)- previously active- now closed
 - Tufts Collaborates (Omnetto)- previously pending, was awarded and now closed
 - Sai Krupa Das
 - NIH/NIDDK (R01 DK099500)- previously pending, now active
 - Edward Saltzman

- FFE-657-2012/043-00 (Roberts)- previously active- now closed
 - Cheryl Gilhooly
 - NIH/NIDDK (R01 DK099500)- previously pending, now active
 - Gerard Dallal
 - No current support due to retirement
 - Gail Rogers
 - Replaced Dr. Dallal as study statistician
 - USDA/ARS 1950-51530-009-01S- previously not listed, now active
 - Alice Lichtenstein
 - USDA-NIFA-AFRI-004031 (Lamon-Fava)- previously pending, now active
 - NIH/NIDDK R01 DK073321- previously not listed, now active
 - AHRQ Contract HHS2902012000121 (Trikalinos)- previously not listed, now active
 - NIH/NHLBI R01 HL101236- previously not listed, now active
 - Anastassios Pittas
 - Center for Disease Control and Prevention (No. 200-2012-53787)- previously active, now closed
- **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:**

9. APPENDICES: None