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TITLE: Interventions for sustainable weight loss in military families

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CONTRACTING ORGANIZATION: Tufts University

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14. ABSTRACT Objective and Study Design: Our objective was to evaluate the efficacy of a novel lifestyle intervention, Healthy Weight for Living (HWL), versus a modified Diabetes Prevention Program (m-DPP) over 12 months. We conducted a parallel-group randomized trial comparing HWL with m-DPP. Participants were adults with overweight or obesity who were dependents of active duty or retired military personnel (N = 121 HWL; N = 117 m-DPP), recruited from 5 states in the U.S. The interventions were implemented as cost-free group programs by registered dietitians, primarily using videoconferencing. HWL was based on a new health behavior change model emphasizing hunger management and the development of healthy food preferences and was operationalized without required daily food and physical activity logging. m-DPP was a standard DPP implemented with increased counselor contact time. The primary outcome was 12-month weight change; additional outcomes were 6-month changes in cardiometabolic risk factors, self-reported health, and adherence and biobehavioral metrics. Intention-to-treat and completers-only analyses were performed using linear mixed models. Results: Participant retention did not differ between groups (72% vs 66% for HWL and m-DPP at 12 months; $P = 0.30$). Adjusted group mean changes in energy intake and duration of physical activity also were not significantly different, but HWL participants reported higher adherence to their dietary composition recommendations for reduced glycemic index and glycemic load and increased dietary fiber and protein ($P = 0.03$ to 0.001). Adjusted 12-month weight loss among completers was 7.8 kg (95% confidence interval [CI]: 6.2, 9.4) for HWL and 6.9 kg (95% CI: 5.1, 8.6) for m-DPP ($P = 0.43$ for the comparison); 38% of HWL and 30% of m-DPP participants achieved $\geq 10\%$ weight loss ($P = 0.32$). Systolic and diastolic blood pressure improved similarly in both groups, as did low-density lipoprotein cholesterol and triglyceride concentrations, fasting glucose, and self-reported general health, sleep, and mood. Estimated annual health care cost savings for participants with obesity averaged \$1,452 per person. Conclusions and Relevance: HWL achieved high adherence and clinically impactful mean weight loss and cardiometabolic benefits that were similar to m-DPP in adult military dependents without burdensome daily food and activity logging. These results suggest new, lower-burden avenues for effective behavioral treatment of overweight and obesity.			

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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 evaluated an innovative behavioral intervention in a clinical trial of adult dependents of active duty military personnel (ADMP) and retired ADMP with overweight and obesity to determine whether the new intervention, called Healthy Weight for Living (HWL), results in more sustainable weight loss and health benefits over 12 months when compared to a modified version of the diabetes prevention program (m-DPP). Our central hypothesis was that weight management interventions composed of multiple strategies focused on hunger suppression are particularly effective for sustainable weight loss in adult family members of ADMP or retirees. This hypothesis was formulated on the basis of strong preliminary data and tested in a one-year randomized trial comparing the HWL intervention to m-DPP. Additional analyses are planned for between-group effects on body weight in a subgroup of participants for whom 2-year follow-up data are available. Outcomes included 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 military families.

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

- Obtain IRB approval to conduct the study and the approval of commanders to conduct the study at military installations (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 study population (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

- Expand to additional military installations to increase our recruitment pool (Projected Completion: Year 2; Actual Completion: Year 2)
- Expand study inclusion criteria to include dependents of retired ADMP (Projected Completion: Year 2, Actual Completion: Year 2)
- Implement the videoconferencing system to deliver the group counseling sessions to participants while continuing to conduct screening and outcomes testing in person at the military installations (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; Actual Completion: Year 4)
- Complete all necessary sponsor reports (Projected Completion: Year 2; Actual Completion: Year 2)

Year 3

- 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; Actual Completion: Year 4)
- Receive approval to include additional military installations as study locations in an effort to reach target enrollment by increasing our recruitment pool (Project Completion: Year 3; Actual Completion: Year 3)
- Receive IRB approval to incorporate new strategy (which we have termed “Remote Outcomes”) to accommodate participants who relocate after enrollment (Projected Completion: Year 3; Actual Completion: Year 3)
- Complete data entry for all scheduled outcome events: (Projected Completion: Year 3; Actual Completion: Year 5)
- Complete all necessary sponsor reports (Projected Completion: Year 3; Actual Completion: Year 3)

Year 4

- Explore new marketing opportunities to increase our recruitment pool through both broad and location-specific approaches (Projected Completion: Year 3; Actual Completion: Year 4)

- Complete recruiting the entire study population (Projected Completion: Year 3; Actual Completion: Year 4)
- Complete baseline assessments and randomize 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)
- Continue to offer the IRB-approved Remote Outcomes option to accommodate participants who relocate after study enrollment (Projected Completion: Year 4; Actual Completion: Year 5)
- Complete data entry for all outcome events that occur within the study period (Projected Completion: Year 4; Actual Completion: Year 5)
- Complete all necessary sponsor reports (Projected Completion: Year 4; Actual Completion: Year 4)

Year 5

- Complete intervention for the entire targeted population (Projected Completion: Year 4; Actual Completion: Year 5).
- Continue to offer the IRB-approved Remote Outcomes option to accommodate participants who relocate after study enrollment (Projected Completion: Year 4; Actual Completion: Year 5)
- Complete data entry for all outcome events that occur within the study period (Projected Completion: Year 4; Actual Completion: Year 6)
- Complete all necessary sponsor reports (Projected Completion: Year 5; Actual Completion: Year 5)

Year 6 (No-Cost Extension)

- Complete data cleaning and quality control checks for all outcome and intervention data collected within the study period (Projected Completion: Year 5; Actual Completion: Year 6)
- Complete data analysis for primary and secondary outcomes (Projected Completion: Year 5; Actual Completion: Year 6)
- Complete manuscript development for the primary outcome (Projected Completion: Year 5; Actual Completion: Year 6)
- Complete all necessary sponsor reports (Projected Completion: Year 6; Actual Completion: Year 6)

What was accomplished under these goals?

Year 1

During Year 1, major activities included obtaining IRB approval from Tufts University, the U.S. Army Research Institute of Environmental Medicine (USARIEM), and the Human Research Protection Office (HRPO), completing the Manual of Procedures and study materials, beginning recruitment of the subject population, and completing all

required sponsor reports. Recruitment began at Hanscom Air Force Base (MA), Natick Soldier Systems Center (MA), Fort Devens (MA), and U.S. Coast Guard First District (Boston, MA).

During Year 1, we did not achieve the stated goals of conducting baseline assessments in the recruited population and beginning data entry for baseline data. This was due to delays in the IRB approval process and slow initial recruitment. However, we were able to obtain all permissions in January 2015, after which recruitment began. Further, in Year 1, we planned to extend our recruitment to Fort Drum, NY, as an additional measure to increase the study's recruitment pool. We also planned the first baseline assessments and start of the intervention to occur in Year 2.

All Technical Reports were completed and submitted for Year 1.

Year 2

During Year 2, major activities included increasing the study's recruitment pool by adding an additional study location (Fort Drum), allowing dependents of retired ADMP to enroll in the study along with their military sponsors, and introducing group counseling sessions online through a videoconferencing system versus the usual in-person format. During this period, participants started to enroll, complete baseline assessments, and start the intervention via group counseling sessions. Data entry for baseline assessments was completed for participants who completed the baseline event in Year 2.

As noted, we expanded our study locations to include Fort Drum in response to slower-than-expected recruitment, which yielded an increase in recruitment in Year 2. At that time, we also planned expansion to other military installations to fulfill the planned enrollment numbers.

We received IRB approval through Tufts University, USARIEM, and the HRPO for all new study materials and changes to the protocol.

All Technical Reports were completed and submitted for Year 2.

Year 3

During Year 3, major activities included increasing the study's recruitment pool by expanding study locations to include Fort Carson, CO, Fort Campbell, KY, and Naval Submarine Base New London in Groton, CT. We also continued recruitment efforts at Fort Drum, Hanscom Air Force Base, Natick Soldier Systems Center, Navy Recruiting District New England, and U.S. Coast Guard First District. During this period, participants recruited from these installations started to enroll, complete baseline assessments, and begin the intervention via group counseling sessions. Data entry for baseline assessments was completed for participants who completed the baseline event by the end of Year 3.

During Year 3, we continued marketing strategies at each of the sites with the aim of increasing recruitment. However, while the addition of three new study locations showed promise in increasing enrollment numbers, we did not accomplish our goal of recruiting and enrolling the entire study population by Year 3. We planned to reach the target study population by the end of Year 4 by continuing to utilize marketing strategies that were successful at approved study sites.

During this period, permanent change of station (PCS) continued to occur at higher-than-expected rates in our study population. Although relocated participants were able to continue the intervention as normal through online videoconference sessions, they were unable to attend semi-annual/annual outcome events, which were conducted at the sites where they were originally enrolled. To accommodate the inclusion of data from relocated participants, the option to submit outcomes data remotely was considered. This voluntary option, known as Remote Outcomes, was created in part for relocated participants who expressed interest in completing outcome assessments off-site. Through the Remote Outcomes option, participants were permitted to obtain outcome measures such as body weight, blood pressure, and blood values through their healthcare provider and submit these data to our study team to be recorded. This alternative also allowed participants to submit body weight (primary outcome) by using the study-provided Wi-Fi scale. All Remote Outcomes procedures and materials were IRB approved.

All Technical Reports were completed and submitted for Year 3.

Year 4

During Year 4, we created a Healthy Families Healthy Forces (HF2) Facebook account to expand our recruitment network at approved military installations. We also continued to use recruitment strategies such as flyers, banners, and word-of-mouth marketing. Even with these expanded efforts, we continued to experience minimal inquiries regarding study participation. Due to this continued slow recruitment, the Scope of Work (SOW) was revised, with our primary objective shifted from 2-year change in weight to one-year change in weight.

While we continued to receive inquiries at a less-than-expected rate, we were able to enroll participants at all study locations to meet our target enrollment of 238 dependents of current or retired ADMP. Therefore, we ceased all recruitment efforts and closed enrollment. Further, baseline measurements and randomization were completed for the entire study population, and all enrolled participants were randomized and had started the intervention by Year 4.

During Year 4, participants continued to complete their participation in the group weight loss intervention and outcome data collection events as scheduled. Data entry was completed for all intervention and outcome events described below:

- At Hanscom Air Force Base, the first 3 groups of participants completed the 24-month milestone. The fourth group of participants completed their 12-

month milestone, and the fifth group will complete their 12-month milestone at the beginning of Year 5. The sixth group of participants were enrolled and started the intervention in November 2017.

- At Fort Drum, the first 3 groups of participants completed the 24-month milestone, while the fourth and fifth groups completed the 12-month milestone. The sixth and final group was enrolled and started the intervention in November 2017.
- At Fort Carson, the first group of participants completed their 12-month milestone. A second group of participants was enrolled and started the intervention in July 2017.
- At Fort Campbell, the first and second groups completed the 12-month milestone. A third group was enrolled and started the intervention in July 2017.
- At the Naval Submarine Base New London, the first group of participants were slated to complete their 12-month milestone at the beginning of Year 5. A second group was enrolled and started the intervention in November 2017.

Participants who relocated and were no longer able to attend in-person outcome events participated in the intervention as normal; Remote Outcomes also were obtained from interested participants.

All Technical Reports were completed and submitted for Year 4.

Year 5

During Year 5, we completed the intervention delivery and outcomes assessments for all participants enrolled in Years 3 and 4. For participants enrolled in Year 3, we obtained outcomes for the 24-month time point. For participants enrolled in Year 4 who would complete a 12-month follow-up as their final assessment, outcomes were obtained. Data entry was completed for the clinic visits. The study was closed to data collection and participant-facing activities by the end of Year 5.

Year 6 (No-Cost Extension)

This NCE year was focused on data cleaning and quality checks, which were extensive due to the complex study design resulting from the shift in primary objective from 2-year weight change to one-year weight change, which also shifted the time point for cardiometabolic outcome assessments for some participants. Further, outcomes data cleaning and quality control checks required the integration of multiple databases and data sources to prepare files for analysis.

Manuscripts were developed using baseline data and demographic information. The primary manuscript presenting weight and cardiometabolic data is in the final stage of preparation prior to submission to the *Journal of the American Medical Association*.

Administrative closeout for all budget and business items is complete, and IRB closeout is slated for July 2020, after submission of the final report.

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

- This project provided opportunities for training at the undergraduate and professional level: Co-Op undergraduate students gained exposure to the clinical research and data cleaning process, and Army dietitians-in-training were able to conduct analyses using baseline data as part of their requirement for a clinical internship, practicum, or research project.
- Tufts University study team members completed the Good Clinical Practice in Research course through the Collaborative Institutional Training Initiative.

How were the results disseminated to communities of interest?

Study findings were presented at military organized meetings and conferences including the Military Health System Research Symposium (MHSRS) in 2019 and 2020. (Of note, the 2020 presentations were posted online to the meeting site, as the meeting was cancelled due to COVID-19.)

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to Report.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Lifestyle interventions using behavioral therapy to support healthy changes in diet and physical activity are the first line treatment for overweight and obesity. However, the intensive interventions that were originally demonstrated to be effective (including the national DPP) have typically achieved only 2% to 4% weight loss when revised into scalable forms and retested in randomized trials. Further, traditional lifestyle interventions prioritize goal setting and development of self-regulation skills through daily self-monitoring of diet and exercise, which are burdensome and hard to sustain. Lifestyle interventions to treat obesity have been particularly ineffective in military families. We tested m-DPP and HWL, a new lifestyle intervention that did not require burdensome food logging, in dependents of ADMP or retired ADMP. Both interventions were primarily delivered by videoconference and thus are appropriate for future scaling in an increasingly digital world. In this study, both programs achieved a high level of success (12-month weight loss of 7.5% and 8.5% in m-DPP and HWL, respectively), suggesting that healthy weight management options, with or without food logging, are feasible in adult members of military families. The interventions can be used to address high rates of obesity in military families and be disseminated to the civilian population.

What was the impact on other disciplines?

The demonstration of effective health behavior change via videoconference (a telemedicine approach) is an important breakthrough. Videoconference is an attractive option for the adoption and scaling of this intervention in the military population, as frequent relocation is common among military families and participants can receive intervention support through widely used devices, including smartphones. Further automation of these programs through artificial intelligence is a potential strategy for supporting scale-up efforts with cost reduction.

What was the impact on technology transfer?

Dissemination of the new HWL program can be informed by the results of this study.

What was the impact on society beyond science and technology?

Obesity is the underlying cause of many non-communicable diseases, including type 2 diabetes, cardiovascular disease, and cancer. In addition, well known side effects of obesity, such as obstructive sleep apnea and arthritis, are both expensive and debilitating. Our demonstration of effective weight management in individuals with overweight and obesity is a major advancement that has implications for all Americans, with the potential to improve health and quality of life. Further, it is estimated that both m-DPP and HWL could save \$1,600 per person per year in health care costs.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Year 1

- Due to a limited number of individuals signing up for screening at the original study locations (Hanscom Air Force Base and Natick Soldier Systems Center), we initiated our contingency plan, which involved expanding the project to other larger military installations.

Year 2

- We continued to implement our contingency plan to expand the project to larger military installations that were not included as original study locations. During Year 2, this plan was carried out at Fort Drum. Opportunities to expand to other interested military installations were considered.
- In an additional effort to increase the recruiting pool, we received approval to recruit adult dependents of retired ADMP.

Year 3

- We continued to implement our contingency plan to expand the project to larger military installations that were not included as original study locations. In Year 2, this contingency plan was successfully carried out at Fort Drum. During Year 3, we expanded

the project to Fort Carson and Fort Campbell, similar military installations to Fort Drum. We also extended the project to Naval Submarine Base New London.

- Due to a high PCS rate in our study population, relocated participants were given the option of Remote Outcomes.

Year 4

- Due to slower-than-anticipated recruitment, we amplified our marketing efforts by creating an HF2 Facebook account to expand our recruitment network at approved military installations.
- Due to slower-than-anticipated recruitment, we shifted our primary objective from 2-year change in weight to one-year change in weight.
- Due to the change in primary objective, participants who had not completed their one-year outcome event by January 2018 were to complete a blood draw at the one-year rather than 2-year time point.
- All intervention sessions and outcome data assessments were slated to conclude by December 2018. The following plan was in place for participants whose enrollment continued into Year 5: (1) participants who would not reach the 18-month time point by December 2018 would complete the study at the 12-month time point; and (2) participants who reached the 18- to 24-month time point by December 2018 would be followed up until that point. Data collected from participants at time points that exceeded one year would be analyzed as a separate cohort. We would continue to offer the option of Remote Outcomes to relocated participants.

Year 5

- Due to the high PCS rate, we continued to offer the option of Remote Outcomes to relocated participants. In Year 5, Remote Outcomes was the only option for the last group at Fort Drum because only 2 participants were willing to attend an in-person event.
- A no-cost extension (NCE) was requested to complete data analysis and prepare manuscripts.

Year 6 (No-Cost Extension)

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them

Year 1

- Due to the complex nature of the IRB approval process (in which we had to receive approval from both Tufts University and USARIEM prior to requesting approval from the HRPO), the start of recruitment was delayed.
- Recruitment was slow at the original study locations. As a result, we planned to expand the project to other larger bases to meet recruitment targets.

Year 2

- Although recruitment increased with the addition of Fort Drum as a study location, recruitment numbers remained below targets. To meet recruitment targets, we planned to expand the project to other larger bases.
- During Year 2, a significant number of participants experienced or anticipated a PCS, which was a barrier to attending in-person events. As a result, Remote Outcomes was added as a voluntary option for relocated participants. These participants also had the opportunity to continue their participation in group counseling sessions via videoconference.

Year 3

- Although recruitment increased with the addition of three military installations, recruitment numbers remained below targets. To meet recruitment targets, we planned to explore new marketing opportunities through both broad and location-specific approaches.
- A significant number of participants continued to experience or anticipate a PCS during Year 3. As a result, relocated participants had the option to complete Remote Outcomes during this period and were still permitted to take part in group counseling sessions via videoconference. Participants also were given the option to submit their body weight using study-provided Wi-Fi scales and complete the online questionnaires and dietary recalls.

Year 4

- Due to slower-than-expected recruitment, the primary objective was changed (see **Year 4** under **5. CHANGES/PROBLEMS: Changes in approach and reasons for change**). As a result, the target population enrollment was reduced from the planned 290 to 238.
- A significant number of participants continued to experience or anticipate a PCS. As a result, relocated participants had the option to complete Remote Outcomes during this period and were still permitted to take part in group counseling sessions via videoconference. Participants also were given the option to submit their body weight using their study-provided Wi-Fi scale and complete the online questionnaires and dietary recalls.

Year 5

- During the latter half of 2018, the primary study coordinator and an interventionist left Tufts University. As these individuals were not replaced, their unanticipated departures increased the workload of the remaining study team members. This reduction in staff also necessitated a redistribution of roles and responsibilities and a slight revision to the timeline. To compensate for these changes and to accommodate additional planning (e.g., study design and statistical handling of the one- and 2-year data sets), an NCE was requested. The Department of Defense granted our request for an NCE from April to December 2019.

Year 6 (No-Cost Extension)

- During Year 6, it was brought to our attention that a number of individuals did not receive full compensation for study participation due to an inadvertent administrative error. On January 6, 2020, the Tufts University study team received approval from the HRPO to reopen the study with the Tufts University Health Sciences IRB for the sole purpose of issuing these outstanding stipends. On February 7, 2020, the study was official reopened. Per the HRPO, the Tufts team had until March 31, 2020, to issue these outstanding stipends; the task was completed within the designated time frame and all participants received full compensation for their participation.

Changes that had a significant impact on expenditures

Year 1

- Due to delays in hiring study staff, expenditures on salary support were slightly less than anticipated.
- Due to slow recruitment, travel expenditures were minimal during Year 1. In addition, due to slow recruitment and delay in program start, there were minimal intervention expenses (babysitting, materials and supplies, consultant services).

Year 2

- Due to the conversion of diet interventions from in-person to online group counseling sessions, travel expenses were less than anticipated for Year 2. Due to our planned expansion to new study locations and an increase in our recruitment pool, we expected these expenses to increase in future years.

Year 3

- As anticipated, the expansion to new study locations and increased enrollment led to increased travel expenses for Year 3. These expenses allowed our study team to travel to and from military installations for screening and outcome events.
- Due to slower-than-anticipated recruitment, we extended the study's recruitment period. As a result, we projected an eventual increase in expenses due to personnel and travel costs.

Year 4

- Expansion to new study locations led to increased travel expenses for screening and outcome events.

Year 5

- The revised SOW and reduction in staff did not impact expenditure. However, they did lead to a reallocation of funds to accommodate the following: (1) a change in effort for

some staff members; and (2) increased needs for data and statistical analysis as compared to the original study design.

Year 6 (No-Cost Extension)

No additional funds were requested or awarded during this period. Data management and analysis were completed with the existing balance from Year 5 to support data analysis and effort for the study personnel.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

6. PRODUCTS:

• Publications, conference papers, and presentations

Journal publications.

- Taetzsch A, Gilhooly CH, Bukhari 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 of Weight Loss With In-Person Program Delivery. *Military Medicine*. 2019 Nov;184(11-12):647-52.
 - Status: Published.
 - Acknowledgement of federal support: Yes.
- Taetzsch A, Roberts SB, Gilhooly CH, Lichtenstein AH, Krauss AJ, Bukhari A, Martin E, Hatch-McChesney A, Das SK. Food cravings: Associations with dietary intake and metabolic health. *Appetite*. 2020 Apr;152:104711.
 - Status: Published
 - Acknowledgement of federal support: Yes.

Books or other non-periodical, one-time publications.

Nothing to Report.

Other publications, conference papers and presentations.

- Taetzsch A, Gilhooly CH, Bukhari 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 of Weight Loss With In-Person Program Delivery. Presented at: MHSRS; 2019 August 19-22. Kissimme, FL.*
- Bukhari AS, Das SK, Taetzsch AG, Krauss AJ, Rogers GT, Gilhooly CH, Hatch-McChesney A, Blanchard C, Livingston KA, Silver RE, Martin E, Chin MK, Lutz LJ, McGraw SM, Vail TA, Montain S, Lichtenstein A, Saltzman E, Roberts SB. Interventions for sustainable weight loss in military families: The Healthy Families Healthy Forces (HF2) Study. Presented at: MHSRS; 2020 (posted online; conference cancelled due to COVID-19).
- Das SK, Roberts SB, Gilhooly CH, Lichtenstein AH, Krauss AJ, Bukhari A, Martin E, Hatch-McChesney A, Taetzsch A. Food Cravings: Associations with Dietary Intake and Metabolic Health. Presented at: MHSRS; 2020 (posted online; conference cancelled due to COVID-19).*
- Das SK, Roberts SB, Bukhari A, Lichtenstein AH, Gilhooly CH, Martin E, Krauss AJ, Hatch-McChesney A, Taetzsch A. Eating Timing: Associations with Dietary Intake and Metabolic Health. Presented at: MHSRS; 2020 (posted online; conference cancelled due to COVID-19).
- **Website(s) or other Internet site(s)**
 - ClinicalTrials.gov Website: <https://clinicaltrials.gov/ct2/show/NCT02348853>
- **Technologies or techniques**

Nothing to Report.
- **Inventions, patent applications, and/or licenses**

Nothing to Report.
- **Other Products**
 - For this study, we developed the ScienceTrax database for data collection. The database is a sophisticated combination of data entry portals for researchers and participants. It also enabled the 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
Nearest person month worked: 0.18 (reporting period: Feb 1, 2020 – March 31, 2020)

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

Name: Das, Sai Krupa

Project Role: Co-Investigator, Outcomes Chair

Nearest person month worked: no change

Contribution to Project: Dr. Das was scientifically responsible for outcomes assessments, quality control, and data management and analysis oversight for all aims of the project.

Name: Lichtenstein, Alice

Project Role: Co-Investigator, Cardiovascular Outcomes

Nearest person month worked: no change

Contribution to Project: Provided expertise on cardiovascular outcomes, evaluation, and analysis.

Name: Gilhooly, Cheryl

Project Role: Co-Investigator

Nearest person month worked: no change

Contribution to Project: Working with Dr. Roberts, Dr. Gilhooly was responsible for training the intervention components common to both interventions and for supervision the interventionists (psychologists/nutritionists) involved in delivery of the m-DPP arm of the intervention.

Name: Pittas, Anastassios

Project Role: Co-Investigator, Diabetes Outcomes

Nearest person month worked: no change

Contribution to Project: Dr. Pittas provided expertise on diabetes outcomes, analyses, and interpretation

Name: Saltzman, Edward

Project Role: Study Physician

Nearest person month worked: no change

Contribution to Project: Dr. Saltzman was responsible for safety oversight of the study, including the oversight of adverse events and the monitoring and preparing of reports on serious adverse events to the Tufts Health Sciences IRB.

Name: Ceglia, Lisa

Project Role: Study Physician

Nearest person month worked: no change

Contribution to Project: Dr. Ceglia replaced Dr. Saltzman and was responsible for safety oversight of the study, including the oversight of adverse events and the monitoring and preparing of reports on serious adverse events to the Tufts Health Sciences IRB.

Name: Dallal, Gerard

Project Role: Lead Statistician

Nearest person month worked: no change

Contribution to Project: Dr. Dallal provided expertise in ensuring that the main study was reasonably powered and randomization and other data methodology were sound.

Name: Rogers, Gail

Project Role: Lead Statistician

Nearest person month worked: no change

Contribution to Project: Gail Rogers replaced Dr. Dallal as Lead Statistician and provided expertise in ensuring that the main study was reasonably powered and randomization and other data methodology were sound.

Name: Taetzsch, Amy

Project Role: Interventionist

Nearest person month worked: no change

Contribution to Project: Responsible for delivering group sessions for the m-DPP intervention.

Name: Krauss, Amy

Project Role: Interventionist

Nearest person month worked: no change

Contribution to Project: Responsible for delivering group sessions for the HWL intervention.

Name: Twyer, Elizabeth

Project Role: Interventionist

Nearest person month worked: no change

Contribution to Project: Elizabeth Twyer replaced Amy Krauss as the Interventionist for the HWL intervention.

Name: Schleicher, Molly

Project Role: Study Coordinator

Nearest person month worked: no change

Contribution to Project: Responsible for operational logistics, tracking of study schedules, outcomes assessments, data collection, data entry for non-electronic forms, and helping respond to queries.

Name: Martin, Edward

Project Role: Study Coordinator

Nearest person month worked: no change

Contribution to Project: Edward replaced Molly and was responsible for operational logistics, tracking of study schedules, outcomes assessments, data collection, data entry for non-electronic forms, and helping respond to queries.

Name: Blades, Rashod

Project Role: Research Assistant

Nearest person month worked: no change

Contribution to Project: Assisted the Study Coordinator; primarily assisted in outcomes assessments, data collection, and data entry.

Name: Taylor, Salima
Project Role: Research Assistant

Nearest person month worked: no change

Contribution to Project: Assisted the Study Coordinator; primarily assisted in outcomes assessments, data collection, and data entry.

Name: Livingston, Kara
Project Role: Data Manager

Nearest person month worked: no change

Contribution to Project: Responsible for data management including data integration, cleaning, quality control checks and preparation of analysis ready files.

Name: Silver, Rachel
Project Role: Data Management Support

Nearest person month worked: no change

Contribution to Project: Rachel Silver worked primarily on data management support.

Name: Chin, Meghan
Project Role: Research Coordinator

Nearest person month worked: no change

Contribution to Project: Meghan Chin served as a Research Coordinator for the analysis stage of the study, primarily working on data cleaning, data management, and IRB submissions.

Name: Blanchard, Caroline
Project Role: Research Coordinator

Nearest person month worked: 0.68 calendar months (reporting period: Feb 1, 2020 – March 31, 2020)

Contribution to Project: Caroline Blanchard served as a Research Coordinator for the analysis stage of the study, primarily working on data cleaning, data management, and IRB submissions.

What other organizations were involved as partners?

- **Organization Name:** USARIEM
- **Location of Organization:** Natick, MA
- **Partner's contribution to the project**
 - Facilities
 - Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

N/A

QUAD CHARTS:

A final Quad Chart has been provided with this report.

9. APPENDICES:

Two journal articles and three abstracts are included as appendices:

- Taetzsch et al (2019)
- Taetzsch et al (2020)
- Bukhari et al (2020) - MHSRS-20-00654
- Das et al (2020) - MHSRS-20-01076
- Das et al (2020) - MHSRS-20-01078

Development of a Videoconference-Adapted Version of the Community Diabetes Prevention Program, and Comparison of Weight Loss With In-Person Program Delivery

Amy Taetzsch*; Cheryl H. Gilhooly*; LTC Asma Bukhari†; Sai Krupa Das*; Edward Martin*; Adrienne M. Hatch‡; Rachel E. Silver*; Scott J. Montain‡; Susan B. Roberts*

ABSTRACT Introduction: Effective, standardized, and easily accessible weight management programs are urgently needed for military beneficiaries. Videoconference interventions have the potential for widespread scaling, and can provide both real time interaction and flexibility in delivery times regardless of location, but there is little information on their effectiveness and acceptability. Materials and Methods: This study as part of a larger weight loss trial describes the videoconference adaption of Group Lifestyle Balance (GLB) program, a community group-based Diabetes Prevention Program intervention, and provides a comparison of weight loss and meeting attendance between in-person and videoconference delivery modes over 12 weeks in adult family members of military service members. Forty-three participants were enrolled from two military installations and received either the videoconference-adapted or an in-person GLB program in a non-randomized trial design. Differences in program attendance and percent weight lost at 12 weeks were compared by independent samples *t*-tests and nonparametric methods. Group differences in the percentage of weight lost over the 12-week period were analyzed using a linear mixed model. Results: All GLB intervention components were successfully delivered by videoconference with minor adaptations for the different delivery mechanism. Participant retention was 70% and 96% in the in-person and videoconference groups, respectively ($p = 0.04$). Completing participants in both groups lost a significant percent body weight over the 12 week intervention ($p < 0.001$) and there was no difference in percent body weight after 12 weeks of intervention ($6.2 \pm 3.2\%$ and $5.3 \pm 3.4\%$ for in-person and videoconference at 12 weeks, respectively; $p = 0.60$). Conclusion: This study describes the first videoconference adaption of the GLB program for use in military families. Attrition was lower in the videoconference group, and there were a similar levels of weight loss in both groups regardless of delivery modality. Videoconference weight loss interventions are effective and feasible for scaling to support healthy weight management in military as well as civilian populations.

INTRODUCTION

The prevalence of overweight and obesity in US military service members and their families is similar to that in the civilian population.^{1,2} These high rates of obesity in military families increase

health care costs across the US military services.³ Although there are some established guidelines⁴ and service specific weight loss programs available to military families,^{5,6} program attendance, adherence, and effectiveness have not been systematically investigated. None of the services offer weight loss program with systematic evaluation for program content, duration, or modality for long-term weight sustainment needs. These observations indicate an urgent need for effective solutions to address obesity and overweight in military service members and their families.

Developing programs that are able to effectively support healthy weight management in military family members with overweight and obesity requires consideration of the unique challenges faced by this population. In particular, frequent family relocation and deployments for service members disrupt traditional behavioral approaches to weight loss, by separating participants and their counselors. Videoconference delivery of behavioral weight management programs could potentially provide behavioral support to military families without the loss of continuity during relocations, by eliminating the need for counselors to be in the same geographic area as the participants. Such approaches have been tested in civilian populations, and preliminary studies indicate weight loss is similar in magnitude to in-person interventions.^{7,8} However, to our knowledge, there has been no evaluation of the effectiveness of

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videoconference approaches to address overweight and obesity in families with active duty military service members.

Group Lifestyle Balance (GLB)^{9,10} is the official community-adapted version of the Diabetes Prevention Program^{11,12} and is in widespread use. The few videoconference implementations of GLB reported suggest it can be effective in civilian populations,^{8,13–15} and retired service members¹⁶ but no videoconference adaptation has been described in sufficient detail to allow replication. Furthermore, no adaptation has been reported for military families, and the studies published to date in other populations lack control groups or comparative in-person implementation groups, which limits evaluation of program integrity and effectiveness of the videoconference delivery format.

This report describes an adaptation of the GLB program and the collection of preliminary data to compare weight loss and attrition between videoconference and in-person intervention program delivery among adult family members of active duty military personnel over 12 weeks. We hypothesized there would be no significant difference in weight loss or participant drop-out between the two program delivery methods.

METHODS

This study was part of the ongoing Healthy Families Healthy Forces (HF2) randomized controlled trial (trial # NCT02348853). Briefly, the HF2 study compares GLB with a different behavioral weight loss intervention⁸ for changes in body weight and cardiometabolic risk factors in adult family members of active duty military personnel or retired military personnel. Participants in the subgroup reported herein were randomized to the GLB arm of the larger trial, and were assigned to either in-person or videoconference groups depending on their date of enrollment and location. The different program implementations occurred as part of an expansion of the trial beyond the immediate locality of the research center, which prompted videoconference rather than in-person intervention delivery. The study evaluated participants during 12 weeks of weight loss. Sample sizes for this analysis were based on enrollment in the initial two in-person groups, which were matched to the subsequent two videoconference groups and enrollment took place between May 2015 and March 2016. The study was approved by the Institutional Review Boards at Tufts University and the US Army Medical Research and Materiel Command (USAMRMC), as well as the USAMRMC Human Research Protection Office. All participants provided written informed consent.

Videoconference Adaptation of GLB

The goal of the GLB videoconference adaptation was to retain as many components of the program as possible, including programmatic goals, specific education content, provided materials, and accountability factors. The adapted version differed only in specific implementation features necessary to work effectively in the videoconference format. Table 1 summarizes the program features in the videoconference delivery and the in-person versions of the intervention. Principal

differences in the videoconference version included: delivery of all materials that could not easily be emailed (e.g., pedometer, book of calorie and fat values) in a single package at the start of the intervention; providing a remote Wi-Fi scale the counselor could access to collect data on body weight independent of participant reporting; emailing session handouts prior to sessions rather than distribution during meetings; and counselor review of accountability and goal exercises (e.g., food logs and goals for physical activity in the coming week) by email during the week. In addition, among the optional interactive program activities provided in the GLB materials,¹⁷ those selected were the ones considered feasible for videoconference use.

Participants

A total of 43 individuals were included in this analysis. Inclusion criteria for study enrollment including being an adult (>18 years of age) family member of an active duty or retired military personnel, with a body mass index (BMI) ≥ 25.0 kg/m² at screening and were enrolled in the GLB arm of the study. In addition, participants needed to be willing to complete online or paper surveys and participate in study interventions and outcome measures to be eligible. Exclusion criteria included prior gastric bypass surgery, current pregnancy, recent weight loss, or any medical complication impacting food absorption or prevent participation in a weight loss intervention involving consumption of a healthy diet.

Intervention Delivery

Implementation of both the in-person and videoconference interventions was conducted by a single experienced weight loss counselor trained in GLB content and delivery (AT) and 5% of videoconference recordings were reviewed for quality assurance. The in-person intervention was implemented as recommended in the curriculum,¹⁷ with the exception of three changes designed to provide parity between the two different interventions being tested in the larger trial, and to support programmatic adherence. These changes included: (1) the addition of weekly emails as a mid-week contact between the counselor and participants; (2) optional booster sessions (which allowed mixing between groups); and (3) optional make-up sessions by phone or for videoconference any missed session. The videoconference intervention was delivered as summarized in Table 1, with the addition of the same three components described above for the in-person delivery mode.

MEASUREMENTS

Body Mass Index and Percent Weight Change

As part of the larger study, fasting weight was measured in duplicate at baseline using a digital calibrated scale weighing to ± 0.1 kg (Escali BFBW200 Digital, Minneapolis, MN) and height was assessed in duplicate using an upright stadiometer measuring to ± 0.1 cm (Model 213, Seca). Weight change from session 1 to session 12 was assessed by non-fasting

TABLE I. Components of GLB in the Original In-Person Format and as Modified for Videoconference Delivery

In-Person		Videoconference
Core goals		
Food intake	Calorie and fat goals prescribed according to starting weight	Same as in-person.
Physical activity	150 minutes of moderate intense physical activity per week	Same as in-person.
Body weight	7% body weight loss	Same as in-person.
Materials		
Participant notebook	Given at 1st session	Given at start of program in package. Opened at 1st session.
Fat and calorie counter	Given at 2nd session	Given at start of program in package. Not discussed until 2nd session.
Keeping Track booklet	Printed copy provided at each session.	Two options were given: a) Printed copy in Participant Notebook with electronic version for subsequent sessions; b) Online food and activity tracker shared with counselor.
Specific session handouts	Printed copies given out at relevant session.	Electronic copies emailed 3–5 days prior to session and shared by videoconference during sessions.
Scales	None given.	Remote scale weight shared with counselor.
Pedometers	Given at session 10.	Given at start of program in package. Pedometers not discussed until session 10.
Session delivery		
Timing	Asked to arrive 5 minutes early to allow time for obtainment of session weight and to turn off phones.	Asked to be on time, turn their videos on and be in a quiet place where they can communicate freely (headphones to limit background noise if applicable)
Weights	Weighed at session.	Remote scale data used from session ± 1 day.
Educational component	Discussion based delivery of session material focused on nutrition, physical activity or behavior.	Same as in-person. Additional visuals (e.g., choosemyplate.gov) were also presented in the videoconference format.
Activities	Worksheets, role-play, demonstrations.	Same as In-Person, except for Session 8 Activity 1 (breakout groups using visual prompts to create healthy restaurant meals), which is modified so participants bring restaurant menus to identify healthy choices as a whole group.
Participation	Encouraged, and all participants are expected to engage in some form of participation	Same as in-person.
Wrap-up	Summarize session material and reinforce take-home messages	Same as in-person.
Home assignment	Assigned at the end of session to apply at least one of the principles discussed	Same as in-person.
Pre and post session mingling	Participants who want to engage with other participants are invited to come early or stay after sessions.	Same as in-person, via the videoconferencing platform.
Accountability and communication		
Home weight, goals for diet and physical activity	Recorded in Keeping Track booklet and handed to Counselor at sessions.	Weight obtained from remote scales that sync with Counselor. Two options were provided for goal setting. (1) Recorded in electronic Keeping Track booklet and emailed to Counselor. (2) Recorded in online food and activity tracker synced with Counselor.
Feedback	Weekly feedback provided. Written on Keeping Track booklet and returned in person at following session.	Weekly feedback Emailed to participant based on previous week's electronic Keeping Track booklet or online food and activity tracker plus remote scale data. Feedback not limited to timing of meetings, can be more rapid than in-person GLB.

weight measurements obtained during the in-person counseling meetings for the in-person group, or from remote weight measurements using a provided Wi-Fi scale for the videoconference group (In-person scales: Tanita BF-679W, Maneo-cho Itabashi-ku: Japan; Remote Wi-Fi scales: Withings WS-30, Paris, France). For the Wi-Fi scales, counselors were provided access to the online data for each participant in the videoconference group. The first weight recorded was used as the measurement. Data were considered missing for

participants who did not attend a session or provide their weight within five days of a meeting.

Session Attendance and Drop Out

Attendance at the in-person meetings and the videoconference meetings was recorded by the counselor. Drop-outs were defined as participants who informed the investigators they were dropping out, did not attend the last four sessions,

or missed the 6-month outcome measurements in the larger trial.

Statistical Analyses

Participants who dropped out of the study and participants who completed the study were compared. Baseline characteristics for the videoconference and in-person participants who completed the 12 week intervention were also assessed. Continuous variables were compared using an independent samples *t*-test (if the variable was normally distributed) or the non-parametric Wilcoxon–Mann–Whitney test (if the variable was not normally distributed). The Fisher’s Exact test was used to compare categorical variables. Differences in percent weight loss over 12 weeks between the in-person and videoconference groups were evaluated using a linear mixed model with adjustment for age, level of education, and baseline weight. A *p*-value <0.05 was considered statistically significant. All analyses were conducted using Stata statistical software version 15 (StataCorp, College Station, TX).

RESULTS

Of the 43 enrollees, seven dropped out before the end of the 12-week study period. There were no significant differences between completers and dropouts in age (*p* = 0.60), baseline BMI (*p* = 0.52), sex (*p* = 0.30), and reported family income (*p* = 0.106). Participants who did not complete the intervention tended to have a lower level of education (*p* = 0.052). The retention rate was greater in the videoconference group compared to the in-person group (70% and 96% for in-person and videoconference, respectively; *p* = 0.04).

Baseline characteristics for participants who completed the in-person and videoconference groups are compared in

Table II. There were no differences between in-person and videoconference groups in participant age, sex, baseline BMI classification, education, or household income.

Figure 1 displays attendance and the trajectory of weight loss for each group over the 12 week intervention period. In a direct comparison of the two groups, there was no significant difference in 12 week percent weight loss ($6.2 \pm 3.2\%$ and $5.3 \pm 3.4\%$ for in-person and videoconference, respectively; *p* = 0.60) or session attendance ($90 \pm 15\%$ and $90 \pm 12\%$ for in-person and videoconference, respectively; *p* = 0.52). In a linear mixed model, both the in-person and videoconference groups experienced significant weight loss over the 12 week intervention (*p* < 0.001), although there was no significant difference in weight loss was observed between the two groups over time (*p* = 0.14). Similar results were observed after adjustment for baseline age, level of education, and baseline weight.

DISCUSSION

This study describes an adaptation of the widely recognized GLB weight management intervention for delivery by videoconference to adult family members of active duty military personnel and retired service members, and provides a preliminary evaluation of the effectiveness of the new format. All aspects of the traditional GLB intervention could be delivered by videoconference with small modifications to presentation style, such as providing physical materials in a single package and modifying class exercises to be conducted as a group with visuals presented by videoconference. This GLB adaptation showed clinically significant mean weight loss for both in-person and videoconference groups. There were no significant differences in weight loss between enrollees in the videoconference intervention and those in the

TABLE II. Baseline Demographic Information on Completers for the In-Person and Videoconference GLB Interventions

	In-Person (N = 14)	Videoconference (N = 22)	<i>p</i> -value
Sex, N(%)			
Female	13 (93)	22 (100)	0.389
Male	1 (7)	0 (0)	
Age, years (mean±SD ^a)	36.2.7 ± 5.8	42.0 ± 9.76	0.051
BMI, kg/m ² (mean±SD)	33.7 ± 9.1	35.1 ± 6.6	0.307
Education, N(%)			0.065
High school, some college, or associates degree	4 (29)	8 (36)	
College degree	4 (29)	12 (55)	
Graduate degree	6 (43)	2 (9)	
Family income, N(%)			0.846
\$20,000–\$39,999	2 (14)	3 (14)	
\$40,000–\$59,999	2 (14)	3 (14)	
\$60,000–\$79,999	3 (21)	3 (14)	
\$80,000–\$99,999	5 (36)	6 (27)	
>\$100,000	2 (14)	7 (32)	

^aSD = standard deviation.

*Significant findings; *p* < 0.05.

Differences between in-person and videoconference groups were assessed using independent *t*-tests for normally distributed continuous variables, Wilcoxon–Mann–Whitney test for non-normally distributed continuous variables, and Fischer’s exact test for categorical variables.

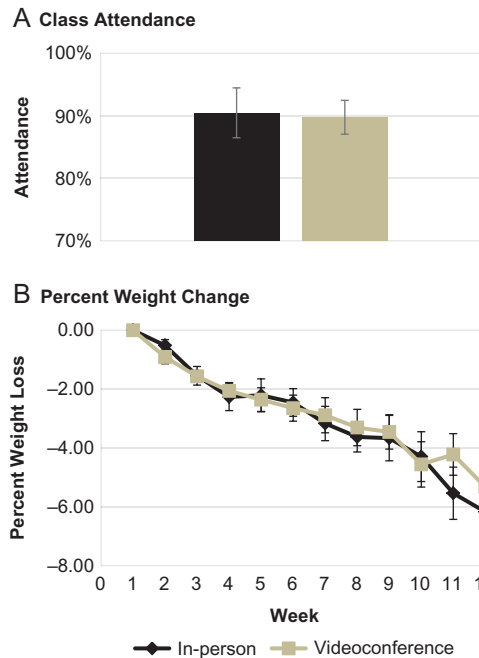


FIGURE 1. Attendance and percent weight change over 12 weeks.

standard in-person program over 12 weeks (5.3% and 6.2% for the videoconference and in-person, respectively), nor was there a difference between the groups in the trajectory of weight change over time. The average session attendance was high and similar between groups (90% versus 90%). However, participant retention was higher in the videoconference group compared to the in-person groups (70% and 96% for in-person and videoconference, respectively). Combined, these results indicate that the videoconference GLB, which is convenient for participants and allows for relocations without intervention disruption, is at least as effective for use in military families as the traditional in-person intervention.

Typical GLB interventions usually yield weight loss of 2–4.5% in the general population, including by videoconference delivery,^{7,9,18} which is lower than the 5% threshold recommended for clinically impactful benefits.¹⁹ These values are lower than the 7% mean weight loss achieved in the original Diabetes Prevention Program research trial,¹² which was an intense research-focused intervention that provided greater counselor–participant interactions and provided food than is feasible in a community-based intervention. It is therefore notable that both groups in this study achieved weight loss >5%. Although reasons for the high program effectiveness described are not fully understood, it may be relevant that the program was delivered by a masters-level registered dietitian with counseling experience and formal training in the GLB program. We also modified the traditional GLB intervention to include the addition of mid-week email contacts between counselors and participants, booster sessions for participants to meet individuals from other groups, and make-up sessions for missed attendance. Additionally, our

results are consistent with a previous study using videoconference methodology in military veterans,²⁰ suggesting that videoconference delivery may be particularly effective in military families and retirees.

The retention rate of 96% in the videoconference group is higher than previously reported weight loss studies²¹ and was significantly greater than the in-person group. Lower dropouts in the videoconference group could be due to the convenience and versatility of the videoconference platform. Participants were able to join meetings from any location with a cell phone service or internet connection using various devices. Similarly, lower attrition rates in videoconference vs in-person weight loss classes were demonstrated in a study using another behavioral based weight loss program.⁸

This study was the first to demonstrate successful videoconference adaptation of the GLB program in military families. It was conducted to understand the impact of a protocol change prompted by recruitment constraints and utilized the initial subset of data from a larger ongoing randomized trial, whose purpose is to compare the effectiveness of different weight management interventions independent of intervention delivery method. As this study was not powered to detect a difference, a larger study examining in-person versus videoconference intervention delivery for weight management is therefore required to confirm the promising results observed here. In addition, this intervention was delivered by a single, highly qualified counselor, and the effect of implementing GLB using counselors who lack a dietetic degree is unknown. Additional studies evaluating the potential effect of the counselor qualifications are therefore needed.

In conclusion, this study showed that videoconference delivery of the widely-recognized GLB weight loss intervention achieved comparable weight loss to the traditional in-person program delivery and lower participant drop-out. This result is consistent with our previous study demonstrating comparable weight loss and program attrition between in-person and videoconference delivery in a non-traditional behavioral intervention.⁸ As GLB has publicly available resources¹⁷ and a formal counselor training program,⁹ the adaptations to create a videoconference intervention are practical and support the widespread use of this intervention.

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We would like to acknowledge the Diabetes Prevention Support Center (DPSC) of the University of Pittsburgh for training and support in the Group Lifestyle Balance program; the current program is a derivative of this material.

FUNDING

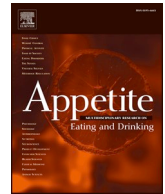
W81XWH-14-2-0005.

PREVIOUS PRESENTATION

This abstract will be presented at the 2019 Military Health System Research Symposium.

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Food cravings: Associations with dietary intake and metabolic health

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Body composition

ABSTRACT

Food cravings are a desire for specific foods which, if uncontrolled may lead to excess energy intake and weight gain. However, information on the relation between food cravings, dietary intake, and indices of metabolic health is limited. This study used baseline data from females ($n = 229$; aged 40.9 ± 0.7 years; BMI 34.7 ± 6.4 kg/m²) who were dependents of active duty and retired military personnel, and enrolled in the Healthy Families Healthy Forces weight loss and maintenance study. Measures obtained included food cravings using the Food Craving Questionnaire-Trait (which provides a habitual and stable measure of food cravings), dietary composition and eating patterns from three 24-h dietary recalls and the Stanford 7-day Physical Activity Recall, body composition from anthropometric measures, cardiometabolic risk factors from blood measures, and demographic information from questionnaires. Linear, quantile, or logistic regression models were used to examine the association of total food craving scores on dietary intake, and indices of metabolic health. In individuals reporting plausible energy intake ($n = 146$; $2210 \pm$ kcal/day) higher food craving scores were associated with a lower diet quality ($P < 0.05$), higher eating frequency ($P = 0.02$), longer daily eating interval ($P < 0.05$), and a lower likelihood of following a time restricted eating pattern ($P = 0.02$). Food cravings were also positively associated with BMI ($P = 0.03$) and waist circumference ($P = 0.01$), but not with measures of cardiometabolic risk (LDL, HDL, total cholesterol:HDL, triglycerides, glucose, glycated hemoglobin, insulin and C-reactive protein concentrations, blood pressure, metabolic syndrome). Our findings of significant associations of food cravings with lower diet quality, poor eating patterns, and unfavorable body composition strongly support efforts of targeting cravings in behavioral programs for weight management.

1. Introduction

The association of excess body weight with increased risk of chronic disease has heightened the focus on targeting potential drivers of eating or food seeking behaviors to promote adherence to sustainable weight loss and a healthy lifestyle (Hales et al., 2018). One such target is food cravings. This widely prevalent subjective trait has been reported to occur by 97% of women and 68% of men at least once in their lifetime (Weingarten & Elston, 1990; Yanovski, 2003). Craved foods are usually palatable, energy dense and collectively contribute to higher energy intake, disordered eating, and metabolic dysregulation (Buscemi et al., 2017; Chao, Grilo, & Sinha, 2016; Gilhooly et al., 2007; Hill et al., 1991; Hormes, Orloff, & Timko, 2014; Massicotte et al., 2019;

McCuen-Wurst et al., 2018; Richard et al., 2017; Zarrinpar, Chaix, & Panda, 2016). When craved foods are consumed, the reward centers of the brain such as the orbitofrontal cortex and ventral striatum, undergo greater activation compared to when non-craved foods are consumed (Rolls & McCabe, 2007; Ulrich, Steigleder, & Gron, 2016). Food cravings therefore present a motivation to eat, often independent of hunger, and are linked to excess energy intake and a higher lifetime body mass index (BMI) (Gilhooly et al., 2007; Hill & Heaton-Brown, 1994; Siwik & Senf, 2006; Weingarten & Elston, 1991).

Food cravings may be conditioned by interventions (Anton et al., 2012; Batra et al., 2013; Buscemi et al., 2017; Gilhooly et al., 2007; Martin, O'Neil, & Pawlow, 2006; Martin et al., 2011). Longitudinal studies promoting restriction of craved foods have resulted in reduced

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Table 1
Demographics of the total sample, plausible energy reporters, and under-reporters.

	Total sample	N	Plausible energy reporters	N	Under-reporters	N	P value
Age, years	40.9 ± 0.7	229	41.8 ± 0.8	146	39.3 ± 1.2	83	0.04
Race, %		223					
White	77.1		78.5	113	74.4	59	0.52
Black	14.4		14.6	21	13.9	11	
Other ^a	8.5		6.9	10	11.4	9	
Ethnicity, %		222					0.82
Hispanic or Latino	9.5		9.8	129	8.9	72	
Not Hispanic or Latino	90.5		90.2	14	91.1	7	
Annual family income, %		221					0.32
< \$40,000	17.2		14.7	21	21.8	17	
\$40,000 - \$79,999	41.6		41.3	59	42.3	33	
≥ \$80,000	41.2		44.1	63	35.9	28	
Education, %		222					0.22
Less than a college degree	48.2		45.1	65	53.9	42	
College degree or higher	51.8		54.9	79	46.2	36	
BMI, kg/m ²	34.7 ± 0.4	229	33.5 ± 0.4	146	36.8 ± 0.8	83	<0.01
Employed, %	48.4	221	52.1	74	41.8	33	0.14
Physical activity, %	38.2	220	32.4	46	48.7	38	0.02
Post-menopausal, %	27.6	214	29.5	41	24.0	18	0.39
Food cravings (total score)	116 ± 2	214	122 ± 3	137	104 ± 4	77	<0.01

Continuous variables are displayed as mean ± standard error and differences between plausible and under-reporters are determined by independent T-test or Wilcoxon Rank test.

Differences between plausible and under-reporters are determined by Chi square tests.

^a Includes multiracial.

body weight and food cravings (Anton et al., 2012; Batra et al., 2013; Buscemi et al., 2017; Gilhooly et al., 2007; Martin et al., 2006, 2011). In a 6-month worksite weight loss intervention, we have previously demonstrated a significant reduction in food cravings-trait, and a correlation between higher baseline food cravings and lower reduction in body weight (Batra et al., 2013). In the same study we observed an activation in the regions of the brain which control rewards and cravings. A craving for low calorie foods vs. high calorie foods was greater following the weight loss intervention compared to baseline values prior to participation in the program (Deckersbach et al., 2014). Although the relationship between body weight and food cravings (Anton et al., 2012; Batra et al., 2013; Buscemi et al., 2017; Gilhooly et al., 2007; Martin et al., 2006, 2011), and separately, the association between excess body weight and increased cardiometabolic risk, has been demonstrated, little data are available evaluating the association of food cravings with cardiometabolic risk. In addition, while a link between food cravings and energy intake has been demonstrated, the association of food cravings and eating patterns has not yet been examined.

Our aim was to examine the association of food cravings with dietary intake, eating patterns, body composition, and indices of cardiometabolic health in women with overweight and obesity using cross-sectional data. We tested the hypothesis that greater food cravings are associated with greater energy intake, and less favorable dietary pattern and metabolic health measures.

2. Materials and methods

2.1. Study characteristics

Data were obtained from baseline information collected from 239 participants enrolled in the Healthy Families Healthy Forces weight loss and maintenance trial in adult beneficiaries of active duty and retired military personnel. To be eligible, participants had a BMI of ≥ 25 kg/m² at screening, no health conditions that influenced nutrient absorption or weight loss, were not pregnant or planning to become pregnant, were not concurrently enrolled in other nutrition programs, and were English speaking. Two hundred and twenty nine females with baseline outcome measurements and at least one dietary recall were included for this secondary data analysis. From the total cohort, four males were

excluded due to the small sample size, one female was excluded for not completing any baseline measurements, and five females were excluded for missing dietary data. The main analysis was limited to the 146 participants who met the additional criterion of reporting plausible energy intake, as defined by the Goldberg cut off (Black, 2000; Goldberg et al., 1991; Mendez et al., 2011). The other 83 participants reported implausible energy intake; all of whom under-reported their energy intake and thus were classified as under-reporters. The study was approved by both the Tufts Medical Center and Tufts University Health Sciences Institutional Review Boards and U.S. Army Institute of Environmental Medicine Institutional Review Board.

2.2. Measurements

Demographics: Demographic variables including age, sex, race, ethnicity, education, and income were obtained using online questionnaires completed by participants remotely or in-person. Health history included menopause status as well as medication use for lipid, blood pressure and glycemic control, physical activity, and employment status.

Food cravings: Food cravings were ascertained by the Food Craving Questionnaire -Trait (FCQ-T) which consists of 39 questions scored on a 6-point scale ranging from *never* to *always* with a total possible score of 234. The FCQ-T contains nine subscales measuring food cravings and includes (1) intentions to consume food, (2) anticipation of positive reinforcement, (3) relief from negative states, (4) lack of control over eating, (5) preoccupation with food, (6) hunger, (7) emotions, (8) cues that trigger cravings, and (9) guilt (Cepeda-Benito, Gleaves, Williams, & Erath, 2000). The FCQ-T is a robust and validated questionnaire that captures stable total food cravings, not situational cravings or cravings specific to foods or food groups. Higher total FCQ-T scores indicate more intense and frequent food cravings, although these cannot be quantified separately. High food cravers were classified as those participants with a FCQ-T score of ≥ 113, which was the median score in our sample.

Dietary intake: Three baseline dietary recalls were collected on three non-consecutive days including one weekend day and two weekdays by trained interviewers via phone using the multiple-pass 24-h recall method and analyzed using Nutrition Data System for Research software (2014) (Conway, Ingwersen, & Moshfegh, 2004; Guenther

Table 2
Description of dietary intake and metabolic health by food cravings in plausible energy reporters.

	Plausible energy reporters	N	Low food cravings	N	High food cravings	N	P value
<i>Dietary intake</i>							
Total daily energy (kcal)	2210 ± 40	146	2120 ± 57	60	2311 ± 58	77	0.02
Carbohydrates (% kcal)	46.7 ± 0.5	146	46.4 ± 0.9	60	46.7 ± 0.7	77	0.81
Protein (% kcal)	15.3 ± 0.2	146	15.5 ± 0.4	60	15.0 ± 0.3	77	0.46
Fat (% kcal)	36.6 ± 0.4	146	36.5 ± 0.7	60	36.8 ± 0.6	77	0.37
Alcohol (% kcal)	1.5 ± 0.3	146	1.6 ± 0.4	60	1.6 ± 0.4	77	0.93
Added sugar (% kcal)	14.7 ± 0.5	146	14.2 ± 0.8	60	15.0 ± 0.8	77	0.56
Fiber (g/1000 kcal)	9.1 ± 0.2	146	9.6 ± 0.4	60	8.6 ± 0.3	77	0.08
Glycemic load	148.8 ± 3.5	146	141.2 ± 5.0	60	156.4 ± 5.1	77	0.07
Diet quality ⁱ	52.0 ± 1.0	146	55.3 ± 1.7	60	49.7 ± 1.3	77	<0.01
Diet diversity ⁱⁱ	4.53 ± 0.04	146	4.58 ± 0.06	60	4.51 ± 0.05	77	0.25
Energy density ⁱⁱⁱ (kcal/g)	2.07 ± 0.04	146	2.0 ± 0.06	60	2.15 ± 0.05	77	0.049
Eating frequency ^{iv}	5.26 ± 0.09	146	5.14 ± 0.13	60	5.34 ± 0.14	77	0.36
Daily eating interval ^v (hours)	11.6 ± 0.2	146	11.6 ± 0.2	60	11.7 ± 0.2	77	0.53
Time Restricted Eating (%) ^{vi}	35.6	146	40.0	60	32.5	77	0.48
Early energy eaters (%) ^{vii}	38.4	146	40.0	60	39.0	77	0.90
Late night eaters (%) ^{viii}	37.8	146	25.5	60	47.2	77	0.01
<i>Metabolic health</i>							
BMI (kg/m ²)	33.5 ± 0.4	146	32.8 ± 0.6	60	34.2 ± 0.6	77	0.17
Body fat (%)	40.5 ± 0.7	145	39.5 ± 0.9	60	41.3 ± 1.0	76	0.19
Waist circumference (cm)	96.4 ± 0.9	146	94.0 ± 1.3	60	98.1 ± 1.3	77	0.07
LDL (mg/dL)	118 ± 3	139	121 ± 4	56	115 ± 3	74	0.22
HDL (mg/dL)	56 ± 1	139	56 ± 2	56	56 ± 2	74	0.98
Total cholesterol:HDL	3.6 ± 0.1	139	3.7 ± 0.1	56	3.6 ± 0.1	74	0.64
Triglycerides (mg/dL)	123 ± 5	139	121 ± 8	56	125 ± 7	74	0.85
Glucose (mg/dL)	98 ± 1	139	98 ± 2	56	98 ± 1	74	0.48
Glycated hemoglobin (%)	5.4 ± 0.0	138	5.5 ± 0.1	55	5.4 ± 0.1	74	0.05
Insulin (uIU/mL)	15.6 ± 1.4	139	17.3 ± 3.3	56	14.3 ± 0.9	74	0.97
C-reactive protein (mg/L)	10.5 ± 1.3	139	8.8 ± 1.7	56	11.7 ± 1.9	74	0.049
Systolic blood pressure (mmHg)	114 ± 1	146	116 ± 2	60	113 ± 1	77	0.15
Diastolic blood pressure (mmHg)	77 ± 1	146	78 ± 2	60	76 ± 1	77	0.24
Metabolic syndrome (%)	38.3	141	43.2	57	56.8	75	0.95

Continuous variables displayed as mean ± standard error and differences determined by independent T-test or Wilcoxon Rank test.

Categorical variables displayed as % and differences determined by Chi square tests.

ⁱ Diet quality was measured using the Healthy Eating Index – 2015.

ⁱⁱ Diet diversity was determined by the average number of food groups consumed per day (1–5).

ⁱⁱⁱ Energy density was calculated using food only.

^{iv} Eating frequency was defined as the number of eating occasions per day.

^v Daily eating interval was defined as the time between the first and last eating occasion of the day.

^{vi} Time Restricted Eating was classified as a daily eating interval ≤ 11 h.

^{vii} Early energy eaters were classified as consuming ≥ 60% of energy during the first half of awake time.

^{viii} Late night eaters were classified as eating within 2 h of bed.

et al., 1995; Johnson, Driscoll, & Goran, 1996), developed by the Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN. **Dietary composition** data from Nutrition Data System for Research includes daily total calories (kcal), percent of calories from macronutrients, fiber (g/1000 kcal), and glycemic load. Diet diversity was scored by awarding one point for each food group consumed (grains, vegetables, fruit, meats/protein, and dairy), resulting in a total maximum score of 5 (Kant & Graubard, 2005; Kant, Schatzkin, Harris, Ziegler, & Block, 1993). Diet quality was determined using the Healthy Eating Index-2015, scored on a scale of 0–100 with a higher score indicating better diet quality (Reedy et al., 2018). Energy density was determined by dividing calories consumed by weight (kcal/g) for food, but not beverages (Vernarelli, Mitchell, Rolls, & Hartman, 2013).

Eating patterns were calculated using the Nutrition Data System for Research 24-h dietary recall and the Stanford 7-day Physical Activity Recall data (Richardson, Ainsworth, Jacobs, & Leon, 2001), both conducted by trained interviewers over the phone or in person. Eating occasions were defined as any episode at which 20 or more calories were consumed and included solid or liquid foods. Eating frequency was defined as the total number of daily eating occasions. Daily eating interval was defined as the number of hours between the first and last eating occasion. Time restricted eating (TRE) pattern was defined as those participants who had a daily eating interval of 11 h or less. The median wake time, time in bed, and time awake were calculated using

the Stanford 7-day Physical Activity Recall, and was used to define early energy eaters and late night eaters. Participants were designated as early energy eaters if they consumed ≥ 60% of their daily calories within the first half of their time awake. Late night eaters were defined as those participants who ate within 2 h of median bedtime.

Metabolic health: **Body composition** was assessed using fasting weight, height, body fat percentage, and waist circumference measures. Weight was measured in duplicate to ±0.1 kg using a calibrated scale (Escali BFBW200, Minneapolis, MN and Tanita BF-679 W, Tokyo, Japan). Percentage body fat was estimated using the same scale by bioelectrical impedance. Height was obtained in duplicate to ±0.1 cm and was used to calculate BMI as kg/m². Waist circumference was measured in duplicate to ±0.3 cm using standard procedures (WHO, 2008).

Cardiometabolic risk was assessed using blood pressure and fasting blood measurements. Systolic and diastolic blood pressure were taken in triplicate to obtain readings within 5 mm/Hg of each other following 5 min of rest. A fasting blood sample was obtained by trained phlebotomists. High density lipoprotein cholesterol (HDL), total cholesterol, triglyceride and glucose concentrations were measured on an automated chemistry analyzer (Beckman Coulter AU480). Low density lipoprotein cholesterol (LDL) concentrations were calculated using the Friedewald formula unless triglyceride concentrations exceeded 400 mg/dL (Friedewald, Levy, & Fredrickson, 1972), and when this was

Table 3

Regressions predicting dietary intake by food cravings in plausible energy reporters.

Independent variable	Food cravings (N = 135)	
	Estimate (95% CI)	P value
Dependent variables		
<i>Dietary composition</i>		
Total daily energy (kcal) ^a	1.74 (−0.55, 4.02)	0.13
Carbohydrates (% kcal) ^a	−0.001 (−0.03, 0.03)	0.92
Fat (% kcal) ^a	0.01 (−0.01, 0.04)	0.26
Protein (% kcal) ^a	−0.005 (−0.02, 0.01)	0.52
Alcohol (% kcal) ^b	0.0003 (−0.01, 0.01)	0.95
Added sugar (% kcal) ^a	−0.006 (−0.04, 0.03)	0.71
Fiber (g/1,000 kcal) ^a	0.001 (−0.01, 0.01)	0.92
Glycemic load ^a	0.06 (−0.13, 0.25)	0.55
Diet quality ^{a, i}	−0.06 (−0.12, −0.001)	0.048
Diet diversity ^{b, ii}	−0.002 (−0.01, 0.001)	0.18
Energy density ^{a, iii}	0.001 (−0.001, 0.003)	0.24
<i>Eating patterns</i>		
Eating frequency ^{a, iv}	0.006 (0.001, 0.02)	0.02
Daily eating interval (hours) ^{a, v}	0.009 (0.0002, 0.02)	0.049
Time Restricted Eating ^{c, vi}	0.987 (0.976, 0.998)	0.02
Early energy eaters ^{c, vii}	0.995 (0.99, 1.01)	0.35
Late night eaters ^{c, viii}	1.01 (0.999, 1.02)	0.06

Significance set as P value less than 0.05, bolded P values indicate both significant model and dependent variable P values.

The continuous variable for food cravings was used.

Covariates: age, income, physical activity; additional adjustment for total energy for dependent variables: diet diversity, glycemic load, eating frequency, daily eating interval, Time Restricted Eating, early energy eaters, and late night eaters.

^a Data determined by robust linear regression, estimate reported as β (95% CI).

^b Data determined by quantile regression and reported as β (95% CI).

^c Data determined by logistic regression and reported as odds ratio (95% CI).

ⁱ Diet quality was measured using the Healthy Eating Index – 2015.

ⁱⁱ Diet diversity was determined by the average number of food groups consumed per day.

ⁱⁱⁱ Energy density was calculated using food only.

^{iv} Eating frequency was defined as the number of eating occasions per day.

^v Daily eating interval was defined as the time between the first and last eating occasion of the day.

^{vi} Time Restricted Eating was classified as a daily eating interval ≤ 11 hr.

^{vii} Early energy eaters were classified as consuming $\geq 60\%$ of energy during the first half of awake time.

^{viii} Late night eaters were classified as eating within 2 h of bed.

the case, LDL concentrations were directly measured on an automated chemistry analyzer (Beckman Coulter AU480). Insulin and C-reactive protein concentrations were measured on a chemiluminescent immunometric analyzer (Siemens, Immulite 200xPi). Glycated hemoglobin was measured on an automated Chemistry analyzer (Roche Cobas MIRA), using an immunoturbidimetric assay (Pointe Scientific, Canton MI). Metabolic syndrome was calculated as defined by the National Cholesterol Education Program Adult Treatment Panel III: high waist circumference (>88.9 cm), high blood pressure ($>130/85$ mmHg), high triglyceride concentrations (>150 mg/dl), high glucose concentrations (>100 mg/dl), and low HDL concentrations (<50 mg/dl) (Grundey et al., 2005).

2.3. Data analysis

Descriptive statistics were calculated for the total sample and categorized by plausible energy reporters or under-reporters as well as high or low food craver status, with continuous variables reported as a weighted mean $\pm$ standard error, and categorical variables presented as percentages. In some cases, the sample size of variables was lower as some participants did not complete the specific questionnaire or

Table 4

Regressions predicting dietary intake by food cravings in the total sample.

Independent Variable	Food cravings (N = 213)	
	Estimate (95% CI)	P value
Dependent Variables		
<i>Dietary composition</i>		
Total daily energy (kcal) ^a	4.6 (2.5, 6.7)	<0.01
Carbohydrates (% kcal) ^a	−0.01 (−0.03, 0.02)	0.66
Fat (% kcal) ^a	0.02 (−0.01, 0.04)	0.16
Protein (% kcal) ^a	−0.01 (−0.03, 0.003)	0.10
Alcohol (% kcal) ^b	0.0001 (−0.003, 0.004)	0.97
Added sugar (% kcal) ^a	0.002 (−0.02, 0.03)	0.90
Fiber (g/1,000 kcal) ^a	0.0003 (−0.01, 0.01)	0.95
Glycemic load ^a	0.26 (0.08, 0.42)	<0.01
Diet quality ^{a, i}	−0.04 (−0.10, 0.01)	0.08
Diet diversity ^{b, ii}	0.002 (−0.001, 0.004)	0.24
Energy density ^{a, iii}	0.002 (−0.0001, 0.004)	0.07
<i>Eating patterns</i>		
Eating frequency ^{a, iv}	0.01 (0.002, 0.01)	<0.01
Daily eating interval (hours) ^{a, v}	0.01 (0.001, 0.02)	0.02
Time Restricted Eating ^{c, vi}	0.99 (0.98, 0.997)	<0.01
Early energy eaters ^{c, vii}	0.996 (0.99, 1.00)	0.36
Late night eaters ^{c, viii}	1.01 (1.003, 1.02)	<0.01

Significance set as P value less than 0.05, bolded P values indicate both significant model and dependent variable P values.

The continuous variable for food cravings was used.

Covariates: age, income, physical activity; additional adjustment for total energy for dependent variables: diet diversity, glycemic load, eating frequency, daily eating interval, Time Restricted Eating, early energy eaters, and late night eaters.

^a Data determined by robust linear regression, estimate reported as β (95% CI).

^b Data determined by quantile regression and reported as β (95% CI).

^c Data determined by logistic regression and reported as odds ratio (95% CI).

ⁱ Diet quality was measured using the Healthy Eating Index – 2015.

ⁱⁱ Diet diversity was determined by the average number of food groups consumed per day.

ⁱⁱⁱ Energy density was calculated using food only.

^{iv} Eating frequency was defined as the number of eating occasions per day.

^v Daily eating interval was defined as the time between the first and last eating occasion of the day.

^{vi} Time Restricted Eating was classified as a daily eating interval ≤ 11 h.

^{vii} Early energy eaters were classified as consuming $\geq 60\%$ of energy during the first half of awake time.

^{viii} Late night eaters were classified as eating within 2 h of bed.

measurement. Differences between high and low food cravers were determined by independent samples t-tests for continuous variables that were normally distributed, the Wilcoxon rank-sum test for continuous variables that were not normally distributed, and the Chi-square test for categorical variables. The association of total energy intake and BMI was conducted in plausible energy reporters and the total sample using a robust linear regression.

Robust linear, logistic, or quantile regression models were used to examine the influence of food cravings (as a continuous variable) on dietary intake and metabolic health. To address the issue of multiple comparisons total energy intake and BMI were chosen *a priori* as primary outcomes for the dietary intake and metabolic health domains, and all other variables were considered exploratory outcomes (Li et al., 2017). Models were run in the total sample (N = 229) and limited to plausible energy intake reporters (N = 146) as determined by the revised Goldberg cutoff as described by Mendez et al. (Black, 2000; Goldberg et al., 1991; Mendez et al., 2011). A standard deviation of ± 2 was used to determine the upper and lower cut-point ratio of reported energy intake to basal metabolic rate. Basal metabolic rate was determined by a modified Mifflin equation, as outlined by Mendez et al. (Mendez et al., 2011), using a Physical Activity Level of 1.55, which indicates light activity (Black, 2000; Goldberg et al., 1991; Mendez

Table 5
Regressions predicting metabolic health by food cravings in plausible energy reporters.

Independent variable	Food cravings		
	Estimate (95% CI)	P value	N
Dependent variables			
<i>Body composition</i>			
BMI (kg/m ²) ^a	0.03 (0.003, 0.06)	0.03	135
Body fat (%) ^a	0.03 (−0.01, 0.07)	0.09	134
Waist circumference (cm) ^a	0.07 (0.02, 0.13)	0.01	135
<i>Cardiometabolic risk</i>			
LDL (mg/dL) ^{a, i}	0.04 (−0.10, 0.18)	0.59	128
HDL (mg/dL) ^{a, i}	−0.01 (−0.07, 0.06)	0.83	128
Total cholesterol:HDL ^{a, i}	0.001 (−0.003, 0.01)	0.51	128
Triglycerides (mg/dL) ^{a, i}	0.07 (−0.18, 0.33)	0.57	128
Glucose (mg/dL) ^{b, ii}	0.01 (−0.04, 0.06)	0.59	128
Glycated hemoglobin (%) ^{a, ii}	−0.002 (−0.004, 0.001)	0.11	127
Insulin (uIU/mL) ^a	0.004 (−0.03, 0.04)	0.83	128
C-reactive protein (mg/L) ^{a, iii}	−0.01 (−0.04, 0.02)	0.63	128
Systolic blood pressure (mmHg) ^{a, iv}	−0.03 (−0.10, 0.03)	0.28	135
Diastolic blood pressure (mmHg) ^{a, iv}	−0.04 (−0.09, 0.01)	0.15	135
Metabolic syndrome (%) ^c	1.00 (0.99, 1.01)	0.63	130

Significance set as P value less than 0.05, bolded P values indicate both significant model and dependent variable P values.

The continuous variable for food cravings was used.

Covariates: age, income, physical activity.

^a Data determined by robust linear regression, estimate reported as β (95% CI).

^b Data determined by quantile regression and reported as β (95% CI).

^c Data determined by logistic regression and reported as odds ratio (95% CI).

ⁱ Additional covariate of lipid medication.

ⁱⁱ Additional covariate of glycemic medication.

ⁱⁱⁱ Additional covariate of BMI.

^{iv} Additional covariate of blood pressure medication.

Table 6
Regressions predicting metabolic health by food cravings in the total sample.

Independent Variable	Food cravings		N
	Estimate (95% CI)	P value	
Dependent Variables			
<i>Body composition</i>			
BMI (kg/m ²) ^a	0.01 (−0.01, 0.04)	0.25	213
Body fat (%) ^a	0.01 (−0.0, 0.05)	0.54	209
Waist circumference (cm) ^a	0.05 (−0.002, 0.10)	0.06	213
<i>Cardiometabolic risk</i>			
LDL (mg/dL) ^{a, i}	0.05 (−0.09, 0.18)	0.50	199
HDL (mg/dL) ^{a, i}	−0.03 (−0.08, 0.02)	0.29	199
Total cholesterol:HDL ^{a, i}	0.003 (−0.0002, 0.006)	0.06	199
Triglycerides (mg/dL) ^{a, i}	0.16 (−0.03, 0.36)	0.10	199
Glucose (mg/dL) ^{b, ii}	0.01 (−0.03, 0.06)	0.57	199
Glycated hemoglobin (%) ^{a, ii}	−0.001 (−0.003, 0.001)	0.56	199
Insulin (uIU/mL) ^a	−0.01 (−0.04, 0.03)	0.70	200
C-reactive protein (mg/L) ^{a, iii}	0.0003 (−0.02, 0.02)	0.98	200
Systolic blood pressure (mmHg) ^{a, iv}	−0.02 (−0.07, 0.03)	0.47	213
Diastolic blood pressure (mmHg) ^{a, iv}	−0.01 (−0.05, 0.03)	0.49	213
Metabolic syndrome (%) ^c	1.005 (0.996, 1.01)	0.28	201

Significance set as P value less than 0.05, bolded P values indicate both significant model and dependent variable P values.

The continuous variable for food cravings was used.

Covariates: age, income, physical activity.

^a Data determined by robust linear regression, estimate reported as β (95% CI).

^b Data determined by quantile regression and reported as β (95% CI).

^c Data determined by logistic regression and reported as odds ratio (95% CI).

ⁱ Additional covariate of lipid medication.

ⁱⁱ Additional covariate of glycemic medication.

ⁱⁱⁱ Additional covariate of BMI.

^{iv} Additional covariate of blood pressure medication.

et al., 2011). Regression models were performed excluding missing data as applicable. The regression results are presented for the plausible energy reporters and were similar to models including the total sample (plausible and under-reporters of energy intake) unless otherwise stated. The assumptions for all regression models were evaluated, and transformations or the use of quantile regression were applied as needed. All models were adjusted for age, income, and physical activity. Medication usage was adjusted for in all models pertaining to metabolic health and body composition. BMI was included as a covariate in models evaluating c-reactive protein as the dependent variable. Total daily energy was included as a covariate in dietary intake models in which the dependent variable did not inherently adjust for energy; this included the dependent variables of diet diversity, glycemic load, eating frequency, daily eating interval, TRE, early energy eaters, and late night eaters. Results were similar to the unadjusted models unless otherwise specified.

The threshold for statistical significance was set as a P value less than 0.05. All analyses were performed with Stata statistical software version 15.1 (Stata Corp, College Station, TX).

3. Results

3.1. Demographics

Data in Table 1 are presented for the total sample (n = 229), plausible reporters (n = 146) and under-reporters (n = 83). The primary analysis was restricted to the plausible reporter subgroup. The mean age of the total sample was 40.9 ± 0.7 years with the majority being white, non-Hispanic, sedentary, pre-menopausal, and with a family income greater than \$40,000 per year. Approximately half of the total sample were also college educated and employed. The mean ± standard error FCQ-T score was 115.6 ± 2.4. Using the Goldberg cutoff for plausible energy intake, we estimated 36% of our sample was comprised of under-reporters (Black, 2000; Goldberg et al., 1991; Mendez et al., 2011). The remaining 64% of participants reporting plausible dietary intake had a lower BMI (P < 0.01), were older (P = 0.04), more sedentary (P = 0.02), and had higher food cravings scores (P < 0.01) compared to those who were under-reporting energy intake. Of note, we observed a positive association between energy intake and BMI (β = 0.003, 95% CI: 0.001, 0.004, P < 0.01), which was not significant in the total sample with the under-reporters included (β = 0.0001, 95% CI: −0.001, 0.002, P = 0.88).

3.2. Dietary intake of plausible energy reporters

The daily energy intake of plausible energy reporters was 2210 ± 40 kcals (mean ± standard error) with 46.7 ± 0.5% of energy from carbohydrates (14.7 ± 0.5% of which were from added sugar), 36.6 ± 0.4% of energy from fat, and 15.3 ± 0.2% of energy from protein (Table 2). Total daily energy (P = 0.02) and energy density (P = 0.049) were higher while diet quality was lower (P < 0.01) in those with high food cravings compared to those with low food cravings. A greater proportion of those with high food cravings were classified as late night eaters (P = 0.01) compared to those with low food cravings.

3.3. Dietary intake associations in plausible energy reporters

Higher food cravings were significantly associated with lower diet quality (P = 0.048), a higher eating frequency (P = 0.02), longer daily eating interval (P = 0.049), and lower odds of having TRE (P = 0.02) compared to lower food cravings (Table 3). When energy was included as a covariate the association between food cravings and eating frequency (β = 0.01, 95% CI: −0.001, 0.01, P = 0.07) and daily eating interval (β = 0.01, 95% CI: −0.001, 0.02, P = 0.09) were no longer significant (Supplemental Table 1).

3.4. Dietary intake associations in total sample

Food cravings were positively associated with daily energy intake ($P < 0.01$) and glycemic load ($P < 0.01$), but not diet quality ($P = 0.08$) (Table 4). The finding for glycemic load was no longer significant after adjusting for energy ($\beta = -0.04$, 95% CI: $-0.16, 0.08$, $P = 0.52$, Supplemental Table 1).

Consistent with plausible energy reporters, food cravings in the total sample were significantly associated with eating frequency ($P < 0.01$), daily eating interval ($P = 0.02$), and TRE pattern ($P < 0.01$) in the total sample (Table 4). These associations were no longer significant after adjusting for energy ($\beta = 0.003$, 95% CI: $-0.002, 0.008$, $P = 0.22$; $\beta = 0.003$, 95% CI: $-0.004, 0.01$, $P = 0.33$, odds ratio = 0.99, 95% CI: 0.98, 1.00, $P = 0.08$, respectively, Supplemental Table 1). Additionally, in the total sample but not in plausible reporters, we observed that food cravings increased the odds of being classified as a late night eater ($P < 0.01$), although this association was not significant when adjusted for energy intake (odds ratio = 1.01, 95% CI: 0.996, 1.02, $P = 0.20$, Supplemental Table 1).

3.5. Metabolic health of plausible energy reporters

Seventy-two percent of plausible reporters were classified as having obesity. Their mean BMI was 33.5 ± 0.4 kg/m², body fat was $40.5 \pm 0.7\%$, and waist circumference was 96.4 ± 0.9 cm (Table 2). Thirty-eight percent of plausible reporters were classified as having metabolic syndrome. Their mean serum triglyceride concentration was 123 ± 5 mg/dL, HDL concentration was 56 ± 1 mg/dL, and blood pressure was $114/77 \pm 1$ mmHg. Those with high food cravings had a greater c-reactive protein compared to those with low food cravings ($P = 0.049$).

3.6. Metabolic health associations in plausible energy reporters

Higher food cravings were associated with greater BMI ($P = 0.03$) and waist circumference ($P = 0.01$), but not with other measures of cardiometabolic risk (Table 5).

3.7. Metabolic health associations in the total sample

There were no statistically significant associations between food cravings and measures of metabolic health in models which included the total sample (Table 6).

4. Discussion

Findings from this study indicate that in the subset of plausible energy reporters, higher food cravings were associated with a greater BMI and waist circumference, higher eating frequency, longer daily eating interval, reduced likelihood of having a TRE pattern compared to non-TRE pattern, and a lower diet quality. The associations of higher food cravings with multiple unfavorable outcomes suggest that targeting the reduction of cravings is a promising approach for interventions aimed at weight loss and establishing healthy eating patterns.

Consistent with previous research, we found that higher food cravings were associated with lower diet quality (Kim, Choue, & Lim, 2016). However, our findings also identified no significant association between cravings and energy intake in adults with overweight or obesity. These data are inconsistent with prior reports in which food cravings were positively correlated with energy intake in adults with (Buscemi et al., 2017) and without obesity (Hill and Heaton-Brown, 1994). A key difference between this study and previous studies is that previous studies did not limit their analysis to plausible energy reporters. Indeed, we also found a positive association between food cravings and energy intake in models that were not constrained to plausible energy reporters, consistent with previously published

studies. The observed positive association between energy intake and BMI, which was not significant in the total sample with the under-reporters included underscores the importance of correcting for plausible reporting in future studies to better understand true associations between exposures and outcomes.

This study was conducted in adult beneficiaries of military personnel in whom the prevalence of overweight and obesity is similar to that of adults in the US civilian population. However, in addition to the usual stressors of daily life, military dependents face frequent relocation, spouse deployment, and other unique stressors that can affect both physical and psychological health (Tanofsky-Kraff et al., 2013). From a public health perspective, it is important to examine triggers that may increase eating or food-seeking behaviors in this population, especially in the context of added stress. This research could lead to tailored health and wellness interventions for military dependents, and could extend to other groups who also experience high levels of daily stress.

To our knowledge, this was the first study to examine the association between food cravings and dietary intake or metabolic health. A unique component of our study that contributes to its strength is that we addressed implausible energy intake. In our sample, over a third of participants were classified as under-reporters of energy intake. Inclusion of dietary data that is misreported has the high potential for altering the true association between eating behavior and diet or diet and health outcomes. Further, plausible energy reporters had higher cravings in comparison to those who underreported their energy intake. We cannot rule out the possibility that under-reporters may also underreport food cravings. However, to our knowledge, no other study has examined food craving in relation to plausible energy reporting, and we have best addressed this issue by presenting all results with and without the data for the under-reporters. An additional strength was that we examined the association between food cravings and dietary intake, both with and without adjusting for energy for dietary variables that did not inherently adjust for energy within their definition. These included: glycemic load, diet diversity, eating frequency, daily eating interval, TRE, early energy eaters, and late night eaters. Adjusting for total energy intake weakened the associations between food cravings and diet quality and eating patterns, confirming the strong influence of total energy intake. Previous studies examining food cravings and body weight related outcomes have used different tools for capturing food cravings. We used the food cravings “trait” questionnaire, the FCQ-T, which is not only a validated questionnaire with high test-re-test reliability for both populations with overweight and obesity, but is also a tool that measures the “stable trait” of food cravings that is not influenced by situational factors (Taylor, 2019).

Our finding of a positive association between food cravings and both BMI and waist circumference are consistent with previous studies (Abiles et al., 2010; Avitia et al., 2018; Chao, Grilo, White, & Sinha, 2014; Massicotte et al., 2019; White Marney et al., 2012) and add to the body of evidence suggesting food cravings are associated with higher BMI and waist circumference.

A limitation of this study is the lack of a positive association between cravings and indices of cardiometabolic risk which may, in part, be attributed to the mean values in our study sample falling within ranges considered as clinically optimal; we may have been limited in the heterogeneity required for detecting a statistical significance. Another limitation is the self-reported nature of the dietary intake data. As this was anticipated, we used the well-established 24 h dietary recall method which was administered by trained personnel, and additionally excluded implausible dietary energy reporters who, in our study sample, were entirely comprised of under-reporters (Subar et al., 2015). In addition, this secondary data analysis was limited to the available data collected for the primary weight loss and maintenance intervention, and the subsequent reduction for plausible reporting which may have limited the sample size needed to detect all possible differences. Further, this secondary data analysis used only baseline data and is descriptive in nature; our findings of associations are observations for

which we cannot ascertain a mechanistic role or infer causality.

5. Conclusions

Modifying eating behavior is an integral part of weight loss programs and our findings suggest that reduction in food cravings may have a positive impact on eating patterns, diet quality, and body composition in women with overweight or obesity. Further research should examine the role of food cravings and dietary intake and metabolic health in both men and women with and without risk factors for cardiometabolic disease.

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Disclosure

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Army or the Department of Defense. Any citations of commercial organizations and trade names in this report do not constitute an official Department of the Army endorsement of approval of the products or services of these organizations.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.appet.2020.104711>.

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Abstract Details:

Breakout Session: Military Family Frameworks for Readiness & Resilience

Category: Oral Presentation

Title: Interventions for sustainable weight loss in military families: The Healthy Families Healthy Forces (HF2) Study

Abstract:

Importance: There is an urgent need for effective, scalable weight loss interventions that can be widely disseminated. In addition consideration for military lifestyle-specific challenges is also critical for successful implementation and sustainability in military families.

Objective: To evaluate the effectiveness of a novel lifestyle intervention, Healthy Weight for Living (HWL), compared with a modified version of the traditional Diabetes Prevention Program (m-DPP) over 12 months.

Design, Setting, and Participants: Parallel-group randomized clinical trial allocating enrollees to HWL or m-DPP. Participants were adult dependents of active duty or retired military service members with overweight or obesity (N=121 HWL, N=117 m-DPP) recruited in five U.S. states.

Interventions: HWL and m-DPP were implemented primarily by videoconference as group programs by trained counselors, and were provided cost-free. HWL was based on a new health behavior change model emphasizing reducing hunger, increasing satiety and forging healthy food preferences, and was implemented without a requirement for daily food and exercise logging. m-DPP increased counselor contact time compared to the traditional program.

Main Outcomes and Measures: The primary outcome was weight change. Additional outcomes were changes in cardiometabolic risk factors, self-reported health, adherence metrics, and biobehavioral variables. Modified intention-to-treat and preplanned completers analyses were performed using linear mixed models.

Results: There was no significant difference in participant retention between groups (72% for HWL versus 66% for m-DPP at 12 months, P=0.3319). Changes in energy intake and duration of moderate+heavy physical activity were also not different between groups, but dietary composition changes were greater in HWL than m-DPP (P=0.001). Weight loss at 12-months was 7.8 kg (95% CI 6.2, 9.4) for HWL and 6.9 kg (5.1, 8.6) for m-DPP (P=0.43); 38% of HWL and 31% of m-DPP participants, had ≥10% weight loss (P=0.4058). Both groups had improvements in systolic and diastolic blood pressure, LDL-cholesterol and triglycerides, general health, sleep and mood, and between-group differences were not significant. In addition, HWL participants had greater improvements in fasting glucose than m-DPP. Post-hoc calculations estimated average annual health care cost savings across groups at \$1,600/person on average.

Conclusions and Relevance: Both groups in this diverse population of adult military dependents achieved clinically beneficial mean weight loss with cardiometabolic benefits. In addition, HWL achieved results that were at least equivalent to m-DPP without requiring burdensome daily food and activity logging. These results open up new opportunities for behavioral treatment of obesity, including offering multiple behavioral approaches in tandem to increase population reach.

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Disclaimer: The views expressed in this abstract are those of the authors and do not reflect the official policy of the Department of Army, Department of Defense, or the U.S. Government.

Learning Objectives

1. Describe similarities and unique features of interventions used in this clinical trial.
2. Recall the key programmatic components necessary for program adherence and retention.
3. Explain the effectiveness of the interventions in improving health-related outcomes.

Submit for Young Investigators Competition? No

May We Publish Abstract on the MHSRS website? No

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Abstract Details:

Breakout Session: Advances in Nutrition & Microbiome for Support in Military Operations

Category: Oral Presentation

Title: Food Cravings: Associations with Dietary Intake and Metabolic Health

Abstract:

Food cravings are a desire for specific foods which, if uncontrolled may lead to excess energy intake and weight gain. However, information on the relation between food cravings, dietary intake, and indices of metabolic health is limited. This study used baseline data from females (n=229; aged 40.9 ± 0.7 years; BMI 34.7 ± 6.4 kg/m²) who were dependents of active duty and retired military personnel, and enrolled in the Healthy Families Healthy Forces weight loss and maintenance study. Measures obtained included food cravings using the Food Craving Questionnaire-Trait (which provides a habitual and stable measure of food cravings), dietary composition and eating patterns from three 24-hour dietary recalls and the Stanford 7-day Physical Activity Recall, body composition from anthropometric measures, cardiometabolic risk factors from blood measures, and demographic information from questionnaires. Linear, quantile, or logistic regression models were used to examine the association of total food craving scores on dietary intake, and indices of metabolic health. In individuals reporting plausible energy intake (n=146; 2210 ± kcal/day) higher food craving scores were associated with a lower diet quality (P<0.05), higher eating frequency (P=0.02), longer daily eating interval (P<0.05), and a lower likelihood of following a time restricted eating pattern (P=0.02). Food cravings were also positively associated with BMI (P=0.03) and waist circumference (P=0.01), but not with measures of cardiometabolic risk (LDL, HDL, total cholesterol:HDL, triglycerides, glucose, glycated hemoglobin, insulin and C-reactive protein concentrations, blood pressure, metabolic syndrome). Our findings of significant associations of food cravings with lower diet quality, poor eating patterns, and unfavorable body composition strongly support efforts of targeting cravings in behavioral programs for weight management

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Learning Objectives

1. Clarify how food cravings can impact dietary habits and weight management efforts.
2. Discuss the tool used to measure food cravings in current study.
3. Explain the implications of food cravings on diet quality and health-related outcomes.

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May We Publish Abstract on the MHSRS website? Yes

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Abstract Details:

Breakout Session: Advances in Nutrition & Microbiome for Support in Military Operations

Category: Oral Presentation

Title: Eating Timing: Associations with Dietary Intake and Metabolic Health

Abstract:

Background. Emerging research indicates that eating timing may impact dietary intake and metabolic health. However, studies to date have not examined the association of multiple measures of eating timing on both dietary intake and metabolic health in adults with overweight and obesity.

Objective. To examine the association of multiple measures of eating timing on dietary intake (dietary composition, diet quality, and eating frequency) and metabolic health (body composition and cardiometabolic risk).

Design. Cross-sectional analysis of baseline data from a weight loss and maintenance intervention in adult dependents of active duty and retired military personnel collected May 2015 to January 2018 at approved military installations in Massachusetts, Connecticut, New York, Colorado, and Kentucky.

Participants/setting. Participants were women with overweight or obesity (mean $\pm$ standard error, BMI: 33.5 $\pm$ 0.4 kg/m², age: 41.8 $\pm$ 0.9 years).

Main predictor measures. Eating timing variables examined included daily eating interval (time between first and last eating occasion), time restricted eating (TRE, $\leq$ 11 hours daily eating interval), early energy eaters (eating $\geq$ 60% of energy during the first half of time awake), and bedtime eaters (eating within 2 hours of bed).

Statistical analysis. The main analysis was limited to those reporting plausible energy intake (64% of total sample, N=146). Linear, quantile or logistic regression models were used to determine the association of eating timing with measures of dietary intake and metabolic health.

Results. In individuals reporting plausible energy intake, each additional one hour in daily eating interval was associated with 53 kcal higher energy intake, higher glycemic load, eating frequency, and waist circumference (P<0.05 for all). Significant associations were observed for: TRE and a lower energy intake, glycemic load, and eating frequency; early energy eating and higher carbohydrate intake; late night eating and a higher energy intake, glycemic load, and eating frequency.

Conclusions. These findings support the mechanistic targeting of eating timing in behavioral interventions aimed at improving dietary intake and body composition.

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Learning Objectives

1. Discuss the impact of meal timing on dietary intake and metabolic health.
2. Explain meal timing related behaviors observed among military beneficiaries.
3. Describe the use of meal timing as a mechanism to improve meal quality and metabolic health.

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May We Publish Abstract on the MHSRS website? Yes