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Dissemination of the Look AHEAD Lifestyle Intervention in the United States Air Force: Study Rationale, Design and Methods

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Abstract

Despite an increase in overweight and obesity similar to the civilian population, there have been few randomized controlled trials examining behavioral weight management interventions in the military settings. This paper describes the design, intervention development and analysis plan of the Fit Blue study, a randomized controlled behavioral weight loss trial taking place in the United States Air Force. This study compares two adapted versions of the efficacious Look AHEAD Intensive Lifestyle Intervention (ILI), a counselor-initiated condition and a self-paced condition. Also described are the unique steps required when conducting military-based health promotion research and adaptations made to the Look AHEAD intervention to accommodate the military environment. To our knowledge, this is the first translation of the Look AHEAD ILI in the military setting and one of the first translations of the ILI in general. If successful, this intervention could be disseminated to the entire U.S. Military as this project is designed to overcome the barriers and utilize the facilitators for weight loss that are unique to a military population. Programs validated in military populations can have a major public health impact given that with 1.4 million active duty personnel, the Department of Defense is the nation's largest employer. However, while this intervention is designed for a military population and there are unique aspects of the military that may enhance weight loss interventions, the diversity of the study population should help inform obesity efforts in both civilian and military settings.

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Introduction

Considerable attention has been given to the alarming increase in overweight and obesity in the U.S. population [1]. However, there is a common misconception that U.S. military personnel are fit, lean, and healthy because of the military lifestyle and its emphasis on health promotion, inferring that the military has somehow escaped the civilian obesity epidemic. Unfortunately, this is not the case: 51% of military personnel are overweight and 12% are obese [2].

There are significant costs of overweight and obesity in the military. Excess weight is associated with approximately $1.1 billion dollars each year in military medical costs [3]. Furthermore, excess weight and inadequate fitness can prevent promotion or even lead to discharge from military service. Every military member has an annual performance report that requires passing a periodic fitness test. If an individual is discharged due to fitness test failures, the military must then recruit and train a replacement at a cost of about $50,000 per person; the military currently spends more than $60 million a year due to failed first-term enlistees [3], some of which are due to fitness test failures. In addition, for military personnel who choose the military career rather than a term of service, discharge becomes a dire personal consequence; individuals who are discharged lose their job, all medical and other benefits, and all pension benefits (unless they have already put in at least 20 years of service). There are few professions that have such severe potential consequences related to excess weight and inadequate fitness.

Nonetheless, given the challenges of conducting research in the military setting (e.g., high mobility, security concerns), there have been few randomized trials examining behavioral weight management programs in this setting [4, 5]. Hunter and colleagues [4] utilized an Internet-based program that was primarily focused on weight gain prevention. Gambera et al. [5] compared an exercise-focused intervention with an exercise and diet-focused intervention, in order to reduce cardiovascular risk. Weight loss in both of these previous programs has been minimal (i.e., less than 3 kg) [4, 5]. Thus, given the current prevalence of overweight and obesity in the military, it is important to examine the impact of an intervention focused on weight loss. The highly efficacious Look AHEAD Intensive Lifestyle Intervention (ILI) [6–8] offers significant promise for long-term weight management in many populations, including a military population.

This paper describes the design, intervention development and analysis plan of a randomized controlled behavioral weight loss trial taking place in the United States Air Force. Our study compares an adapted version of the ILI intervention (i.e., the Counselor-Initiated condition) with a self-paced version of the same intervention. To our knowledge, this is the first translation of the Look AHEAD ILI in the military setting and one of the first translations of the ILI in general.

Materials and Methods

Study Design

The initial year of the current project was dedicated to the translation of the Look AHEAD ILI to accommodate the military lifestyle, followed by a two-group randomized pilot study (which followed the participants for 4 months). The two-group randomized full trial started in the second year (in which the participants will be followed for one year). The treatment groups vary in the degree of intervention intensity and the amount that the participants need to self-initiate the treatment. The primary dependent variable is weight loss at 12 months. Participants are randomized at the individual level, using a block randomization scheme of block size 4 to assign the participants with a 1:1 ratio to the Counselor-Initiated intervention and the Self-Paced intervention. All study procedures were determined to be in compliance with the ethical research standards set by the Institutional Review Board of the Wilford Hall Ambulatory Surgical Center in San Antonio, TX.

Intervention Development

There are a number of unique steps required to conduct this military-based health promotion research. First, we needed to accomplish the military approval process (i.e., obtain approval from a military institutional review board and establish a Cooperative Research and Development Agreement, which is a contractual agreement that defines the relationship and itemizes what resources the Air Force will provide and what resources the research team will provide, and receive the Commander's approval to conduct research with Airmen). Second, we had to carefully design the intervention within the confines of the Air Force operational mission, being sensitive to long work hours and the unique military requirements. A unique consideration is the focus on improving military readiness. (Readiness, the ability to quickly mobilize for national defense, is critical, especially as the time or place of the next crisis is never certain [9].)

In addition, there were other aspects of the military environment that had implications for how the intervention could be delivered. Specifically, our intervention had to utilize a distance-based modality because of the high mobility of military personnel. While they have a primary duty station, they are literally moved all over the world through what is called Temporary Duty assignments, Combat Deployments or Permanent Changes of Station, sometimes with little warning. Additionally, for security reasons, military computers have limited access to many Internet sites. Military personnel do have access to email, although emails that come from systems other than the U.S. military domain name system (i.e., .mil) are typically blocked as spam. However, through years of cooperative collaboration with the U.S. Air Force, our research staff are granted e-mail accounts within the ".mil" system. For these reasons, we utilized a one-on-one phone- and email-based modality for the intervention delivery, rather than the group-based in-person delivery of the Look AHEAD intervention.

We conducted one 90-minute formative group session with active duty military personnel at Lackland Air Force Base (AFB). We recruited participants by an email announcement to a listserv specific to the base and through an in-person announcement in a nutrition and

weight focused class for those who have failed their fitness test. The formative session was facilitated by one of the investigators, who is a trained focus group facilitator, using a series of prepared semi-structured open-ended questions such as “What images should we consider as we are developing a logo for this project?”. Follow-up probe questions were used to expand the discussion. We had three research staff members who took detailed notes during the session including direct quotes. Immediately after the session, three investigators and the three research staff members/note-takers reviewed the notes to determine and to resolve areas of confusion or disagreement. While we did not conduct a formal qualitative analysis of the data, we present, below, what we learned from this formative session that helped determined the design of the study.

First, we discussed our plan to replicate the Look AHEAD design as closely as possible by randomizing participants to either the Look Ahead Intensive Lifestyle Intervention or a Diet and Physical Activity Education condition, an active information group that stresses nutrition, exercise and support during three sessions over a 12-month period (similar to the Diet Support and Education control group in the original Look AHEAD trial). Given the pressures to pass their fitness tests and maintain readiness, we knew that randomization to the comparison condition would be a “hard sell,” which is why we proposed the 4:1 ratio. However, the participants stated that they would be unwilling to accept even a 20% chance of being randomized to the comparison intervention as originally proposed. Instead, the participants suggested the development of a self-paced intervention, by which they could avail themselves of intervention resources (e.g., lesson materials, telephone contact with interventionists, feedback on self-monitoring) if they decided that these would be helpful or if weight loss challenges arose. The research team has experience utilizing similar “reactive vs. proactive” intervention designs with tobacco quitlines, [10–12]. While reactive quitlines are typically less effective than proactive quitlines [13, 14], a self-paced intervention could be a cost-effective option for future military implementation due to lower interventionist time costs. For these reasons, we designed a self-paced weight loss intervention as the comparison condition.

The participants also provided their feedback on the program name and logo. They chose “Fit Blue” as the program name, as blue is the official Air Force color. They were adamant that the program name should not be an acronym, as they stated that acronyms are overdone in their military environment. They provided guidance for the development of the study logo in that they felt that it should not include a picture of a “fake” (i.e., model) Airmen, instead the logo should contain a stick figure.

The participants in the formative session also provided guidance to the research team regarding meal replacements. They stated their concern about having enough “volume” to be satisfying. Some participants indicated their preference for shakes, specifically powdered shake mixes as they felt these tasted better, were more convenient, and offered flexibility (e.g., adding fruit). Other participants indicated that shakes would not work for them—that they wanted “something to chew,” such as oatmeal. There were also participants who expressed concern about processed food that would be present in any meal replacement, and indicated that they would want to use meal plans instead of meal replacements. Finally, they

indicated that it was crucial to have a portion of the program where meal replacements were not provided, to allow for a transition to “real food”.

The approval process and protocol and material development took approximately 11 months. Next, we conducted a 4-month pilot study (n=20) to preliminarily evaluate the materials and procedures developed, prior to launching the full study. The participants identified as 70% female and 20% Hispanic. Participants were racially-diverse: 30% African American, 10% Asian, 5% Native American, and 55% Caucasian. Twenty percent were college graduates. The majority of participants (65%) were married. Participants ranged in age from 24 to 48 years old. As the goal of the pilot study was to determine feasibility of the protocol, the pilot study was not powered to examine weight loss differences by condition.

Participants

Recruitment for the full study began in December 2013 and continues through September 2015. Participants in this study are active duty military personnel stationed at Lackland AFB in San Antonio, Texas. To be eligible for the study, participants must have at least one year left of their anticipated time at Lackland AFB, in order to maximize the likelihood that the participant would be available for in-person data collection at 4- and 12-months follow-up. They must also be 18 years of age or older, have a Body Mass Index (BMI) greater than or equal to 25.0 kg/m^2, have computer and email access, and obtain clearance by a healthcare provider for participation in the study.

Exclusion criteria include: medical conditions that would impact participation in a weight loss study that includes dietary changes and physical activity. Specific medical conditions that lead to exclusion are: uncontrolled hypertension; a disability or condition that would limit regular aerobic exercise (e.g., severe bronchitis or emphysema); a history of cerebral, coronary or peripheral vascular disease or uncontrolled cardiac arrhythmia; uncontrolled congestive heart failure in the past 12 months; a history of significant kidney or liver disease; presence of uncontrolled thyroid disease or pheochromocytoma; a malignancy (other than non-melanoma skin cancer) in the last 5 years; presence of diabetes mellitus treated with a medication that could cause hypoglycemia; presence of unstable emotional or psychiatric condition; current use of medication that influences weight; current pregnancy, a child birth within the last 6 months, or planning to become pregnant during the study period; and a history of bariatric surgery or significant recent weight loss (i.e., greater than 10 pounds in the past 3 months). Potential participants must not have had more than one failure of the military-proctored physical fitness test in the past 12 months, as fitness-related discharge could occur among these individuals and follow-up data collection would become extremely difficult. In addition, participants could be excluded or temporarily excluded for any medical condition or medication expected to affect weight change from the study and any other medical, psychiatric, or behavioral factors that in the judgment of the screening physician may interfere with study participation or the ability to follow the intervention protocol. Finally, only one member of the same household is eligible to participate. Some potential participants have temporary conditions that limit certain types of physical activity; these participants are not excluded if they are able to perform some type of aerobic activity

(e.g., swimming). The total sample size will be 204 participants (see power calculation below).

Recruitment, Screening and Randomization

Potential participants for the Fit Blue program are recruited through the use of posters, electronic bulletins, presentations to various groups on base, emails, newspaper advertisements, and word-of-mouth. Potential participants are able to learn more about the study by phone or a web-based self-screener. Study staff conduct a subsequent phone screener to determine if the individual meets initial eligibility criteria. If the person meets the preliminary eligibility criteria and continues to be interested in the study, they are asked to complete an in-person screening visit.

At the screening visit, informed consent is obtained and BMI eligibility is confirmed. Individuals are also asked to complete various forms and questionnaires regarding demographic characteristics; contact information; quality of life; dietary intake, physical activity, and weight-related attitudes and behaviors (as detailed later in the Assessment section). Potential participants are then asked to complete a behavioral run-in consisting of two components—a) one week of dietary and physical activity self-monitoring using the Lose It!™ website/application and b) obtaining a letter from their healthcare provider approving participation in the intervention. They are then scheduled for an in-person baseline visit in one to two weeks.

At the randomization visit, study staff determine whether the potential participant successfully completed both components of the behavioral run-in. Those who fail to complete either element are given one more opportunity to complete the tasks. Those who fail to successfully complete a behavior run-in are disqualified from the study. At baseline, physical measurements (i.e., abdominal circumference, resting blood pressure and resting heart rate) are also conducted. Participants then are randomized at the individual level, if the behavioral run-in was completed and there are not health-related concerns that would prevent them participating in the study. The condition assignment is accomplished via computerized block design. Once the random assignment is completed, study staff carries out the appropriate orientation to the intervention condition.

Common Goals (Counselor-Initiated and Self Paced Conditions)—Consistent with the goals in the ILI [7], all participants are encouraged to aim for a weight loss of 10% or more, as this degree of weight loss is associated with positive health benefits [15]. Each participant’s personalized weight loss goal is posted on their study web portal. Participants are encouraged to lose 1 to 2 pounds per week. In order to facilitate achieving the weight goals, participants receive personalized dietary goals (i.e., calorie and fat goals) based on their baseline weight, at their in-person baseline visit and discuss their progress toward these goals during phone sessions. Participants with a screening weight below 175 pounds are assigned goals of 1200–1300 calories and 40–43 fat grams (i.e., 30% of calories from fat) per day. Participants with a baseline weight of 175–215 pounds are assigned goals of 1500–1600 calories and 50–53 fat grams per day. Participants with a baseline weight of greater than 215 pounds are assigned goals of 1800–1900 calories and 60–63 fat grams per day.

These personalized calorie and fat goals are also displayed on the participants' LoseIt! ™ account.

Taking into account the baseline amount of physical activity for each participant at the beginning of the program, participants are asked to gradually increase their cardiorespiratory (aerobic) exercise to five days or more per week at a moderate to vigorous intensity level (each bout lasting a minimum of 10 minutes), until they reach a total of 225–250 minutes per week. A written personalized exercise plan is developed based on the self-reported amount of exercise (from the GPAQ) and given to participants at their in-person baseline visit. Upon reaching the physical activity goal of 225–250 minutes per week, they are asked to maintain this level of physical activity, in order to optimize weight maintenance. The personalized incremental exercise plan is posted on their study web portal.

Intervention Conditions

We are comparing two intervention conditions that vary in the degree of intervention intensity and the amount of treatment self-initiation required.

Elements of the Counselor-Initiated Condition—Participants randomized to this condition are offered 28 one-on-one telephone sessions over a 12 month period by an interventionist trained in behavior change skills (e.g., goal setting, problem solving, relapse prevention, stimulus control) and motivational interviewing techniques. The addition of motivational interviewing has been shown to be effective in improving behavioral weight control outcomes [16]. The telephone calls are designed to provide strategies to help participants with weight loss. Participants receive a call once a week for the first 16 weeks (16 calls), every other week for the next 16 weeks (8 calls), and monthly for the remainder of the treatment (4 calls). For each intervention session, participants have a paper copy of the lesson material (adapted from the Look AHEAD ILI); they also have access to the lesson materials on their personalized password-protected study website.

Because self-monitoring has been shown to be significantly associated with weight loss [17–23], participants are asked to monitor food intake, physical activity and weight daily. Participants are asked to use the Lose It!™ app/website, which, with participant permission, study staff are able to access in order to retrieve participants' food and physical activity information. Weight monitoring is facilitated by the use of the BodyTrace ™ e-scale. Each participant is provided this scale, which uploads their daily weight to a secure website, also accessible by interventionist. Participants receive interventionist feedback on dietary, physical activity and weight self-monitoring through e-mail, at the same frequency as the telephone sessions (weekly, then biweekly, then monthly). Participants are also able to view a personalized graph of their weight trajectory over time on the study website.

To achieve study weight loss, calorie and fat goals [24], meal replacements (i.e., Healthy Choice ™ or Marie Callender ™ meals, Better Oats ™ oatmeal, powdered Slim-Fast ™) and snacks (i.e., single serving Smart Pop ™ popcorn) are provided to participants. Participants are encouraged to replace two meals and a snack with meal replacements for the first 4 months of the intervention. During months 5–8 of the study, participants are encouraged to replace one meal with a meal replacement and then have two meals per day of conventional

foods (or purchase their own meal replacements). During months 9–12 of the study, participants transition to eating all meals composed of conventional foods.

Participants are also provided detailed meal plans (for all meals) with common foods that are designed to control portion size and calories; participants are encouraged to use the meal plans if they elect not to use the meal replacements and for their meals with conventional foods. Participants in this condition also have access to the study's Toolbox, which includes additional treatment options for those who wish to take advantage of them. When particular challenges arise, interventionists recommend certain items from the Toolbox to participants, including food scales, exercise videos, resource books and cookbooks. These items can be checked out, but must be returned prior to the completion of the study (as the Air Force limits the overall value of items that are given to research participants).

Finally, consistent with the Look AHEAD ILI, there are four challenges presented to these participants, which are designed to increase participant motivation and provide a specific goal during the twelve-month study period. The four challenges each take place over a four-week period and are: *Log It to Lose It* (i.e., self-monitoring weight, food intake, and exercise during weeks 5–8), *Step It Up* (i.e., using a pedometer to increase daily steps during weeks 17–20), *Weigh to Win* (i.e., self-monitoring weight during weeks 31–34) and *Let's Get Physical* (i.e., increasing or maintaining levels of moderate to vigorous exercise during weeks 43–46). Participants who successfully complete the challenges are given a small prize (i.e., a t-shirt, reflective shoe laces, a blender bottle, and a reflective arm/ankle band).

Elements of the Self-Paced Condition—Participants randomized to this condition receive a handout (upon randomization at the baseline visit) that lists the resources available to them during the 12-month intervention. These resources include individual telephone sessions when the participant calls the study phone line (from 8AM-5PM on Monday to Friday) and requests a session with a counselor. Participants may receive up to 28 telephone sessions over the 12-month study period by trained interventionists. Participants have access to the lesson materials (that are identical to those provided to the Counselor-Initiated participants) through their personalized password-protected study website.

Participants are asked to monitor food intake, physical activity and weight daily using the Lose It!™ application/website and the BodyTrace ™ e-scale. Participants receive interventionist feedback, by request, on dietary, physical activity, and weight self-monitoring through e-mail. They are also able to view their personalized graph of their weight trajectory over time on the study website.

Participants in the self-paced condition are encouraged to follow the meal plans, which can be accessed on the study website. They are also encouraged to purchase their own meal replacements if they feel that this strategy would be helpful for them.

Assessment Components

All measures are completed at baseline, and at 4-month and 12-month follow-up. Participants receive a pedometer and a water bottle for participating in the 4-month and 12-month data collection visits, respectively.

Biological and Physical Measures—Weight change is the primary outcome measure. Weight (in kilograms) is measured in street clothes, without shoes, on a calibrated scale (Tanita BWB-800S). Height (in centimeters) is measured, without shoes, using a wall-mounted stadiometer (The Standard Stadiometer ™, Perspective Enterprises). BMI is calculated from these measures. As an indicator of subcutaneous and visceral fat in the abdominal region and a component of the Air Force fitness test, abdominal circumference is measured using a non-distensible measuring tape and standard protocols for positioning [25]. Resting blood pressure is measured using an Omron HEM-907XL IntelliSense Digital Blood Pressure Monitor and is represented as the mean of two measurements in which systolic blood pressure differed by 10 mm Hg or less and diastolic blood pressure differed by 6 mm Hg or less. Resting heart rate is measured using an Omron Digital Blood Pressure Monitor. All measures are taken in duplicate.

Physical activity, diet, and other behavioral factors—The Global Physical Activity Questionnaire (GPAQ), which has established reliability and validity [26], is used to capture current levels of physical activity of various types and the amount of sedentary behavior [27], The GPAQ provides a measure of adherence to the physical activity protocol. The Brief Beverage Intake Questionnaire, a 15-item assessment, assesses the types and amounts of beverage intake over the past month [28, 29]. The Multifactor Screener provides approximate intake of fruits and vegetables, percentage energy from fat, and fiber [30]. Finally, a behavioral questionnaire is used to capture attitudes and behaviors associated with weighing (from [19]), dietary behaviors (adapted from Look AHEAD questionnaires), sleep behaviors, and motivations for weight loss.

Fitness—Air Force Fitness Test scores (i.e., abdominal circumference, push-ups, sit-ups, and a 1.5 mile timed run) will be obtained for all participants, for the most recent fitness test completed prior to starting the intervention and the fitness tests completed during and/or immediately after the intervention. Airmen receive age and gender-specific composite scores based on the component scores. Maximum scores for each component are: 60 points for aerobic, 20 points for body composition, 10 points for push-up and 10 points for sit-ups; 100 total points possible. To pass the fitness test, members must achieve a minimum of 75 points for the composite score as well as meet minimum component standards. If they achieve a composite score of 90 or greater with all minimum component standards met, they receive an “Excellent” score and must complete the test again in one year. If they score between 75 and 90, they must retest in six months. If they score less than 75, they fail the fitness test, must retest in 90 days, and with repeated failures, could be subject to administrative action, including discharge from the military.

Program Evaluation—At the 12-month follow-up visit only, participants complete quantitative and qualitative questions (developed for this trial) about their perspectives on the helpfulness of various program components (e.g., phone sessions, lesson materials, dietary and exercise self-monitoring, electronic scale, meal replacements, meal plans, emailed feedback from the interventionists, study website, challenges) and recommendations for program modifications (e.g., “What recommendations would you make for changes in

the program to help it be better?," "What had you hoped to have covered in the program that was not covered?").

Measures of Treatment Adherence—Frequency of daily self-weighing, frequency of daily dietary/physical activity self-monitoring, achievement of weekly calorie, fat, and exercise goals, meal replacement consumption, and session participation is also being systematically collected by the interventionists, as measures of intervention dose. Daily self-weighing behavior and daily dietary/physical activity self-monitoring behavior is coded as present or absent. Achievement of weekly calorie, fat, and exercise goals is coded as having achieved or not achieved each goal per week. The number of meal replacements consumed is totaled per week. The total number of sessions attended is calculated (0–28 possible).

Health Related Quality of Life—Consistent with the measure utilized in the Look AHEAD trial, the Health Utility Index questionnaire [31, 32] will be used to assess changes in quality of life associated with weight reduction, as well as to calculate quality adjusted life years for use in cost-effectiveness analyses.

Program Costs—Cost of materials and interventionist time incurred in the delivery of treatment for each condition is being collected. Materials include meal replacements, treatment materials, scales, challenge prizes, data collection incentives at 4- and 12-months, and measuring cups and spoons. Interventionist time includes telephone session facilitation and review of self-monitoring journals. Personnel costs will be calculated based on the average hourly wage (with benefits) of the actual interventionists. We will also calculate "infrastructure" costs for the website development and maintenance, phone service, rent, and utilities. Research costs will be excluded from the economic evaluation.

Study Informatics—All data collection, processing and management, as well as electronic intervention information dissemination for the study, occurs via a standards-based informatics system. All of the informatics structures within this system operate in a true client/server network environment and, as such, exceed expected data security benchmarks. Only study personnel with appropriate access privileges may gain access to informatics system via a secured VPN connection by authenticating to the UTHSC network through the University Active Directory. Within the informatics system Cardiff TeleForm Workgroup provides customized data collection at screening, baseline, four-month, and 12-month visits on scannable paper forms specially designed to facilitate automated data entry. Once complete, each form is scanned at the study site, encrypted, and transmitted to the University of Tennessee Health Science Center server in Memphis, TN, for processing. FileMaker Pro, the end-user application interface for data handling and management, automatically receives the processed data and makes it available to study staff for quality assurance checks. Additionally, study staff perform direct entry of process data (self-monitoring of weight, diet, physical activity, achievement of calorie, fat, and exercise goals, meal replacement consumption, and attendance) for each session. Finally, Oracle provides the robust, enterprise-level database engine for the content-managed study website hosted by Apache Web Server.

Study Website

The password protected study website includes features for both prospective and enrolled participants (in both the Counselor-Initiated and the Self-Paced conditions). Prospective participants are able to learn more about the study and review the initial eligibility criteria. Enrolled participants are given a unique username and password to log onto their personalized study web portal and access lesson materials and weight loss tools (e.g., BMI calculator, target heart rate calculator, portion size guide, list of healthy cookbooks, meal plans), see frequently asked questions and their answers, view a personalized weight chart (data are transmitted from Body Trace ™), review their calorie, fat, and exercise goals, access Lose It!™ for dietary and physical activity self-monitoring, and see upcoming scheduled events (i.e., phone session appointments, data collection visits).

Interventionists and Treatment Fidelity—A critical part of any military intervention is the ability of the interventionist to understand the culture and the language of the participants. We have addressed this with our research staff by ensuring that we have interventionists who have retired from the military and are available to educate and answer any questions our non-military staff might have. The research staff are recruited based on their military experience as well as other characteristics; the interventionists have bachelor's or master's degrees in diverse areas of study (i.e., social work, counseling/psychology, child and family development, nursing, justice administration).

Several methods are being employed to ensure that the interventions are implemented as designed. Detailed manuals and counselor guides have been created that all interventionists are required to read and review. All interventionists complete an intensive training on the study protocol and motivational interviewing. Interventionists are then trained and certified in providing both counselor-initiated and self-paced intervention sessions, through a structured process of conducting practice sessions with other research staff and audio-recording the sessions. One of the study investigators reviews the audiofiles, provides corrective feedback, and determines whether or not the interventionist successfully conducted at least two intervention sessions, prior to "certification". As ongoing training, the interventionists participate, every week, in a one-hour supervision session and a one-hour motivational interviewing training. Fifteen percent of Counselor-Initiated sessions are randomly selected, recorded (assuming the participant gives consent) and reviewed to verify that the protocol is being implemented correctly. Feedback is provided to the counselor on every session reviewed. As the Self-Paced sessions may or may not occur (depending upon the participant's initiative to call for a session), it was not possible to randomly select these sessions.

Counselors also receive periodic training regarding email feedback to participants. Practice emails are submitted and discussed in a group setting to ensure positive and constructive feedback is provided, share ideas, and discuss specific challenges that participants are encountering.

Statistical Analysis and Power Calculation

For statistical power analysis, we used the expected percentage of weight difference between baseline and 12-month assessment for the Counselor-Initiated and the Self-Paced conditions. Based on the Look AHEAD trial weight losses of 8.6% [8], we are estimating a mean weight loss of 8% among the participants in the Counselor-Initiated condition. Our estimated mean weight loss for the Self-Paced condition is 4%, based on the 6-month weight loss results from the Steinberg and colleagues [19] trial using the Body Trace ™ escale (6.55% weight loss). While Steinberg et al. provided the e-scale with a recommendation to weigh daily, access to the weight trajectory graph, calorie and physical activity goals, meal plans and lesson materials like our proposed Self-Paced condition, the participants in the Steinberg et al. study also received weekly personalized feedback. Since the participants in the Self-Paced condition receive feedback only by request and thus may not engage to the same degree in self-weighing or in other aspects of the Self-Paced condition, we conservatively estimated their mean weight loss at 4%. Assuming that the average weight loss will be 8% and 4% in the Counselor-Initiated and Self-Paced arms, respectively, and a standard deviation of 8%, to achieve 90% power with 5% Type-1 error rate, we are accruing 204 participants, who are randomized equally to each arm of the study. We used a 15% attrition rate considering that participants may change their duty station or may be deployed, which may potentially decrease the likelihood of follow-up. This rate of attrition is in line with other weight management trials in the military (17% at 6 months [4] and 0% at 3 months [5]).

The primary data analysis will adhere to the intention-to-treat principle and in the final analyses, participants will be categorized according to their initial randomization, regardless of adherence. We will be using the baseline weight as a covariate in the final primary analysis of covariance model where we compare the two conditions in terms of the percentage of weight loss. We also plan to carry out secondary analyses to investigate the efficacy of the intervention in subgroups of participants based on demographic characteristics of interest. We will also evaluate the impact of adherence on outcome using the process data collected. Treatment costs will be combined with quality adjusted life years (QALYs) calculated from the Health Utilities Index questionnaires to examine overall levels of cost effectiveness of the two treatment arms (cost per QALY) as well as the incremental cost effectiveness of the Counselor-Initiated versus the Self-Paced intervention (change in cost/change in QALYs). Since one major objective of this program is to reduce involuntary military discharge and the associated training costs, we will also compare the program's treatment costs with savings associated with reduced discharge (cost savings analysis).

Discussion

This paper describes the design, interventions, assessments, and analytic plan for the first trial to test the efficacy of a Look AHEAD ILI translation in the U.S. Military. While other behavioral weight management programs, such as the Diabetes Prevention Program (DPP), have been successfully translated [22, 33–35], the Look AHEAD ILI, while based on DPP, is a more contemporary weight loss program based on the latest research, including the use of more structured dietary strategies from the outset including meal replacements, structured

menus, and combining fat and calorie self-monitoring [36]. Perhaps due to these modifications, the Look AHEAD ILI produced superior weight loss relative to DPP [36]. For these reasons, an examination of the translation of the Look AHEAD ILI in the military setting is warranted.

This randomized clinical weight loss trial is unique because it will assess a weight loss treatment in an operational military setting for participants who may face severe occupational consequences related to weight and fitness. In addition to the periodic fitness test, there are other distinct potential facilitators for weight loss in this environment, such as regular physical activity within some squadrons and military messaging on fitness. There are also novel challenges that may influence our results including the stressor of potential deployment for oneself or family members, the potential difficulty in obtaining follow-up data for participants who unexpectedly deploy or have a permanent change of their duty station). Furthermore, unlike most weight loss studies [37], we are likely to have many male participants, given the composition of the military population [38]. Finally, given the racial and ethnic diversity in the military [38], a significant proportion of participants will likely be non-white, as we saw with our pilot study. Thus, results from this study will provide valuable information regarding treating these populations.

It is important to note that while the intent of this trial is to translate the Look AHEAD ILI, the trial is designed as an “efficacy” rather than an “effectiveness” trial, in order to examine whether the Look AHEAD ILI can be translated to the military setting if conditions are “ideal”. For this reason, we included a behavioral run-in as part of the eligibility criteria. Therefore, the generalizability of results to a potentially less motivated subgroup of military members will need to be tested in future investigations.

We have made several unique and important modifications to the Look AHEAD study design to enhance translation within the military setting. In order to accommodate the mobility of military personnel, we are conducting individual rather than group-based sessions and are conducting these sessions over the telephone rather than in-person. Furthermore, to our knowledge, this is the first study to implement a “proactive” (i.e., Counselor-Initiated) compared to “reactive” (i.e., Self-Paced) model for weight loss, a model that has been traditionally used for smoking cessation [10, 11, 13, 14]. This project will provide critical information regarding the effectiveness of a military-based translation of the Look AHEAD trial, including weight loss, fitness, behavioral outcomes, and cost. Furthermore, given the distance-based approach taken with this program, this study may also inform other distance-based translations of the Look AHEAD ILI.

If the Fit Blue program proves to be successful and cost-effective or even cost saving, there are several possibilities for dissemination. As overweight and obesity are key concerns not just for the Air Force, but for all branches of the military [2], the Fit Blue program potentially could be adapted for use in other branches of the military. In addition, as excess weight is the most common reason that potential recruits are not eligible for the military [39], the Fit Blue program could be utilized to assist interested individuals to qualify for military service.

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