PROPOSAL FOR HUMAN RESEARCH

APPROVED w/Amend 6
JAN 27 2017
60MDG IRB TRAVIS AFB CA

CLINICAL INVESTIGATION FACILITY
60th Medical Group (AMC)
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FWA00003321, DoD 50004, IRB00002726

For assistance, call the Chief, Research Oversight and Compliance at (707) 423-7206

1. Title of Investigation

Effectiveness of a Group Lifestyle Balance Class in a Military Population.

2. Investigator and Investigation Staff

Name	Rank	Study Role	Date of Investigator Training	Staff/ Resident/ Fellow	Dept/ Office Symbol	Phone	DoD Assurance Number	E-mail
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Research Monitor (RM): N/A

3. Facility and/or Contractor

David Grant Medical Center (DGMC)

4. Purpose of Investigation

The purpose of this study is to examine the effectiveness of the Group Lifestyle Balance™ (GLB) program compared with two currently available programs, the Fitness Improvement Program (FIP) and the Better Body Better Life (BBBL) program, on the following health indicators: improvement of individual physical fitness as measured by change in abdominal circumference, weight and physical activity as measured by the Modifiable Activity Questionnaire (MAQ); decrease in risks associated with chronic disease as measured by changes in lipid and HbA1c levels; and improvement in self-perceived function and well-being as measured by the RAND 36 Item Short Form Health Survey (RAND SF- 36). In addition, the researchers seek to obtain feedback about the programs from the participants. The results of this study could expand the body of knowledge and inform clinical practice and Air Force policy.

5. Category of Study and Risk Assessment

5.1. Category of Study

In this study researchers will be evaluating the effectiveness of lifestyle interventions on weight loss and chronic disease indicators. The aim of the interventions is to promote weight loss and healthy behaviors which could lead to decreased risks for developing chronic disease.

☐ **Medical Utilization** ☒ **Prevention** ☐ **Medical Readiness** ☐ **Diagnosis/Treatment/Other**

5.2. Proposed Risk:

☒ Minimal Risk
☐ Greater Than Minimal Risk

6. Proposed Research

6.1. Background and Review of Literature:

Individuals who are accepted for entry into the U.S. armed services must meet and maintain certain physical requirements, including general health, weight and fitness standards, so that they can optimally perform their mission. Unfortunately, as active duty members age, many develop problems with weight gain which may lead to increased risk for chronic disease and poorer physical functioning and well-being. Studies have shown that in addition to weight gain during the course of active duty service, further weight gain often occurs after leaving active duty service (Bohnker, Sack, Wedierhold, & Malakooti, 2005; Smith, et al., 2012). While this is consistent with the general U.S. population, it is particularly concerning for active duty personnel who must meet standards to optimally perform their mission. As overweight and obesity rates increase, so do co-morbid conditions such as type 2 diabetes, resulting in diminished readiness, a significant personal burden for active duty personnel, retirees and other beneficiaries, as well as enormous financial costs to the Department of Defense (DoD) Military Health System (MHS).

The GLB program has been shown to be effective in reducing risk factors for type 2 diabetes and CVD and promoting weight loss in various at-risk populations in diverse community settings (Seidel, et al., 2008; Kramer et al., 2009; McTigue, et al., 2009; Kramer, et al., 2010; Kramer, McWilliams, Chen, & Siminerio, 2011; Kramer, et al., 2012; Ma et al., 2013; Kramer, Perez-Cepak, Venditti, Semler & Kriska, 2013; Piatt, Seidl, Chen, Powell, & Zgibor, 2012). However, the GLB program has not been studied in an active duty population. While clinicians are charged with assisting all AFMS beneficiaries, it is particularly important for them to ensure that active duty personnel are in the healthiest and highest performing segment of the U.S. so that they can perform their mission. The active duty population is a subset of DoD beneficiaries with unique health care needs. Interventions found to be effective and feasible in other populations may not have the same effectiveness or feasibility in the active duty population. Therefore, it is necessary to understand the effects of interventions specifically within the active duty population.

Chronic Disease Burden in the Military

Obesity-related chronic diseases such as type 2 diabetes and heart disease are common problems in the general population and lead to significant health care costs. It is estimated that 29.1 million Americans have diabetes and 86 million adults aged 20 and older have pre-diabetes. Furthermore, the estimated health care cost of treating diabetes is $245 billion annually (Centers for Disease Control and Prevention [CDC], 2014a). Heart disease is the leading cause of death in the U.S. for both men and women. Coronary heart disease is the most common type of heart disease in the U.S. with an estimated health care cost of $108.9 billion dollars annually (CDC, 2014b). Therefore, the burden of both diabetes and heart disease on the health care system, including the MHS is immense.

In one study researchers found that the overall prevalence rate of active duty USAF members for diabetes and dyslipidemia were 0.3% and 4.6% respectively (Hatzfeld, LaVeist, & Gaston-Johansson, 2012). This relatively low rate was possibly related to over half of the study participants being under 30. In another study, the overall prevalence for coronary or aortic atherosclerosis in U.S. military members who died in combat was 12.1%. The researchers of this study also found that age was most strongly associated with atherosclerosis prevalence with those aged 40 and older having 7 times the prevalence compared with those aged 24 and younger. Also, lower education level and higher military entrance Body Mass Index (BMI) were significantly associated with atherosclerosis prevalence (Webber, Seguin, Burnett, Clark, & Otto, 2012).

Physical Fitness in Military Personnel

Military members must meet certain fitness and weight standards while on active duty. Active duty members of the USAF are required to complete a fitness assessment every 6-12

months (USAF, 2013). The fitness assessment is comprised of four components: a timed 1 ½ mile run to assess aerobic capacity, timed push-up and sit-up repetitions to assess strength, and abdominal circumference measurement to assess body composition. Points are awarded for measurements in each component based on age and gender. In order to pass the fitness assessment, personnel must achieve a total of at least 75 points out of 100 possible in addition to a minimum threshold measurement for each component. Minimum threshold requirements for the run, push-ups, and sit-ups components change with age; however, the requirements for the abdominal measurement component do not change (USAF, 2013). The rationale for including an abdominal circumference component in the fitness assessment is that increased abdominal fat has been associated with increased risk for chronic disease. In fact, health risk levels associated with different abdominal circumference measurements are included in the fitness assessment charts (USAF, 2013).

With certain medical conditions Airmen may be exempt from performing one or more of the testing components in which case minimum thresholds must only be met for the components that are performed. For example, if someone had a shoulder injury he or she might be exempted from performing the push-up and sit-up components of the fitness assessment but would still be required to perform the run and abdominal circumference measurement. While there are many medical conditions that could lead to an exemption for the run, push-up, or sit-up components, it is extremely rare for personnel to be exempt from the abdominal circumference measurement. Recently reported metrics indicated exemptions for the abdominal measurement component were less than one percent of the other three component exemptions (USAF, 2014). Therefore, personnel who have excess weight causing increased abdominal circumference are at risk of poor performance or failure of a fitness assessment. Furthermore, persistent fitness assessment failure could lead to discharge from service (USAF, 2013). Lastly, although commanders are encouraged to develop unit physical training programs as per Air Force Instruction (AFI) 36-2905 (USAF, 2013), the focus of these training programs has traditionally been on strength and aerobic training rather than on modifying eating patterns to achieve optimal body weight. This suggests a potential need to incorporate programs at the unit level aimed at modifying eating behaviors in addition to physical fitness programs.

When ADAF personnel fail a fitness assessment, they are required to participate in some type of interventional training that is directed by their commander, and then re-take the fitness assessment in 90 days. According to AFI 36-2905, physical fitness and nutrition education should be incorporated into unit physical training programs (USAF, 2013). Airmen can choose whatever program is available to them that most helps them improve their health and fitness. However, Airmen who get an unsatisfactory fitness score are mandated to start the Balanced Eating, Workout Effectively, Live Long (BE WELL) course within 10 duty days of their unsatisfactory assessment. The BE WELL course is currently an on-line intervention now called the Fitness Improvement Program (FIP) that provides information about exercise, nutrition and

spiritual health. In addition, a new intervention program called Better Body Better Life (BBBL) is being integrated into Air Force base-level Health Promotions programs as an alternative to the FIP.

Functioning and Perception of Well-being

Health related quality of life is thought to be an important concept and has been linked with prevention of disease. Concepts related to health-related quality of life include functioning and perception of well-being. Several tools have been developed and used extensively for measuring health-related quality of life outcomes. One such tool is the Medical Outcomes Study Short Form 36 (SF-36), also known as the RAND SF-36 (CDC, 2000). This tool has been widely used in research to measure function and overall well-being in diverse populations. Functioning and well-being have been found to be important components in the health of veterans. In one study on Iraq and Afghanistan War veterans, the authors found the presence of protective factors including basic functioning and psychological well-being were associated with reduced risk of aggression and community violence (Elbogen, et al., 2012). In addition, the effects of a nutrition and exercise intervention on health perception and functioning have been studied. In one such study, a 6-month exercise and nutritional guidance intervention was found to significantly improve health perception, vitality and social functioning in a group of Japanese women as measured by the SF-36 questionnaire (Uritani, Matsumoto, Asano, Yshizaki, Nishida, & Shima, 2013).

Lifestyle Intervention

It is well known that obesity, poor diet, and inactivity increase the risk of diabetes and heart disease and that the risks increase with age. The factors that lead to these diseases are multifaceted and complex. However, some lifestyle modification interventions have been shown to be effective in preventing these chronic diseases. In a systematic review of randomized controlled trials of exercise and diet interventions, the authors found that overall exercise plus diet interventions reduced the risk of diabetes compared to treatment as usual. They also found that in general these interventions reduced BMI, waist circumference, and blood pressure but had only modest effects on lipids (Orozco, Buchleitner, Gimenez-Perez, Roque I Fiquls, Richter, & Mauricio, 2008).

Lifestyle interventions have also been used in active duty populations although not well studied. USAF personnel who fail a fitness assessment are typically required by their commander to attend the on-line BE WELL intervention or some other formal program as available at the local base. In addition, Airmen who have not failed a fitness assessment but want to improve their eating and fitness habits, are encouraged to attend the BE WELL or other unspecified lifestyle intervention class (USAF, 2013). The in-person BE WELL intervention has been shown to be effective in boosting fitness assessment scores for Airmen who have failed a

USAF fitness assessment to include effectively lowering abdominal circumferences after the intervention (Webber, Nelson & Gildengorin, 2012). The live classroom BE WELL has been discontinued and it is unknown whether or not the current on-line BE WELL (now called the FIP) intervention would have the same effects. It is also unknown how many people who are not directed by their commanders to attend the BE WELL intervention use this web-based tool or if it has any effect on chronic disease risk.

Lifestyle intervention has been shown to be effective in lowering risk for diabetes in several studies. In one of these studies, the U.S. Diabetes Prevention Program (DPP) demonstrated a 58% reduction in risk for development of type 2 diabetes and significant reduction in risk factors for CVD using a comprehensive behavioral lifestyle change intervention (Knowler, et al., 2002; Diabetes Prevention Program Research Group, 2005). The GLB program is a direct adaptation of the successful DPP lifestyle intervention (Kramer, et al., 2009). The GLB program includes the same goals as the original DPP lifestyle intervention: a 7% weight loss from baseline and engaging in 150 minutes of moderate intensity physical activity each week.

Several studies by Dr. Kaye Kramer (an AI on the current project) and others have demonstrated the effectiveness of the GLB program in multiple community settings, extending from community centers to churches to primary care practices (Seidel, et al. 2008; Dodani, et al. 2009; Kramer, et al. 2009; McTigue, et al. 2009; Kramer, et al. 2010; Kramer, et al. 2011; Kramer, et al. 2012; Ma, et al. 2013; Piatt, Seidel, Chen, Powell & Zgibor, 2012; Piatt, et al. 2013). Results of these GLB studies have demonstrated an average weight loss of 5% or greater with significant increases in self-reported physical activity levels and improvements in multiple risk factors for diabetes and CVD. The GLB program average weight loss is consistent with other DPP translation efforts (CDC, 2011) and it meets the standards required by the CDC's Diabetes prevention Recognition Program (DPRP) for national recognition. The CDC-DPRP is a national program designed to recognize U.S. organizations that are providing effective (i.e. at least 5% average weight loss) lifestyle intervention programs for diabetes prevention (CDC, 2011). The GLB program is a CDC-DPRP approved curriculum.

Summary and Gaps in Knowledge

Many active duty personnel struggle with weight gain and becoming overweight during the course of their active duty service. This can lead to difficulty in maintaining fitness standards and limit their ability to fully function in performing their mission. In addition, this may lead to increased risk for chronic disease development. Few published studies exist that evaluate interventions aimed at weight loss and chronic disease prevention in the active duty population. The GLB program has been shown to be effective in facilitating weight loss and reducing chronic disease risk in civilian populations. However, the effectiveness of this class in preventing chronic illnesses, facilitating weight loss, increasing physical activity and promoting

perceptions of improved functioning and well-being has not been studied in active duty populations. The purpose of this study will be to examine the effectiveness of the GLB program compared with the currently available FIP and BBBL on the following health indicators: individual physical fitness as measured by change in weight, abdominal circumference and minutes engaged in physical activity; changes in risk associated with chronic disease as measured by changes in lipid and HbA1c levels; and changes in self-perception of function and well-being as measured by the RAND SF-36 questionnaire.

6.2. Relevance/Significance:

Active duty populations have been found to have increasing numbers of members who are overweight and therefore at higher risk for developing diabetes and cardiovascular disease (Smith, et al., 2012). Not only does being overweight or obese lead to increased health care costs but could also lead to missed duty time and inhibited career progression for active duty members. Active duty Airmen must pass periodic fitness assessments that include an abdominal circumference measurement as a measure of body composition and risk for disease. Failure of the abdominal circumference component could lead to failure of the entire assessment which in turn could lead to unsatisfactory performance evaluations and discharge from the service.

No published research is available regarding the effect of a GLB class on weight, abdominal circumference, physical activity, biomarkers indicative of chronic disease risk, or well-being in active duty personnel. In addition, no published research was found on the effectiveness of the currently available FIP and BBBL interventions. Results of this study could help fill this gap in knowledge and determine whether or not the GLB program in comparison to the FIP and BBBL is effective in reducing chronic disease risk and improving physical fitness and well-being in the active duty population. Clinicians could then use this information to plan interventions for active duty members who may be at increased risk of developing chronic disease or failing a fitness assessment due to being overweight or having increased abdominal circumferences. Clinicians could also use this information when advising U.S. Air Force leaders on programs that could positively affect health and fitness assessment outcomes for active duty personnel.

6.3. Hypotheses or Research Questions or Objectives:

Specific Aims:

1. To determine if the GLB lifestyle intervention program provided to an at-risk AD population is effective. ***Hypotheses:*** There will be a significant reduction in the primary endpoint (weight) and improvement in several secondary outcome measures (abdominal circumference, physical activity, fasting lipids, HbA1c, and self-perceived well-being) for participants in the GLB intervention delivery mode measured pre and post intervention, and as compared to those randomly assigned to usual care (online FIP) or the BBBL.

2. (Secondary Aim) To determine the usefulness of the GLB, BBBL, and FIP interventions to AD personnel through a qualitative content analysis of open-ended responses on a questionnaire administered after the interventions are completed.

6.4. Research Design and Methods:

This will be a quantitative randomized control intervention study to determine the effects of a GLB class on physical indicators of fitness, disease risk and overall perception of functional health and well-being in an active duty population, and to compare outcomes with the FIP intervention (care as usual) and newly implemented BBBL intervention currently offered to Airmen. This study will be conducted at David Grant Medical Center (DGMC), Travis AFB, California.

Recruitment:

Recruitment will be through DGMC to include Health Promotions, the Fitness Assessment Cell, and Unit Training Managers at Travis AFB. Research coordinators, PI/AIs and other appropriately trained research staff will be responsible for conducting recruitment and enrollment procedures. Advertising for the study will consist of flyers that will be distributed through primary care clinics and the Preventive Health Assessment (PHA) clinic located at DGMC, the base fitness center and other public venues on Travis AFB (see Attch 2). In addition, an email will be sent to Unit Training Managers with information about the study that they may pass on to their active duty personnel. Also, flyers will be distributed through 'The Chief's Group' 'The Top Three' and social media sites of AF approved private organizations and units. Flyers may be posted in public areas throughout Travis AFB. The investigators will meet with staff members of all recruitment areas to explain the study and to request that they refer any active duty patients who may meet eligibility criteria and are potentially interested in participating. Lastly, slides that illustrate study procedures will be shown at Commanders Calls and other above venues to provide better information to potential participants.

Individuals who are interested in participating will be given contact information and asked to contact the research coordinator or PI. The research coordinator or one of the investigators will determine if the potential participants meet eligibility criteria by asking a few pre-screening questions. If the prospective participant meets eligibility criteria, the research coordinator/assistant will make an appointment with him or her to explain the study in detail and to obtain informed consent and HIPAA authorization.

Study Procedures:

Once consent is obtained, the research coordinator/assistant will then go over detailed eligibility criteria at which point the participant will be considered enrolled. Female participants

will be asked to give a urine sample for a urine pregnancy test for exclusion criteria. The research coordinator/assistant will then ask participants to complete a demographic questionnaire. Demographic questions will include: date of birth, gender, race, rank, unit, years of service, presence and type of any chronic medical conditions, which shift they predominantly work, how much duty time they have to exercise, whether or not they have deployed and, if so, whether their eating and activity patterns are different when deployed (Attachment 3). At this initial visit coordinators will also take baseline measurements and ask participants to complete baseline quality of life questionnaires (RAND SF-36) (Attachment 4) and the MAQ (Attachment 8). The research coordinator/assistant will order baseline laboratory work during this initial visit. Participants may complete these labs at their convenience, but before their first intervention. They will be advised that a 12-hour fasting is required before visiting the laboratory. Participants will be given a $20 gift care upon completion of the initial bloodwork.

The research coordinator will randomly assign the enrolled participant to the GLB, BBBL, or FIP group using a standardized randomization plan for three groups generated from www.randomizer.com. Randomization will by stratified be sex to ensure that women are adequately represented in each group. Currently women comprise approximately 19% of the active duty Air Force. Lastly, the participant will be scheduled into either a GLB class, a BBBL class, or a time frame to take the FIP depending on which group they are in.

For the GBL and BBBL groups, participants will be scheduled into the next available class. The participants will be asked to complete the FIP within 4 weeks after their baseline visit. FIP participants will be asked to print out and give the research coordinator/assistant a copy of their FIP certificate of completion. Attendance at both the GLB and BBBL classes will be taken. The research coordinator will follow-up with any participants who missed a class and will arrange for them to make up the class through watching the DVD (GLB) or scheduling a make-up class if possible (BBBL). Attendance and missed classes as well as GLB classes watched on DVD will be tracked on an Excel spreadsheet and will be included in the data analysis along with other demographics. Research coordinator/assistant will obtain the completion date and numbers of sessions completed from the class instructor for the BBBL participants.

Participants from all groups will meet with a research coordinator/assistant at three months to obtain weight and abdominal circumference measurements and to complete the RAND SF 36 form. All participants will also be scheduled for a discharge visit with a research coordinator/assistant at around 6 months after starting their intervention. During the discharge visit, final questionnaires (to include the MAQ) and measurements will be obtained and HbA1c and fasting lipid labs will be ordered. Participants will be given a $50 gift certificate upon completion of final blood work. Participants will also be asked to complete the intervention evaluation questionnaire at this visit. Participants in the GLB group will complete a total of three one-on-one research coordinator/assistant visits and attend 16 1-hour GLB group sessions with a GLB instructor. Participants in the BBBL group will complete a total of three one-on-one

research coordinator visits (baseline, three months, and discharge visit) and five 2-hour BBBL sessions with a trained BBBL instructor. Participants in the FIP group will complete a total of three one-on-one research coordinator/assistant visits (baseline, three months, and discharge visit) and will take the FIP training on their own. The FIP training takes approximately 90 minutes to complete. The research assistant or research coordinator will contact participants monthly to remind them of when their next visit is due and to given them an opportunity to ask any questions. Once participants complete all study procedures, the Research Coordination/Assistant will email them a certificate of appreciation for completing the study. No study procedures will take place prior to obtaining informed consent and HIPAA authorizations.

6.5. Risks/Benefits:

IRB approval will be obtained from the U.S. Air Force prior to conducting any research. This study will be a minimal risk study with the primary risks pertaining to blood draw site reactions and potential loss of confidentiality. Informed consent will be obtained from participants as approved by the IRB. Only active duty men and women will be asked to participate in this study. Pregnant women will be excluded from participating in this study because the GLB class has not been designed to meet the additional caloric and nutritional requirements of pregnancy. Female participants will be given a urinary pregnancy test to determine eligibility for the study prior to being allowed to enroll. In addition, any female participants who become pregnant during the course of the study will be withdrawn. The GLB intervention is focused on behavior modification for lifestyle changes aimed at eating fewer calories and fat and increasing engagement in physical activity, and it has been found to be safe and effective in pre-diabetic patients. The FIP on-line program provides general information on nutrition, fitness, and emotional well-being and is currently available to all active duty Airmen and mandated for Airmen who fail a fitness assessment. The BBBL provides information about diet and activity and is also available to any Airman.

Potential risks of this study include discomfort from blood draws and loss of confidentiality. The GLB intervention itself poses minimal risk in that it involves attending a class and learning about ways to change lifestyle habits in diet and exercise. The FIP and BBBL interventions also poses minimal risks and provides information that would be considered part of usual care or routine part of the duty day for active duty Airmen. The risks of blood draws include mild pain, swelling, and bruising at the blood drawing site. Blood tests that are performed are the same type of tests that participants may have performed during a routine physical exam. In addition, there is always a risk of potential loss of confidentiality. Care will be taken to protect patient information whether electronic on firewalled or CAC-card protected files or physical documents by keeping these secured in lock cabinets within locked office space. Only the researchers will have access to these files. The researchers will maintain confidentiality

of participants and comply with the HIPAA Privacy Rule through de-identification of data prior to analysis. No identifiable information will be used in any published reports or papers resulting from this research. Furthermore, all data (electronic and hard copy) will be kept in a locked file cabinet until at least 6 years after dissemination of study or as directed by IRB policy.

There is a possibility that there could be some incidental findings during the course of obtaining bloodwork for lipids and HbA1c. It is possible that learning about an incidental finding could cause a participant to become anxious or to have greater difficulty obtaining future health or life insurance. Participants will be made aware of the possibility of incidental findings and associated risks as part of the informed consent process.

Potential direct benefits to the participants are that they may experience weight loss and a reduction in levels of bio-indicators of chronic disease. In addition, findings from this study may contribute to knowledge that could be applied to the larger military population and potentially lead to decreased health care costs. Therefore, the benefits to participating in the study outweigh the minimal risks involved.

Coercion could be a possible concern in this study in that the PI will likely be a higher military rank than the vast majority of the study participants. Therefore, to avoid possible feelings of coercion, the PI will not seek informed consent while in uniform. Research coordinators who are not active duty members will be the researchers primarily responsible for obtaining informed consent and interacting with the participants.

6.6. Subject Population

Age Range: ☒ ≥ 18 y/o ☐ Children (≤ 18)

Sex: ☒ Male ☒ Female

Vulnerable Population: ☒ No ☐ Yes (explain)

Number of Subjects:

- Total Number of Subjects (nation-wide/study-wide): 131
- Number of Subjects Planned for DGMC: _131_
- Number of Subjects Planned for (Specify Institution): _N/A_

A sample size estimate was calculated based on a power analysis for the primary and secondary outcomes of weight and HbA1C changes using a MANOVA analysis for three groups. This calculation indicated a total of 69 participants would be needed to achieve .90 power. In addition a sample size estimate was calculated for a linear mixed model for four variables (intervention group, weight, age, and gender). This calculation indicated a total of 85 participants would be needed to achieve .80 power and a significance level of .05. In three studies of similar

topic and design to this study, attrition rates ranged from 17%-19% at a 6-month follow-up (Ma, et al., 2013; Shrestha, Combest, Fonda, Alfonso & Guerrero, 2013). An original attrition rate of 20% was accounted for however actual attrition has been much higher at 35%. Therefore a total of 131 participants will be needed to arrive at 85 who complete the study considering a 35% attrition rate.

It is estimated that there are approximately 1800 active duty people at Travis AFB who would meet the eligibility criteria. Therefore, the pool of people to sample from is more than adequate to accomplish this study at the chosen site.

Inclusion/Exclusion Criteria:

Individuals will be eligible to participate in the study if they meet the following inclusion criteria:

- An active duty member of any U.S. armed service
- Have at least one of the following conditions:
  - An abdominal circumference over 35 inches for men or 31.5 inches for women
  - BMI over 25 kg/m^2
- Are willing to commit to weekly 1 hour classes for 12 weeks and monthly 1 hour classes for an additional 3 months

Exclusion criteria are:

- Women who are pregnant or breastfeeding
- Participants who are within 8 months of a Permanent Change of Station or deployment
- Anyone who has been restricted from participating in moderate activity equivalent to a brisk walk
- Taking glucose-lowering medication
- Recently (in the past 6 months) started on a cholesterol lowering medication or had a change in dose of a cholesterol lowering medication (participants who have been on a stable dose of cholesterol lowering medication for greater than 6 months are eligible)
- Anyone who for medical reasons cannot have a calorie-restricted diet

Failure of the body composition portion of the Air Force Fitness Assessment will not preclude Airmen from participation in the research study. According to AFI 40-101, a standardized weight reduction intervention must be available to Airmen who fail the body composition portion of the Air Force Fitness Assessment (USAF, 2014b). All interventions in the study meet this requirement. However, Airmen who receive an unsatisfactory fitness assessment must start an intervention within 10 days of their unsatisfactory assessment (USAF, 2013). Therefore, Airmen who have failed the abdominal circumference component of the Fitness Assessment and

who otherwise meet eligibility criteria will not be excluded from the study. If the participant is randomized to an intervention that is not available to start within 10 days of an unsatisfactory fitness assessment, then he or she will be withdrawn from the study.

Consent:

Prospective participants who have expressed interest in the study will be scheduled for an informed consent review/initial visit at the Clinical Investigation Facility (CIF). The prospective participant will be brought to a private exam room or office where they will be individually consented by the research coordinator, the PI or other research team member that has been trained on the protocol. The study team member will explain the nature and scope of the study, discuss potential risks and benefits of participation, answer questions for the subject and ensure the participant fully understands informed consent. The study will be explained to the participant in lay terms. At least one hour of study staff time will be set aside for each participant to receive information, ask questions and consider participation in the study. The participant may elect to discuss the study with others if they so choose, prior to agreeing to participate. If the participant agrees to participate, the IRB approved informed consent document (ICD) and HIPAA Authorization Form will be signed and personally dated by the subject and investigator or study staff that have been delegated responsibility and have been trained on the protocol. A copy of the signed consent form will be made and provided to the participant. The original signed consent form will be turned into the protocol office and a copy will be placed in the participant's study folder and stored with other protected health information in a locked filing cabinet in an office that is locked when the office owner is not in the room. Participants will be assured that they may withdraw from the study at any time and for any reason and their medical treatment will not be compromised. Research procedures will not start until the IRB approved ICD has been signed and dated by the participant and research team member who has been delegated responsibility for consenting participants and has been trained on the protocol.

6.7. Safeguards for Protecting Subjects:

DGMC policy for protecting protected health information under the Privacy Rule of the Health Insurance Portability and Accountability Act may be found in MDGI 40-6 Health Information Privacy Practices 15 Dec 2011.

Incidental Findings: A qualified person will review these results just as would occur if these procedures were done as part of routine medical care. Participants will be notified of any incidental findings. Depending on the type of incidental finding, participants be may contacted by phone. In the case of a potential serious emergency, the research team will notify participants at the point the incidental finding is detected. Incidental findings will become part of the

permanent electronic medical record. The research team will also give information about this incidental finding to the participants' primary care provider or will refer participants' to an appropriate provider for further evaluation.

Data Entry: Data will be entered by authorized study personnel only. Upon completion of data entry all hard copy documents will be stored as per the hard copy records policy outlined below. All electronic PHI data will be housed on the DGMC EPHI drive and will only be accessible via a Common Access Card enabled computer accessible only to study personnel within a secured office. All electronic transmissions of data will be encrypted over a secured network.

Data security and transfer: Study documents will reside in the Clinical Investigation Facility within the 60MDG SGSE Directory in a limited access password protected directory designated exclusively to the study. Access will be granted only to study personnel.

To be in compliance with Government regulations study personnel will utilize 128 bit AES encryption. AES is widely used across the government healthcare sector to secure data-at-rest, data-in-motion and data-in-transit. All data transfers will be made via (password protected CD, encrypted Electronic Mail, Secured FTP server, other). All data files will utilize the Advanced Encryption Standard approved cryptographic algorithm used to protect electronic data.

Hard Copy Records: A copy of the IRB approved informed consent signed and dated by the participant and study team designee will be provided to the study participant. The original signed and dated IRB approved informed consent form will be placed with other study records, in a locked cabinet and secured area within the IRB Protocol Office at the Clinical Investigation Facility. These records will be accessible only to study personnel, the IRB, and employees of authorized Federal departments and regulatory agencies. Duplicates will be provided to the volunteer upon written request.

All subjects will be treated in compliance with AFI 40-402 and applicable FDA and DHHS guidelines.

6.8. Data Collection/Analysis:
Specific Aim 1: To determine if the GLB lifestyle intervention program provided to an at-risk AD population is effective. ***Hypotheses:*** There will be a significant reduction in the primary endpoint (weight) and improvement in several secondary outcome measures (abdominal circumference, physical activity, fasting lipids, HbA1c, and self-perceived well-being) for participants in the GLB intervention delivery mode measured pre and post intervention, and as compared to those randomly assigned to the BBBL or FIP.

The effectiveness of the GLB program compared with the BBBL and FIP on weight and abdominal circumference will be achieved by obtaining these measurements prior to starting the respective intervention, at 3 months, and at 6-7 months. Weights will be obtained from a calibrated scale and the same scale will be used for both weight measurements. Abdominal circumferences will be obtained according to the same standards that are outlined in AFI 36-2905 (USAF, 2013). Research coordinators will be trained to obtain abdominal circumferences by physical training leaders knowledgeable in fitness assessment measurement taking.

The effectiveness of the GLB program compared with the BBBL and FIP on physical activity will be achieved by asking participants to record and report the number of minutes they participated in moderate and intense activity per week (Attachment 5). These data will be collected at baseline, 3 months, and 6-7 months. Physical activity will also be assessed through the MAQ which will be administered at baseline and the 6-7 month visit. The MAQ was designed by Dr. Andrea Kriska at the University of Pittsburgh. It has been used to assess activity in a variety of populations and age groups over various time frames (Kriska, 1997) and was used to assess physical activity levels in the Diabetes Prevention Program. The MAQ includes both a leisure and an occupational activity section since the homogeneity of energy expenditure related to both of these components of activity within many study populations cannot be assumed (Kriska, 1992). In addition, as the name suggests, the MAQ was designed to be modified, based upon pilot testing, prior to its usage, in order to maximize the feasibility and appropriateness of the physical activity instrument to the population of interest (Kriska, 1992). The MAQ has been shown to be both reliable and valid (through comparisons with activity monitors, fitness (field) testing, and the doubly labeled water technique) in adults and adolescents alike (Kriska, 1990; Schultz, 1994; Aaron, 1995). The MAQ has been used to assess a variety of time frames from past year and past week to a lifetime of activity. Since this study will evaluate participants' progress over 6 months, we will use a past month version of the MAQ. The MAQ takes approximately 10-15 minutes to complete.

The effectiveness of the GLB program compared with the BBBL and FIP on fasting lipids and HbA1c will be determined by obtaining fasting lipid and HbA1c results at baseline and at 6-7 months after being enrolled. The research coordinators will order blood work to include fasting lipids and HbA1c levels during the initial visit and again during the discharge visit. Elevated HbA1c levels have been associated with increased risk of developing diabetes with higher levels being associated with higher risk of developing disease (Edelman, Olsen, Dudley, Harris, & Oddone, 2004). Therefore HbA1c was chosen as an outcome measure for diabetes risk. Elevated serum lipid levels, in particular low density lipoprotein (LDL) levels are associated with the development of heart disease. Therefore, lipid levels were chosen as an outcome measure for heart disease risk. Participants will be instructed to go the clinical laboratory to get blood drawn for HgbA1c and lipids (including total cholesterol, HDL, LDL,

and Triglycerides) after fasting for 12 hours prior to participating in their assigned intervention and again within 1 week of the discharge visit. Laboratory work will be ordered for research purposes only; however these assays are an acceptable clinical practice regardless of volunteer participation. Therefore, laboratory results will become part of the participants' medical record. Incidental abnormal lab findings will be reported to the participant as well as to their Primary Care Manager (PCM).

Changes in measurements for abdominal circumference, weight, fasting lipids, HbA1c and minutes of activity for individuals between the three time frames (within group differences) will be analyzed by a biostatistician using Stata software to perform a one-way ANOVA test with the significance level set at $\alpha = .05$. Mean changes for each group will be compared (between group differences) using a one-way ANOVA test with the significance level set at $\alpha = .05$. Between group differences in the above outcome measures will also be examined using regression modeling.

The effectiveness of the GLB program compared with the BBBL and FIP on self-perception of well-being will be determined by asking participants to complete the RAND SF-36 at the baseline visit, 3 months, and 6-7 months. The RAND SF-36 questionnaire was developed for the Medical Outcomes Study to measure quality of life. The measures rely on self-reported responses and the form consists of 36 questions that are scored according to chosen responses. Eight scale scores are obtained each with possible ranges of 0-100. The eight scales reflect eight health concepts of: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. The RAND SF-36 has been found to be a valid and reliable tool for assessing health-related quality of life outcomes in adult patients (Rand Health, 2009). The RAND SF-36 is freely available for use (Attachment 6). A Kruskal Wallace test will be used to assess the between group differences in median RAND SF-36 scores among the three study groups.

Specific Aim 2: (Secondary Aim) To determine the usefulness of the GLB, BBBL, and FIP interventions to AD personnel through a qualitative content analysis of open-ended responses on a questionnaire administered after the interventions are completed.

The usefulness of each of the interventions will be determined by collecting data through a questionnaire that will be administered during the 6-month discharge visit for all groups (Attachment 7 – Intervention Feedback Questionnaire). Responses from the open-ended questions on this Questionnaire will be analyzed using content analysis common themes will be described and reported. Results from this analysis could be used to inform future potential modifications to the GLB.

Source of Research Material per Participant:

Source of Research Material per Participant	Standard Care	Research Driven
Demographic questionnaire	0	1
Weight and abdominal circumference measurements	0	3
Physical Activity questionnaire	0	3
Modifiable Activity Questionnaire (MAQ)	0	2
Blood Sample-Lipid Panel	0	2
Blood Sample – HbA1c	0	2
Rand SF-36 questionnaire	0	3
Intervention Feedback Questionnaire	0	1

7. Conflict of Interest

None of the investigators or other members of the research team has a conflict of interest.

8. Investigation Schedule

	2015 Apr-Jun	2015 Jul-Dec	2016 Jan-Jun	2016 Jul-Dec	2017 Jan-Jun	2017 Jul-Dec	2018 Jan-Mar
Recruitment	X	X	X				
Enrollment	X	X	X	X			
Baseline Data	X	X	X	X			
Intervention		X	X	X	X		
Data Collection		X	X	X	X	X	
Statistical Analysis				X	X	X	
Publications/Reports						X	X

9. Use of Investigational Drug(s) ☒ No ☐ Yes

10. Use of Investigational Device(s) ☒ No ☐ Yes

Lab Support:

Request CLIA certificates from all laboratories for your files.

Test Name	Standard Care?	Which lab will perform each test?	Support letter attached?
Lipid Panel	No	DGMC clinical lab	Yes
HbA1C	No	DGMC clinical lab	Yes

CIF Support:

Requesting support from the CIF for research coordinator assistance, biostatistician assistance and office space for a research assistant who will be hired with TSNRP grant funds.

12. Budget, Equipment, and Supplies

Requesting Funds: ☒Yes ☐No
This study is being funded by the TriService Nursing Research Program (TSNRP). Grant Number: N15-0006
Award period is: 1 April 2015-31 March 2018.

☐R&D ☐O&M ☐HMJ ☒ OTHER (explain source): TSNRP

☒ I understand that the funding is the responsibility of the PI, which includes; management, tracking, recording and must be reported to the IRB annually with your continuation report

13. Manpower

Rank	AFSC	# hours duty time	# hours off-duty time
Col	46N3	10 hrs/wk	2 hrs/wk
Maj	46N3	4 hrs/wk	0
Civilian	Health Promotions Director	4 hrs/wk	0
Civilian	U Pitt Faculty	4 hrs/wk	0
CTR	CRC	6 hrs/wk	0
CTR	Biostatistician	0.5 hrs/wk	0
CTR	Research Assistant	20 hrs/wk	0
CTR	GLB Instructor	20 hrs/wk	0

14. Institutional Official (IO)
MATTHEW P. WONNACOTT, Colonel, USAF, MC
Deputy Commander, 60th Medical Group

15. Bibliography
Air Force Medical Service (n.d.). Retrieved on 25 July 2014 from: https://kx2.afms.mil/kj/kx5/SurgeonGeneral/Pages/home.aspx

Armitage, N.H., Severtsen, B.M., Vandermause, R., & Smart, D.A, (2014). Training for the Air Force fitness assessment: The experience of postpartum women. Military Medicine, 179 (7), 766-772. doi: 10.7205/MILMED-D-13-00437

Armitage, N.H. & Smart, D.A. (2012). Changes in Air Force fitness measurements pre- and post-childbirth. *Military Medicine, 177,* 1519-1523. doi:10.7205/MILMED-D-12-00248.

Bohnker, B.K., Sack, D.M., Wedierhold, L., & Malakooti, M. (2005). Navy physical readiness test scores and body mass index. *Military Medicine,* 170, 851-854.

Centers for Disease Control and Prevention. (2014a). *National Diabetes Statistics Report: Estimates of Diabetes and its Burden in the United States, 2014.* Atlanta, GA: U.S. Department of Health and Human Services.

Centers for Disease Control and Prevention. (2011). Diabetes Prevention Recognition Program: Standards and Operating Procedures. Retrieved May 26, 2014, from http://www.cdc.gov/diabetes/prevention/pdf/DPRP_Standards_09-02-2011.pdf

Centers for Disease Control and Prevention. (2014b.) Heart Disease Facts. Retrieved from http://www.cdc.gov/heartdisease/facts.htm 27 Sep 2014.

Diabetes Prevention Program Research Group (2005). Impact of intensive lifestyle and metformin therapy on cardiovascular disease risk factors in the Diabetes Prevention Program. *Diabetes Care, 28,* 888-894.

Dodani, S., et al. (2009). Fit body and soul: a church-based behavioral lifestyle program for diabetes prevention in African Americans. *Ethnicity & Disease, 19,* 135-141.

Edelman, E., Olsen, M.K., Dudley, T.K., Harris, A.C., & Oddone, E.Z. (2004). Utility of hemoglobin A1c in predicting diabetes risk. *Journal of General Internal Medicine, 19,* 1175-1180.

Elbogen, E.B., Johnson, S.C., Wagner, H.R., Newton, V.M., Timko, C., Vasterling, J.J., & Beckham, J.C. (2012). Protective factors and risk modification of violence in Iraq and Afghanistan War veterans. *Journal of Clinical Psychiatry, 73,* e767-e773. doi: 10.4088/JCP.11m07593

Hatzfeld, J.J., LaVeist, T.A., & Gaston-Johansson, F.G. (2012). Racial/ethnic disparities in the prevalence of selected chronic disease among US Air Force members, 2008. *Preventing Chronic Disease, 9,* 110136. doi: 10.5888/pcd9.110136

Knowler, W.C., et al. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine, 346,* 393-403.

Kramer, M. K., et al. (2009). Translating the Diabetes Prevention Program: A comprehensive model for prevention training and program delivery. *American Journal of Preventive Medicine, 37:* 505-511.

Kramer, M. K., et al. (2010). A novel approach to diabetes prevention: Evaluation of the Group Lifestyle Balance program delivered via DVD. *Diabetes Research and Clinical Practice, 90,* e60-e63.

Kramer, M. K., McWilliams, Chen, & Siminerio. (2011). A community-based diabetes prevention program. *The Diabetes Educator, 37,* 659-668.

Kramer, M., Perez-Cepak, Y, Venditti, E, Semler, L, Kriska, A (2013). Evaluation of the Group Lifestyle Balance programme for diabetes prevention in a Hispanic Women, Infants and Children (WIC) Programme population in the USA. *Diversity and Equality in Health and Care, 10,* 73-82.

Kramer, M., Siminerio, L., Mauffray, R., Migliore, L., Kriska, A., Venditti, E., Semler, L., Orchard, T. (2010). Group Lifestyle Balance: A Model for translation of the Diabetes Prevention Program within the military setting. Centers for Disease Control and Prevention Diabetes Translation Conference, 2010.

Kramer, M., Venditti, E.M., Semler, L.N., Kriska, A.M., Miller, R.G., Orchard, T.J. (2012). Long-term strategies for diabetes prevention: Evaluation of the Group Lifestyle Balance post-core sessions focusing on carbohydrate and hunger management. *Journal of Diabetes and Metabolism* http://dx.doi.org/10.4172/2155-6156.S2-006

Kriska, A., Eaglehouse, Y.L., Vanderwood, K.K., Kramer, M.K. (2014). Evaluation of a flexibly-delivered lifestyle program designed to prevent diabetes and provided via DVD. (Abstract)

Ma J, Yank V, Xiao L, Lavori PW, Wilson SR, Rosas LG, Stafford RS. (2013). Translating the Diabetes Prevention Program lifestyle intervention for weight loss into primary care: a randomized trial. *JAMA Internal Medecine,173*,113-21. doi: 10.1001/2013.jamainternmed.987

McTigue, K. M., et al. (2009). Weight loss through living well: Translating an effective lifestyle intervention into clinical practice. *Diabetes Educator, 35*, 199-208.

National Institutes of Health (NIH) (2008). Diabetes Prevention Program. NIH Publication No. 09–5099 October 2008. Retrieved on 27 Jan 14 from: http://diabetes.niddk.nih.gov/dm/pubs/preventionprogram/index.aspx

Nelson, M.S., Robbins, A.S., Thornton, J.A. (2006). An intervention to reduce excess body weight in adults with or at risk for type 2 diabetes. *Military Medicine, 171*, 409-14.

Nelson, MS & Gordon MS, (2003). Physical activity determinants of military health care recipients *Military Medicine, 168*, 212-218.

Orozco, L.J. Buchleitner, A.M., Gimenez-Perez, Roque I Figuls, M., Richter, B. & Mauricio, D. (2008). Exercise or exercise and diet for preventing type 2 diabetes mellitus. *Cochrane Database Systematic Reviews, 2008 Jul 16 (3).* doi:10.1002/14641878.CD003054.pub3

Pender, N., Murdaugh, C., & Parsons, M.A. (2015). *Health promotion in nursing practice, 7th Ed.* Upper Saddle River, New Jersey: Pearson Education, Inc.

Piatt, G. A., et al. (2013). Comparative effectiveness of lifestyle intervention efforts in the community: Results of the Rethinking Eating and ACTivity (REACT) study. *Diabetes Care. 36,* 202-209. doi: 210.2337/dc2312-0824.

Piatt, G.A., Seidel, M.C., Chen, H.Y., Powell, R.O., Zgibor, J.C. (2012). Two-year results of translating the diabetes prevention program into an urban, underserved community. *Diabetes Educ, 38*, 798-804. doi: 10.1177/0145721712458834

Rand Health (2009). Scoring Instructions for the MOS 36-Item short form survey instrument. Retrieved on 29 Jan 2014 from: http://www.rand.org/health/surveys_tools/mos/mos_core_36item.html

Seidel, M., et al. (2008). Translating the Diabetes Prevention Program into an urban medically underserved community: A nonrandomized prospective intervention study. *Diabetes Care, 31*, 684 - 689.

Shrestha, M., Combest, T., Fonda, S.J., Alfonso, A. & Guerrero, A. (2013). Effect of an accelerometer on body weight and fitness in overweight and obese active duty soldiers. *Military Medicine, 178,* 82-87.

Smith, T.J., Marriott, B.P., Dotson, L., Bathalon, G.P., Funderburk, L., White, A., Hadden, L. & Young, A.J. (2012). Overweight and obesity in military personnel: Sociodemographic predictors. *Obesity, 20,* 1534–1538. doi:10.1038/oby.2012.25

Strickland, L., Siminerio, L., True, M., Watson, N., Wolf, D. & Kramer, M.K. (2010). Delivering a Diabetes Prevention Program in the Military Health System. Paper presented at the Centers for Disease Control and Prevention Diabetes Translation Conference, 2010.

University of Pittsburgh (n.d.). Group Lifestyle Balance™ Program. Retrieved on 27 Jan 14 from: http://www.diabetesprevention.pitt.edu/grouplifestyleoverview.aspx

Uritani, D., Matsumoto, D., Asano, Y., Yshizaki, K., Nishida, Y., & Shima, M. (2013). Effects of regular exercise and nutritional guidance on body composition, blood pressure, muscle strength and health-related quality of life in community-dwelling Japanese women. *Obesity Research in Clinical Practice, 7,* e155-e163. doi: 10.1016/j.orcp.2011.10.005

U.S. Air Force (2012). *Better Body. Better Life. Air Force Weight Management Program.* Retrieved on 1 Oct 14 from: https://kx2.afms.mil/kj/kx4/HealthPromotion/Documents/Forms/ShowFolders.aspx?RootFolder=/kj/kx4/HealthPromotion/Documents/Better_Body_Better_Life/Program_Overview

U.S. Air Force (2013). *Air Force Instruction 36-2905, Fitness Program.* Retrieved on 27 Jan 14 from: http://www.afpc.af.mil/affitnessprogram/index.asp

U.S. Air Force (2014a). Fitness Management System Metrics. Retrieved on 29 Jan 2014 from: https://www.my.af.mil/affms/cfmx/fms/metrics/Fitness_Metrics_Chart.cfm

U.S. Air Force (2014b). *Air Force Instruction 40-101, Health Promotion.* Retrieved on 28 Jan 2015 from: http://www.e-publishing.af.mil/

Webber, B.J., Nelson, M.S., Gildengorin, V. (2012) Indicators of sequential fitness assessment failures for Travis Air Force Base Airmen who attend the Be Well course, *Military Medicine, 177,* 302-307.

Webber, B.J., Seguin, P.G., Burnett, D.G., Clark, L.L, & Otto, J.L. (2012). Prevalence of and risk factors for autopsy-determined atherosclerosis among US service members, 2001-2011. *JAMA, 308,* 2577-2583.

16. Attachments

1. Informed Consent Document

2. Recruitment Flyer

17. Commander's Acknowledgment of Review and Approval

Principal Investigator: I am aware that I am not authorized to accept any funds or other form of compensation for conducting research. All subjects will be treated in compliance with applicable Air Force, DoD and federal regulations, as well as applicable FDA and DHHS guidelines. I have read, understand, and signed the attached Certificate of Compliance. I understand I must complete a review of this protocol at least every 12 months to prevent expiration of the study's approval. I will notify the protocol office **prior** to relocations, separation actions, or closure.

☐ Initial Submission
(ALL signatures required)

☒ Amendment Submission
(PI signature ONLY)

ARMITAGE.NICOLE.H.1076277350 Digitally signed by ARMITAGE.NICOLE.H.1076277350 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=ARMITAGE.NICOLE.H.1076277350 Date: 2017.01.20 09:03:10 -05'00'

NICOLE H. ARMITAGE, Colonel, USAF, NC
Chief, Clinical Research

20 Jan 2017
Date