

Dissemination of the Look Ahead Weight Management Treatment in the Military

Date: 10/04/2017

NCT number: NCT02063178

**PROTOCOL FOR CLINICAL INVESTIGATION – NON-EXEMPT HUMAN
(Wilford Hall Ambulatory Surgical Center – WHASC)**

PROTOCOL SUMMARY

1. Title:

Dissemination of the Look Ahead Study: Weight Management Treatment in the Military
FWH20130095H

2.0. Principal Investigator (PI):

WHASC PI:

WHASC Co-PI:

Name	Dr. Ann Hryshko-Mullen, PhD, GS-13	Dr. Gerald W. Talcott, PhD, Col, USAF (ret)*
Rank/Corps or Civilian Rating	N/A	N/A
Date of IRB Approved CITI Training & Date of Good Clinical Practice Training	2 Mar 2017	25 Sept 2017
Branch of Service	N/A	N/A
AD Mil/DoD Civilian/Ctr/Non-DoD Civ	DoD Civilian	Non-DoD Civ
Department & Base	Specialty Services Flight/ WHASC	University of Virginia/ WHASC
Phone & Pager #	210-292-5968	210-292-3813/210-632-9178(c)
E-Mail Address & AKO/DKO E-Mail Address	Ann.s.hryskomullen.civ@mail.mil	gerald.w.talcott.ctr@mail.mil
WHASC & DoD Assurance # and Expiration Date	DoD Assurance: F50007 Expires: 31 Dec 2018	FWA00006183 Expires: 13 Jun 2018

3.0. Research Plan:

3.1. Purpose:

This study aims to take the procedural and research-based lessons learned from a pilot weight loss intervention study (WHASC# FWH20130053H), conducted by the WHASC and The University of Tennessee Health Science Center in 2013, and apply them to the current study of 248 active duty military personnel stationed at Lackland AFB. The pilot study translated and tailored the Look Ahead weight loss intervention to an overweight/obese active duty U.S. Air Force population, while accommodating the lifestyle and environment that is unique to military members, and evaluated materials and procedures used.

3.2. Hypotheses, Research Questions or Objectives:

The objective of this intervention research is to conduct a behavioral weight loss program and compare the intervention groups.

4. Brief Summary of the study:

This study is a weight loss intervention program tailored to a military population. We will randomize the 248 participants to either an intensive counselor-initiated weight loss intervention or a self-paced weight loss intervention. Neither of the aforementioned conditions are controls and both treatments are expected to result in weight reduction.

5. Subjects:

Study participants will be active duty military personnel stationed at Lackland Air Force Base in San Antonio, Texas.

6. Inclusion/exclusion criteria:

Participants must be Active duty military personnel stationed at Lackland Air Force Base with at least one year left on station, ≥ 18 years of age, English speaking, have a Body Mass Index (BMI) $\geq 25\text{kg/m}^2$, and obtain clearance by a healthcare provider for participation in the study.

7. Number of Subjects: TOTAL NUMBER OF SUBJECTS (nation-wide/study-wide): WHASC 248

8. Use of an Investigational New Drug: N/A

9. Use of an Investigational Device: N/A

10. Use of a Placebo: N/A

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Department & Base	Specialty Services Flight/ WHASC	University of Virginia/ WHASC
Phone & Pager #	210-292-5968	210-292-3813/210-632-9178
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DoD Assurance # and Expiration Date	FWA00001750, exp. 14 Oct 2019 DoD # F50007 exp. 31 Dec 2018	FWA00006183 Expires: 13 Jun 2018

2.1. Associate Investigators (AI):

Provide the current list of all “engaged” AIs for the study based on 45 CFR 46.102, e.g., for purposes of research the AI: (1) obtains data through intervention or interaction with a research subject(s); and/or (2) obtains identifiable private information and/or protected health information about the research subject(s); and/or (3) obtains the informed consent of human subjects for research. **All “engaged” investigators must complete IRB approved CITI training.**

Name	AD/DoD Civ/Ctr/ Non-DoD Civ	Rank/Corps or Civilian Rating/Title	Date of CITI Training	Phone & Pager #
Robert Klesges	Non-DoD Civ	Co-PI/UVa	3 Jan 2015	901-448-5900
Rebecca Krukowski, PhD	Non-DoD Civ	Co-PI/Assistant Professor/UTHSC	15 Jul 2015	901-448-2426
Marion Hare, MD	Non-DoD Civ	Associate Professor/UTHSC	5 Feb 2015	901-448-3752
Melissa Little, PhD	Non-DoD Civ	Assistant Professor/UVA	8 Jan 2015	901-448-6878
Phyllis Richey, PhD	Non-DoD Civ	Associate Professor/UTHSC	9 Mar 2015	901-448-8635
Karen Johnson, MD	Non-DoD Civ	Interim Dept Chair/UTHSC	16 May 2016	901-448-5900
Daniel Cassidy, PhD	AD	Capt/WHASC Psychologist	13 Jul 2017	210-292-5869

2.2. Research Assistants (RA) & Coordinators (RC):

Provide the current list of all “engaged” RAs & RCs for the study based on 45 CFR 46.102, e.g., for purposes of research the RA or RC: (1) obtains data through intervention or interaction with a research subject(s); and/or (2) obtains identifiable private information and/or protected health information about the research subject(s); and/or (3) obtains the informed consent of human subjects for research. **All “engaged” Ras and RCs must complete IRB approved CITI training.**

Name	AD/DoD Civ/Ctr/ Non-DoD Civ	Rank/Corps or Civilian Rating/Title	Date of CITI Training	Phone & Pager #
Karen LeRoy	Non-DoD Civ	Research Director	18 Apr 2016	210-292-3504
Christin Pasker	Non-DoD Civ	Research Specialist	13 Jan 2016	210-671-5565
Allen Jones	Non-DoD Civ	Research Specialist	12 Jan 2016	210-671-1994
Tina Boothe	Non-DoD Civ	Research Specialist	05 Jan 2016	210-671-8175
Rickey King	Non-DoD Civ	Research Specialist	8 Mar 2017	210-671-8174
Leslie Gladney	Non-DoD Civ	Program Coordinator	19 Jun 2017	210-671-1997
Kevin Love	Non-DoD Civ	Research Specialist	21 Jan 2016	210-671-1085
Lisa McKenna	Non-DoD Civ	Administrative Coordinator	16 Dec 2014	210-292-3813
Mark Amen	Non-DoD Civ	IT Specialist	22 Jan 2015	210-292-4469
Annette Martinez	Non-DoD Civ	Research Specialist	29 May 2015	210-671-2076
Trina Bolden	Non-DoD Civ	Research Specialist	18 Apr 2016	210-671-1600

2.3. The research relevance of this protocol focuses on:

☐ Diagnosis ☒ Treatment ☐ Medical Utilization/Managed Care ☐ Prevention ☐ Medical Readiness
☐ Other

2.4. Location(s):

- a. Collaborating Facilities: WHASC
- b. Air Force Sites seeking Regional IRB: N/A
- c. List study sponsors: NIH- National Institute of Diabetes and Digestive and Kidney Diseases

3.0 Research Plan:

3.1. Purpose:

This study aims to take the procedural and research-based lessons learned from a pilot weight loss intervention study (WHASC# FWH20130053H), conducted by the WHASC and The University of Tennessee Health Science Center in 2013, and apply them to the current study of 248 active duty military personnel. The pilot study translated and tailored the Look Ahead weight loss intervention to an overweight/obese active duty U.S. Air Force population, while accommodating the lifestyle and environment that is unique to military members, and evaluated materials and procedures used.

3.2. Hypotheses, Research Questions or Objectives:

The objective of this study is to conduct a behavioral weight loss program and compare the intervention groups.

3.3. Significance:

The current study is inspired by the successful Look Ahead trial, a behavioral science obesity intervention treatment program that included: a collaborative approach, education, behavioral support, and motivational interviewing. The unique nature of this weight reduction study is significant. To our

knowledge, there had not been a successful translation of a highly efficacious obesity treatment in the military until the WHASC and The University of Tennessee Health Science Center implemented a pilot version of the Fit Blue program for active duty U.S. Air Force members in 2013. Following a successful pilot and extant results from the Look Ahead trial, we expect success during the full scale Fit Blue study.

3.4. Military Relevance:

Obesity and being overweight are serious problems throughout the military. Overweight and obesity is a major cause of discharge of military personnel. Additionally, treating obesity-related problems in the military is extremely costly. If successful, this project would represent, to our knowledge, the first full scale translation of a highly efficacious obesity treatment in the military.

3.5. Background and Review of Literature:

According to the report *Mission: Readiness. Too Fat to Fight*, being overweight is now by far the leading medical reason for rejection in the military. Also, obesity is a major cause for the discharge of uniformed personnel. Unfortunately, the impact of weight problems on the military does not stop with those turned away from military service. From 1998 to 2008, the Armed Forces Health Surveillance Center reported the percent of active military members who experienced medical encounters for overweight or obesity increased. The estimated total days of work lost from absenteeism associated with active-duty personnel who are overweight or obese was 658,000. DOD estimated that being overweight and obese has cost the DOD \$103 million dollars in health care costs annually (Dall, TM et al., 2007). Note this estimate is for active duty personnel only.

In reference to specific instrumentation to be used in this study: Bull et al. (2009) examined reliability and validity of the Global Physical Activity Questionnaire (GPAQ) among participants in 9 countries; Reliability coefficients were of moderate to substantial strength (Kappa 0.67 to 0.73; Spearman's rho 0.67 to 0.81), and results on concurrent validity between an established measure of physical activity, the International Physical Activity Questionnaires, and GPAQ also showed a moderate to strong positive relationship (range 0.45 to 0.65). The Health Utility Index's validity and reliability demonstrated in many populations (Horsman et al., 2003). Hedrick, Comber et al. (2013) found significant test-retest reliability between the visit 1 and 2 Behavioral Questionnaire (BEVQ) responses for the fifteen beverage items. Hedrick et al. also determine that the BEVQ-15 can detect change in beverage intake over time based on an intervention. In another study, Hedrick, Savla et al. (2012) reported on the concurrent validity between three 24-hour dietary recalls and the BEVQ-15; they found that the BEVQ-15 index of total beverage energy was highly correlated with the 24-hour dietary recalls of beverage intake ($R^2=0.59$). In reference to the Multifactor Screener, Thompson et al., (2004) reported that in various validation studies, the correlations between screener estimates and estimated true intake were 0.5–0.8.

3.5.1. Bibliography:

1. Mission:Readiness. Too Fat to Fight. Washington, DC, 2010.
2. Bull FC, Maslin TS, Armstrong T. Global physical activity questionnaire (GPAQ): Nine country reliability and validity study. *J Phys Act Health*. Nov 2009;6(6):790-804.
3. Dall TM, Zhang Y, Chen YJ, et al. Cost associated with being overweight and with obesity, high alcohol consumption, and tobacco use within the military health system's TRICARE prime-enrolled population. *Am J Health Promot*. Nov-Dec 2007;22(2):120-139.
4. Hedrick VE, Comber DL, et al. A rapid beverage intake questionnaire can detect changes in beverage intake. *Eating Behaviors*. 2013;14(1), 90-94.
5. Hedrick VE, Salva J, et al. Development of a brief questionnaire to assess habitual beverage intake (BEVQ-15): Sugar-sweetened beverages and total beverage energy intake. 2012

6. Horsman J, et al. The Health Utilities Index (HUI): Concepts, measurement properties, and applications. *Health and Quality of Life Outcomes*, 1:54.
7. Thompson FE et al. (2004) Performance of a short tool to assess dietary intakes of fruits and vegetables, percentage energy from fat and fibre. *Public Health Nutrition*, 7(8), 1097-1106.

3.6. Research Design and Methods:

This is a two-arm individually randomized trial. The Counselor-initiated group will follow a more intense counselor-initiated approach, where the counselor schedules weekly telephone sessions and contacts the group participants directly. The Self-paced group uses a less intense approach, where the participants can receive the same telephone counseling sessions as the counselor-initiated group, only if they call the counselor. Neither of the intervention groups are controls, and both treatments are expected to result in weight reduction. A more detailed description of each randomization group is located below in section 3.6.1.

Potential participants will be recruited through the use of advertisements, electronic bulletins, emails, newspapers, and word-of-mouth. Persons interested in learning more about the study will call the study phone number, or can request a call back through the website or in person event. If the participant decides that he/she is interested based on initial information by phone, a civilian research staff member will complete a phone-based pre-screening consultation. Through this pre-screening consultation, the individual will receive a more detailed description of the project if they meet eligibility criteria (see Section 3.6.7). If the person is considering participation, they will be scheduled for a screening visit (in-person) at the Lackland AFB Health and Wellness Center (HAWC) within the next week. The pre-screening consultation will take approximately 15 minutes.

At the in-person screening visit, a civilian research staff member will review the consent document with the study candidate, allow time for the individual to read the document and ask any questions. If the individual wishes to review the consent with their family or physician, they will be allowed the time to do so and will be re-scheduled to complete the screening visit once they are ready to sign the consent form. If the individual wants to volunteer, they will be asked to sign the consent document and the HIPAA Authorization document. Another civilian member of the research team will witness the consent. Once informed consent is obtained, the research staff will confirm eligibility by collecting demographic information, physical measurements (i.e. height, weight), an array of screening visit questionnaires (see Section 3.6.2), and contact information. A 1-2 week run-in will be explained (see section 3.6.2) and the participant will receive additional instructions that must be completed in order to be included in the study (i.e. obtain military medical clearance, participate in 1 week of dietary and physical activity self-monitoring). The screening visit will take approximately 60 minutes.

The participant will return for the baseline visit in approximately 1-2 weeks at the HAWC. At this visit, run-in material will be reviewed for completeness, physical measurements will be taken (i.e. weight, abdominal circumference, blood pressure and heart rate), and the participant will be randomly placed into one of the two treatment groups. The abdominal circumference measurement will be assessed using the criteria stated in AFI 36-2905, "Fitness Program," Section 7. At this time, research staff will also inquire into current adverse events, such as physical injuries, illnesses or hospitalizations. Fifty percent of participants will be randomly assigned, using a computerized block design unique to the Filemaker v12 relational database application, to the more structured counselor-initiated weight loss intervention and 50% to the self-paced weight loss intervention. If the participant is assigned to the counselor-initiated group, he/she will be oriented to the group and study website, provided lesson materials, exercise guidelines, an electronic body scale, meal replacements, and measuring cups and spoons. If the participant is assigned to

the self-paced group, he/she will be oriented to the group and study website, and will be provided exercise guidelines, an electronic body scale, measuring cups and spoons, and a Fit Blue t-shirt. The Body Trace electronic body scales will be issued to the subject on a hand receipt and will be returned at the completion of the study. This baseline visit will take approximately 60 minutes. For the Look Ahead Pilot Study (FWH20130053H), the AF/SG Legal Office made the determination that meal replacements, weight scale and measuring cups/spoons were integral to the study and should not be considered as gifts to the research subjects. It was also determined the use of meal replacements was not in violation of regulations governing a BAS food allowance for active duty members. The gift of a T-shirt was within the monetary allowance for gifts to military members and did not require any special approval through the Hospital Commander. The WHASC IRB agreed these items did not increase the risk to the subjects nor were they unfair inducements or coercive.

The participants will spend the next 12 months involved in study interventions, diet and exercise self-monitoring, daily weighing, and may also include telephone counseling sessions. A detailed description of intervention procedures is listed in section 3.6.1.

The next in-person session will occur 4 months after randomization. This is the 4-month follow-up visit. At this visit, physical measurements will be collected (i.e. height, weight, abdominal circumference, blood pressure and heart rate) and participants will complete various questionnaires. A Quality of Life questionnaire will also be administered by study personnel. A business card magnet will be given to them as a reminder of the 12 month follow up visit.

The final in-person session will occur 12 months after randomization. At this visit, physical measurements will be collected (i.e. height, weight, abdominal circumference, blood pressure and heart rate), participants will complete various questionnaires and a program evaluation. A Quality of Life questionnaire will also be administered by study personnel. A template EPR/OPR bullet will be given to them upon completion of the last data collection visit.

A total of four research-related in-person visits will be required over the 12-month span of the study. All in-person visits will occur at the HAWC and will be conducted by civilian research staff. Adverse events will be assessed at the baseline visit, follow-up visits, and via self-report during the 12-month intervention period.

Retention methods that may be used for telephone session reminders and follow up data collection visits can include: phone calls, emails, and text reminders of appointments, as well as a letter sent via encrypted email to participants from Dr. Talcott and/or Dr. Hryshko-Mullen. In addition, we will mail greeting cards to increase retention throughout the year long program. There will also be quarterly e-newsletters and retention events for all active ppts. The newsletter could include such things as tips about weight loss, inform ppts about the next retention event, a featured 5K in the community, recruitment and study updates. Ppts will be given an option to opt out of the e-newsletter. All active ppts will be invited to events related to diet and exercise. Possible events could include guest speakers, classes on healthy food preparation, gardening demonstration, guided tours at a local farmer's market or grocery store.

3.6.1. Interventions, Observations, or Data Sought:

The study will compare two modalities of implementing the successful Look AHEAD intervention. One treatment group will follow a Counselor-initiated approach, while the other group will follow a Self-paced approach.

Procedures for the Counselor-initiated intervention group:

- Individual Telephone Sessions are a main component of this study. Participants will receive 28 telephone sessions over a 12 month period by interventionists trained in behavior change skills (e.g., goal setting, problem solving, relapse prevention, stimulus control) and motivational interviewing techniques. The telephone calls will be designed to provide strategies to help participants with weight loss. Participants will receive a call once a week for the first sixteen weeks (16 calls), every other week for the next 16 weeks (8 calls), and monthly for the duration of the treatment (4 calls). Quality control will be assessed randomly by a study investigator to ensure consistency and fidelity of the intervention. Random quality control is conducted only with the participant's consent.
- Email Communication: Email will be used to provide participants with feedback and suggestions to help with weight loss.
- Self-Monitoring: Because self-monitoring has been shown to be significantly associated with weight loss, participants will be asked to monitor food intake, physical activity and weight daily. Participants will be asked to use the Lose It app/website which, with their permission, the study staff will be able to access in order to retrieve their food and physical activity information. Monitoring of weight will be facilitated by the use of the BodyTrace e-scale. Each participant will be provided a scale which will upload their daily weight to a secure website (HIPPA compliant) which our study staff can access. Participants will receive feedback on self-monitoring through e-mail.
- Dietary goals: Dietary goals will be based on weight and will be personalized based on participants' weight-loss progress and goals.
- Meal Replacements: Meal replacements will be provided to participants in the counselor-initiated group at no cost. Vouchers for meal replacement products will be given to participants to use at local grocery stores. Participants will be encouraged to replace 2 meals (typically breakfast and lunch) and a snack with meal replacements. Participants may elect not to use meal replacements. If so, detailed meal plans (for all meals) using common foods that are designed to control portion size and calories will be provided to the participant.
- Physical Activity Goals: Taking into account the amount of physical activity for each participant at the beginning of the program, participants will be asked to gradually increase their cardiorespiratory (aerobic) exercise > 5 days per week at a moderate to vigorous intensity level for 40 to 60 minutes per day (each bout lasting a minimum of 10 minutes), until they reach a total of 225-250 minutes per week. Upon reaching the physical activity goal of 225-250 minutes per week, they will be asked to maintain this level of physical activity.
- Toolbox: The Toolbox includes additional treatment options for those who wish to take advantage of them. Items may include: food scales, exercise videos, cookbooks, etc. These items may be checked out from Fit Blue staff members, but must be returned prior to the completion of the study.
- Challenge – There will be several challenges (e.g. 10,000 steps per day for 30 days, dietary self-monitoring everyday for 30 days) designed to increase participant interest and provide a specific goal (e.g. increase self-monitoring, increase activity level) during the twelve month study period. Participants who successfully complete the challenges will be given a small award (e.g. T-shirt valued at approximately \$4.34). Value of all study-related awards and incentives will not exceed \$50 annual limit/person and do not require any special approval through the Hospital Commander.

Procedures for the Self-paced intervention group:

- Individual Telephone Sessions are provided only when the participant calls the study phone line and requests a session with a counselor. Participants may receive up to 28 telephone sessions over a twelve month period by interventionists trained in behavior change skills (e.g., goal setting,

problem solving, relapse prevention, stimulus control) and motivational interviewing techniques. The telephone calls will be designed to provide strategies to help participants with weight loss. Quality control will be assessed randomly by a study investigator to ensure consistency and fidelity of the intervention. Random quality control is conducted only with the participant's consent.

- **Self-Monitoring:** Participants will be asked to monitor food intake, physical activity and weight daily. Participants will be asked to use the Lose It app/website which, with their permission, the study staff will be able to access in order to retrieve their food and physical activity information. Monitoring of weight will be facilitated by the use of the BodyTrace e-scale. Each participant will be provided a scale which will upload their daily weight to a secure website (HIPPA compliant) which our study staff can access. Participants will receive feedback, by request only, on self-monitoring through e-mail.
- **Dietary goals:** Dietary goals will be based on weight and will be personalized based on participants' weight-loss progress and goals.
- **Meal Replacements** will not be provided to self-paced participants for the study. However, participants will be encouraged to purchase their own meal replacements, although it is not required. Detailed meal plans (for all meals) using common foods that are designed to control portion size and calories will be provided to the participant.
- **Physical Activity Goals:** Taking into account the amount of physical activity for each participant at the beginning of the program, participants will be asked to gradually increase their cardiorespiratory (aerobic) exercise > 5 days 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. Upon reaching the physical activity goal of 225-250 minutes per week, they will be encouraged to maintain this level of physical activity.

3.6.2. Data Collection and Processing:

Pre-screening (via phone):

- Description of the research project
- Determine eligibility
- Collect name and contact number with oral approval by potential participants
- Schedule in-person screening visit

Screening visit (in-person):

- Confirm eligibility
- Measure weight and height
- Obtain informed consent
- Collect demographic information
- Collect contact information
- Quality of Life questionnaire (administered by study personnel)
- Complete brief dietary, physical activity, and weight-related attitudes and behavior questionnaires
- Explain the 1 to 2 week run-in: The run-in consists of two components: one week of dietary and physical activity self-monitoring and obtaining a letter from their AF healthcare provider approving participation in the intervention (by visiting their healthcare provider or utilizing MiCare, the Air Force's secure patient portal)
 - Participants will use the Lose It! web/mobile based app to collect their diet and physical activity information. Participants will be asked to provide a valid personal e-mail address to access and use Lose It!. If they do not have one or do not wish to use their current personal email address, study staff will assist them in creating a new account for the purpose of

accessing Lose It!. Materials and instruction on using Lose It! will be provided to the participants.

Baseline visit (in-person, 1-2 weeks after screening visit):

- Determine whether run-in requirements were completed
- Measure weight, abdominal circumference, resting blood pressure and resting heart rate
- Randomize participant: If all of the above are completed satisfactorily, participants will be randomized to either the Counselor-initiated intervention group or the Self-paced intervention group.
- Orientation to group assignment and study website

After randomization, participants will be upgraded to the Lose It! Premium app and added to the Fit Blue Premium account which will allow study counselors to access their dietary and physical activity logs in order to provide feedback and suggestions. It will also allow this information to be downloaded to the Fit Blue database for further analysis and tracking. In order to upgrade to the Lose It! Premium Fit Blue account, a valid email address different from that used during the screening run-in diary phase will be required. As before, if the participant does not have a second email, or does not wish to use a current personal email address to access the Lose It! Premium Fit Blue account, study staff will assist them in creating a new email account to use that will provide them with the necessary access for participation. Lose It! provides their Premium version to the University of Tennessee Health Science Center as a gift at no cost.

- Provide study materials based on group assignment, including FIT Blue participant lesson materials (for the counselor-initiated group only), Body Trace electronic scales, measuring cups and spoons, and exercise guidelines.
- Self-paced group will be given instructions on how to receive counseling from study staff if desired and a T-shirt (Counselor-initiated group given T-shirt at time of Self-Monitoring Challenge)
- Assess for adverse events
- The counselor-initiated group will be given an appointment for their first counseling session.

Follow-up visit (in-person at 4 months):

- Height, weight, abdominal circumference, resting blood pressure and resting heart rate will be measured
- Complete the dietary, physical activity, and weight-related attitudes and behavior questionnaires
- Quality of Life questionnaire (re-administered by study personnel)
- Assess for adverse events

Follow-up visit (in-person at 12 months):

- Height, weight, abdominal circumference, resting blood pressure and resting heart rate will be measured
- Complete the dietary, physical activity, and weight-related attitudes and behavior questionnaires
- Quality of Life questionnaire (re-administered by study personnel)
- Assess for adverse events
- Program evaluation
- Air Force Fitness Test scores will be collected (only for Air Force personnel) through Health Promotion personnel

Additional procedures for participants who are going to deploy/PCS/separate/retire or have an extended TDY:

- **DEPLOYED: Protocol for 4 month and 12 month data collection**

- We will ask the participant if they might be willing to receive follow-up information forms while deployed. The follow-up information would be sent via the participants' preferred email address one time, if the participant agrees.
- If the participant agrees to receive an email with attached follow-up forms while deployed, an email will be sent immediately reminding them of this approval.
- If the participant does not want to receive a follow-up email, no email will be sent.
- Communication frequency if participant agrees to continue participation in the study while deployed:
 - One email only during deployment with attached follow-up assessment forms.
- Measures:
 - Weight
 - Questionnaires if interested and able
 - Will not obtain abdominal circumference, blood pressure, and heart rate
- Method of data collection: email
 - Deployment email address will NOT be used, unless specifically requested by participant
- Will give an additional 2 week window on either side of the typical 4-week data collection window
- For those already deployed, an email will be sent giving options for treatment engagement and asking for interest/ability to provide follow-up information

- **PCS/RETIRED: Protocol for 4 month and 12 month data collection**

- If retired and in the San Antonio area:
 - Communication frequency:
 - Usual protocol
 - Measures: full data collection
 - Weight and height (on the Body Trace scale and another scale, if not in-person)
 - Questionnaires if interested
 - Abdominal circumference, blood pressure, and heart rate
 - Method of data collection: in-person (if possible); if not- phone, email, or mail (in this order)
- If not in the San Antonio area:
 - Communication frequency:
 - Usual protocol
 - Measures:
 - Weight (on the Body Trace scale and another scale)
 - Questionnaires
 - Will not obtain abdominal circumference, blood pressure, and heart rate
 - Method of data collection: phone, email, or mail (in this order)
- Will give an additional 2 week window on either side of the typical 4-week window to attempt in-person data collection

- **EXTENDED TDY: Protocol for 4 month and 12 month data collection**

- If in-person data collection is not possible:
 - Communication frequency:

- Usual protocol
- Measures:
 - Weight (on the Body Trace scale and another scale)
 - Questionnaire
 - Will not obtain abdominal circumference, blood pressure, and heart rate
- Method of data collection: phone, email, or mail (in this order)
- Will give an additional 2 week window on either side of the typical 4-week window to attempt in-person data collection

3.6.3. Setting:

Subjects will complete pre-screening via phone. The screening, baseline visit, and follow-up visits will be in-person and will take place at the Lackland AFB Health and Wellness Center (HAWC).

3.6.4. Date(s):

Participants will be involved in study related activities for twelve months from the time of enrollment.

3.6.5. Source of Research Material:

Source of Research Material per Participant (Procedures)	# Routine Care	# Research Driven	# Total Procedures
Weight	0	4	4
Height	0	3	3
Abdominal Circumference	0	3	3
Resting Blood Pressure	0	3	3
Resting Heart Rate	0	3	3
Phone screen form	0	1	1
Screening Visit Interview Questions form	0	1	1
Contact information form	0	1	1
Demographics form	0	1	1
Global Physical Activity Questionnaire (GPAQ)	0	3	3
Behavioral Questionnaire	0	3	3
Health Utility Index/Quality of Life questionnaire	0	3	3
Brief Beverage Intake Questionnaire (BEVQ-15)	0	3	3
Multifactor Screener	0	3	3
Baseline Visit Interview Questions form	0	1	1
Program Evaluation	0	1	1
Air Force Fitness Test score (AF participants only)	0	1	1
Physical Assessment Form	0	4	4

3.6.6. Subjects: Participants will be active duty military personnel currently stationed at Lackland AFB.

3.6.7. Inclusion/Exclusion Criteria:

Inclusion: Age > 18 years, with a BMI > 25 kg/m², and with clearance from a military healthcare provider for participation in the study.

Exclusion (determined using pre-screening questionnaire):

1. Uncontrolled hypertension defined as BP \geq 140/90
2. Disability or condition that would limit regular aerobic physical activity

3. Current use of weight loss medication or other medication/supplement that influences weight
4. History of cerebral, coronary, peripheral vascular disease, or uncontrolled cardiac arrhythmia
5. History of uncontrolled congestive heart failure in last 12 months
6. History of significant kidney or liver disease
7. History of uncontrolled thyroid disease or pheochromocytoma
8. Malignancy in last 5 years (does not include non-melanoma skin cancer)
9. History of diabetes mellitus treated with a medication that could cause hypoglycemia
10. Current pregnancy status, child birth within the last 6 months, breastfeeding for less than 6 months postpartum, or planning to become pregnant during the study follow-up time (12 months)
11. Presence of unstable, emotional or psychiatric condition (depression; schizophrenia)
12. Severe bronchitis or emphysema that precludes exercise
13. History of bariatric surgery or history of significant recent weight loss (> 10 pounds in the past 3 months)
14. Scheduled extended leave away from the San Antonio area in the next 13 months (i.e. planned PCS/Deployment/extended TDY greater than 30 days)
15. No computer access for self-monitoring using Lose It! and for email feedback from counselor
16. More than one failure of the military-proctored physical fitness test in the last 12 months based on AFI 36-2905 (3 Aug 2010), "Fitness Program."
17. A military member of the same household is already a FIT Blue study participant
18. Any medical condition or medication that could increase or decrease weight loss that might result from the proposed intervention protocol
19. 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

3.6.8. Instrumentation:

Phone screen form (during Pre-screening phone call) – Includes name and contact number for scheduling screening visit and eligibility criteria

Screening Visit Interview Questions form (at preliminary screening visit) – aimed at learning about subject's thoughts/feelings concerning weight loss, how much weight they'd like to lose, and readiness for weight loss

Baseline Visit Interview Questions form (at baseline visit) – aimed at learning about subject's thoughts/feelings concerning aspects of their participation thus far

Contact information form (at screening visit) - used to collect and update pertinent contact information

Demographics form (at screening visit) – used to collect pertinent demographic data

Physical Assessment Form (at screening, baseline and follow-up visits) – used to capture weight, height, abdominal circumference, heart rate and blood pressure

Global Physical Activity Questionnaire (GPAQ) (at screening and follow-up visits) – will capture current levels of physical activity of various types and the amount of sedentary behavior

Behavioral Questionnaire (at screening and follow-up visits) – includes descriptive questions related to attitudes and behaviors associated with weighing, dietary behaviors, sleep, and weight loss

Health Utility Index/Quality of Life questionnaire (at screening and follow-up visits) – assesses health status and quality of life

Brief Beverage Intake Questionnaire (BEVQ-15) (at screening and follow-up visits) – brief 15-item assessment of types/amounts of beverage intake over the past month

Multifactor Screener (at screening and follow-up visits) – a rapid assessment of approximate intakes of fruits and vegetables, percentage energy from fat, and fiber

Program Evaluation (at 12-month follow-up visit) - includes questions about the participants' perspectives on the helpfulness of various program components and the participants' recommendations for program modifications

Air Force Fitness Test Scores (AF personnel Only) (at the 12-month follow-up visit)

4.0. Human Subject Protection:

4.1. Recruitment:

Participants will be recruited through advertisements at the Base Health and Wellness Center (HAWC) and other locations on Lackland AFB. We plan to use flyers, business cards, posters, newspaper, word-of-mouth, and electronic advertisements in base bulletins. Advertisements will include a phone number and Fit Blue website by which to reach study personnel for more information.

4.2. Consent Processes:

No study specific procedures will be performed without a written and signed informed consent document and HIPAA Authorization. Participants who do not demonstrate the ability to understand or the willingness to sign the written informed consent document will be excluded from study entry.

4.3 Participation Compensation: Subjects will not be paid for participation in this study.

4.4. Assent Process: N/A

4.5. Benefits:

Both study interventions (Counselor-initiated and Self-paced) may produce weight loss. Participants in both intervention groups may increase their knowledge about healthy eating and physical activity. Participants in both intervention groups will receive a complementary Fit Blue T-shirt. The gift of a T-shirt (at baseline visit for self-paced and after a challenge is met for counselor-initiated) is within the monetary allowance for gifts to military members and does not require Hospital Commander approval. However, there is no guarantee or promise of direct benefit for subjects participating in the study.

4.6. Risks:

All study procedures involve only minimal risks to subjects. Since regular exercise will be encouraged, some people may experience some muscle soreness. There are no major risks associated with taking measurements (height, weight, waist circumference, and blood pressure), taking a health history or

collecting questionnaire data. There is, however, the potential risk of loss of confidentiality. Being a part of this study while pregnant may expose the unborn child to significant risks, therefore, pregnant women will be excluded from the study. Women who become pregnant during the course of the study will be withdrawn from the study and referred to their doctor for medical care. Although, we do not anticipate that any study related procedures would increase a participant's risk of suffering from emotional distress or having thoughts of suicide, study procedures are in place so that research staff can respond appropriately if this should occur (see section 4.9 for description of Study Procedures for Distressed Participants).

4.7. Costs: N/A

4.8. Safeguards for Protecting Information

The research consents will be stored in a locked cabinet in a locked room. All research data including patient demographics will be kept in an electronic database, which will be encrypted, double password protected and the access will be restricted. The research data will be de-identified and any links to identifiable data will be destroyed as soon as possible. The research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval.

Other study related documents will also be stored in a locked cabinet in a locked room. In addition, this research data will be scanned into an electronic database at UTHSC via a secure connection using Cisco VPN client. The data will be encrypted, double password protected, and access will be restricted. The research database will be managed and maintained at UTHSC. Upon completion of the study protocol, UTHSC will destroy paper forms and links.

4.9. Safeguards for Protecting Subjects:

The principal investigator will be responsible for the protocol safety monitoring. The PI will make study documents readily available for inspection by the local IRB and oversight staff for confirmation of the study data.

Note: A Data Safety Monitoring Plan (DSMP) has been developed for this study (see attached).

Study procedures for distressed participants were developed for research staff to follow in the event that a participant is suffering from emotional distress or having thoughts of suicide.

Several precautions have been taken to both limit the likelihood of participants suffering from a significant psychological event and in the unlikely event that one occurs, we have established appropriate steps for the Counselor to follow in order to get the participant help.

A. PRESCREENING FOR DISTRESS

1. All prospective participants are pre-screened by a military medical provider who both screens the participants in person and reviews their electronic medical record. Specifically, all prospective participants are asked whether they have any, "Emotional or psychiatric conditions (depression, schizophrenia)" asked on the *Fit Blue Research Project Medical Clearance Form*.
2. Additionally, every prospective participant is asked prior to randomization and every enrolled participant is asked at each follow-up data collection visit the following distress-related questions from the *Health Utilities Index (HUI)*, a quality of life measure, in a Counselor-administered interview:

“33. Would you describe yourself as having felt:”

- a) Somewhat unhappy***
- b) Very unhappy***
- c) So unhappy that life was not worthwhile?***
- ___ Don't know***
- ___ Refused***

“35. How often did you feel fretful, angry, irritable, anxious or depressed?”

- a) Rarely***
- b) Occasionally***
- c) Often***
- d) Almost always***
- ___ Don't know***
- ___ Refused***

“36. During the past four weeks, did you feel extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help?”

- a) Yes***
- b) No***
- ___ Don't know***
- ___ Refused***

3. If any of the following responses are endorsed by the prospective/enrolled participant, the Counselor will (after completing the full Health Utilities Index interview) probe briefly for more information about the circumstances of their distress, including potential suicidality.
 - a. Critical responses include:
 - 1) Item 33 responses b (“very unhappy”) and c (“so unhappy that life was not worthwhile”)
 - 2) Item 35 responses c (“often”) and d (“almost always”)
 - 3) Item 36 response a (“yes”)
 - b. Counselor will ask whether the participant has a plan to harm his/herself (to act on his/her suicidal thoughts):
 - 1) Do you have thoughts about suicide?
 - 2) If yes, do you have a plan to hurt yourself?

B. PROCEDURES FOR PARTICIPANT DISTRESS

1. MILD TO MODERATE DISTRESS

- a. If the participant reports mild to moderate stress (but no suicidal thoughts or morbid ideations such as thoughts of wanting to be dead), the participant will be provided a listing of community resources and encouraged to seek help.
- b. Counselor will help the participant develop an action plan to be seen by a mental health professional should their distress persist over multiple sessions or worsen.
- c. Counselor will document the conversation and support materials provided.
- d. Continued distress without professional assistance and support can be a reason to temporarily or permanently withdraw the participant from the **Fit Blue** Weight Loss Intervention protocol.

2. **SEVERE DISTRESS AND SUICIDE IDEATIONS WITH NO INTENT OR PLAN** Participant reports suicidal thoughts but no intent or plan.
 - a. Counselor will develop an action plan to get help from a mental health professional. This conversation with the participant and the action plan will be documented.
 - b. Counselor will follow-up in two business days to ensure that the participant has an appointment with mental health scheduled.
 - c. Counselor will also inform the participant that if their condition worsens the following emergency resources are available:
 - 1) Mental Health Clinic (open for Walk-Ins during duty hours: 210-292-7361)
 - 2) SAMMC ED: 210-916-0808
 - 3) Crisis Hotline call: 1-800-273-TALK
3. **SEVERE DISTRESS AND SUICIDAL IDEATION WITH INTENT OR PLAN**
 - a. Participant reports suicidal thoughts and intent or plan.
 - b. Once a participant endorses suicidal intent they are not to be left alone.
 - c. Whether the Counselor – Participant contact is by phone or in-person, the Counselor will attempt to maintain contact with the participant, identify the location of the Participant and maintain verbal contact until help arrives.
 - d. Counselor will contact another staff member and indicate they have an emergency and direct them to call 911 (Lackland Command Post: 210-671-4225; Security Forces: 210-671-3030; Ambulance: 210-292-7331) and provide an address.
 - e. Counselor will document the conversation with the prospective participant and all actions taken.

4.9.1. Minimizing Risks:

This study follows evidence-based lifestyle recommendations for weight loss and improving health, including diet change and regular exercise. If followed according to program guidelines, no adverse medical conditions are expected to result from the research activities.

There are no major risks associated with taking measurements (i.e. height, weight, blood pressure, and waist circumference), taking a health history or collecting questionnaire data. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep participant information confidential as described in Section 4.8. In the event that questions asked make participants feel uncomfortable, they may refuse to answer and may take a break at any time during a study visit. However, we are not collecting any information that would in any way jeopardize participants' careers in the Air Force.

Being a part of this study while pregnant may expose the unborn child to significant risks. Therefore, pregnant women will be excluded from the study. Women who are able to become pregnant will be asked if they are pregnant at enrollment and each follow-up visit. Women who become pregnant during the course of the study will be withdrawn from the study and referred to their doctor for medical care. Women may breast feed while participating in this study so long as they have continuously breast fed for at least six months postpartum prior to entering the study.

The research may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

Any significant new findings developed during the course of this research project, which may impact upon the safety and efficacy of the procedure or treatment under study and consequently influence participants' willingness to continue participation, will be provided to them.

4.9.2. Vulnerable Populations: N/A

4.9.3. Clinical Care:

As all participants will be active duty military members, medical care (if needed) is provided at no cost through their Military Treatment Facility (MTF).

4.9.4. Injury Compensation: N/A

4.9.5. Data Safety Monitoring:

The trial will be conducted in compliance with this protocol, International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), and any applicable national and international regulatory requirements. The principal and associate investigators will be monitoring all aspects of the study in accordance with the appropriate regulations in order to:

- 1) Ensure protection of study subjects, compliance with the protocol, and accuracy and completeness of records.
- 2) Verify the prompt reporting of all data points, including reporting Serious Adverse Events (SAEs) and checking availability of signed informed consent,

The principal investigator will be responsible for the protocol safety monitoring. The PI will make study documents readily available for inspection by the local IRB and oversight staff for confirmation of the study data.

Note: A Data Safety Monitoring Plan (DSMP) has been developed for this study (see attached).

5.0. Alternatives:

Alternatives include not participating in the study, consulting with their Primary Care Provider (PCP) or Health and Wellness Center dietary/exercise experts to assist them with weight loss efforts, joining a private weight loss program not affiliated with the military, or self-monitoring of dietary intake and physical activity to achieve weight loss. Meal replacements may also be bought at local stores.

6.0. Data Analysis:

We will analyze changes in BMI and abdominal circumference, as well as data pertaining to dietary intake and physical activity from baseline, 4-month follow-up, and 12-month follow-up.

6.1. Outcome Measures:

The primary outcome is percentage of weight loss. Secondary outcomes are abdominal circumference, BMI, and self-reported dietary intake and physical activity. Dietary intake will be measured by the Multifactor Screener and the Beverage Intake Questionnaire (BEVQ-15) and physical activity will be measured by the Global Physical Activity Questionnaire (GPAQ). Attitudes and behaviors associated with weighing, dietary behaviors, sleep, and weight loss will be measured using descriptive questions.

Participants will be monitored for excessive weight loss (> 12 pounds per month) and a DSMP has been established that outlines plans for monitoring adverse events and excessive drop-outs.

6.2. Sample size estimation/power analysis:

The study aims to enroll 248 participants, 124 participants in each group. This distribution will provide a diverse representation within each intervention group and will provide the necessary information for data and power analysis.

6.3. Statistical Analysis:

The primary data analysis will adhere to the intention-to-treat principle and in the final analysis, the participants will be categorized according to their initial randomization. We will be using the baseline weight as a covariate in the final primary model where we compare the two arms in terms of the percentage of weight loss. We also plan to carry out secondary analyses where we will investigate the efficacy of the intervention in subgroups of Airmen based on gender, race, and years of service in the Armed Forces. We will also evaluate the impact of adherence on outcome, whether it is number of intervention sessions completed, or adherence to dietary intake and physical activity recommendations. Finally, we'll determine the prevalence of Adverse Events and Serious Adverse Events in the two treatment conditions.

6.4 Number of Subjects:

Number of subjects planned for WHASC	Enrolled in full study	248	to result in	248	completing the full study.
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TOTAL NUMBER OF SUBJECTS (nation-wide/study-wide): 248

7. Duration of Study: Approximate duration of the study: 54 months

8. Local and External Support Services:

A letter of support from the 559th Medical Group Commander (559 MDG/CC) is attached. The Health and Wellness Center on Lackland AFB will also provide work space for three study staff members as well as for participant visits/follow ups.

9. Intramural (GME) and Extramural Funding Support:

The National Institute of Diabetes and Digestive and Kidney Diseases provided extramural funding for this study.

10. Conflict of Interest:

If you or any investigator participating in the repository has, or anticipates having, any income from or financial interest in: the sponsor of the repository protocol, the supporting organization, or the company that owns/licenses the technology being studied, contact the WHASC IRB. A *“Conflict of interest exists if an employee’s position or authority may be used to influence or make decisions that lead to any form of financial or personal gain for that employee or for his or her family which includes spouse or dependent children.”*

[NOTE: A conflict of interest or even the appearance of conflict calls into question the judgment or actions of the investigator in areas that affect the rights and welfare of research subjects and the integrity of the research process. At its worst, conflict of interest may endanger lives, e.g., not only those of the immediate research subjects under study, but those of future patients treated on the basis of biased research results.]

a. Financial Conflict of Interest: None

b. Personal Conflict of Interest: None

c. Current Off-Duty Employment: None

11. Use of an Investigational New Drug, use of a Drug for a non-FDA approved purpose, use of an investigative device or use of a placebo:

This research uses an Investigational New Drug

☐ YES ☒ NO

This research uses a FDA approved drug for a non-FDA approved purpose

☐ YES ☒ NO

This research uses an Investigational Device

☐ YES ☒ NO

This research uses a placebo.

☐ YES ☒ NO

12. Medical Research Area for the Study: (Pick as many as appropriate)

<input type="checkbox"/> Analytical Chemistry	<input type="checkbox"/> Anatomy	<input type="checkbox"/> Anesthesiology	<input type="checkbox"/> Biochemistry
<input type="checkbox"/> Cardiovascular Surgery	<input type="checkbox"/> Cardiology	<input type="checkbox"/> Cell Biology	<input type="checkbox"/> Dentistry
<input type="checkbox"/> Dermatology	<input type="checkbox"/> Dietetics	<input type="checkbox"/> Electrophysiology	<input type="checkbox"/> Endocrinology
<input type="checkbox"/> Emergency medicine	<input type="checkbox"/> Gastroenterology	<input type="checkbox"/> General Surgery	<input type="checkbox"/> Hematology
<input type="checkbox"/> Histology	<input type="checkbox"/> Immunology/Allergy	<input type="checkbox"/> Infectious Disease	<input type="checkbox"/> Microbiology
<input type="checkbox"/> Molecular Biology	<input type="checkbox"/> Neonatology	<input type="checkbox"/> Neurology	<input type="checkbox"/> Neurosurgery
<input type="checkbox"/> Nursing	<input type="checkbox"/> OB/GYN	<input type="checkbox"/> Occupational Medicine	<input type="checkbox"/> Occupational Therapy
<input type="checkbox"/> Oncology	<input type="checkbox"/> Ophthalmology	<input type="checkbox"/> Oral/Maxillofacial Surgery	<input type="checkbox"/> Orthopedics
<input type="checkbox"/> Pathology	<input type="checkbox"/> Pediatrics	<input type="checkbox"/> Pharmacology	<input type="checkbox"/> Physical Therapy
<input type="checkbox"/> Mental Health	<input type="checkbox"/> Radiology/Imaging	<input type="checkbox"/> Urology	<input checked="" type="checkbox"/> Wellness
<input checked="" type="checkbox"/> Other (state): Prevention, Behavioral			

13. Attachments:

1. Certificates of Compliance
2. Informed Consent Document
3. HIPAA Authorization Document
4. Letter of Support - 559 MDG/CC
5. Letter of Support- HAWC
6. Extramural Funding Support Document
7. Medical Clearance Letter
8. Phone pre-screen form
9. Screening Visit Interview Questions form
10. Baseline Visit Interview Questions form
11. Contact information form
12. Demographics form
13. Physical Assessment Form (screening, baseline & follow-up visits)
14. Global Physical Activity Questionnaire (GPAQ)
15. Behavioral Questionnaire
16. Health Utility Index/Quality of Life questionnaire
17. Brief Beverage Intake Questionnaire (BEVQ-15)
18. Multifactor Screener
19. Program Evaluation
20. Counselor-initiated Program Participant Lessons
21. Self-paced Program Participant Lessons
22. Recruitment flyer/poster design
23. Recruitment electronic/newspaper advertisement
24. Recruitment business card
25. Data Safety Monitoring Plan (DSMP)

14.0. Signature Section

14.1. 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 all applicable organizational, service, DoD and Federal regulations, and all applicable FDA and HHS guidelines. I will notify the protocol office **prior** to PCS/separations actions, or closure.

Dr. Ann Hryshko-Mullen, PhD, GS-13
Printed Name of Principal Investigator

Signature of Principal Investigator

Date_____

14.2. PI's Flight Commander or Department Chair Coordination (WHASC)

I have considered this protocol and the personnel and resource support involved. I find this protocol to have sufficient scientific merit for consideration by the Squadron Commander and Institutional Review Board Designee.

Printed Name of Flight Commander or Department Chair or Program director (WHASC)

Signature block of Flight Commander or Department Chair or Program director (WHASC) Date_____

14.3. PI's Squadron Commander (WHASC)

After consideration of this protocol, I find it to have sufficient scientific merit and I approve squadron personnel and resource support, as needed. I understand that I will be the point of contact for correction of deficiencies should the principal investigator fail to meet his/her obligations.

Printed Name of Squadron Commander or Department Chair (WHASC)

Signature block of Squadron Commander or Department Chair (WHASC) Date_____

14.4. Joint Study. N/A