TUFTS MEDICAL CENTER
TUFTS UNIVERSITY
Energy Metabolism Laboratory- Jean Mayer USDA HNRCA at Tufts University

INFORMED CONSENT FOR DEPENDENTS OF ACTIVE DUTY OR RETIRED MILITARY PERSONNEL TO PARTICIPATE IN RESEARCH

Interventions for sustainable weight loss in military families: The Healthy Families Healthy Forces Study

Principal Investigator:
Susan Roberts (Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University)

Co-Investigators:
Sai Krupa Das, Cheryl Gilhooly, Alice Lichtenstein, Gail Rogers and Edward Saltzman (Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University); Anastassios Pittas (Tufts Medical Center); Scott Montain, LTC Renee Cole and Adrienne Hatch (U.S. Army Research Institute of Environmental Medicine (USARIEM); LTC Asma Bukhari (Walter Reed National Military Medical Center)

Study Physician:
Edward Saltzman, MD (Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University)

Study team telephone number: (617) 556-3143

Study Sponsor: This study is being sponsored by the U.S. Department of Defense (DoD).

INTRODUCTION

You are being invited to take part in a 2-year research study testing two weight loss programs in adult dependents of active duty (AD) or retired military personnel. The term "**AD or retired military personnel"** refers to the Active Duty or Retired Military Person living in your household. Your participation in this study will help determine how well these weight management programs work for weight loss and heath in adult dependents of AD or retired military personnel. It is anticipated that participation in the study will help you make healthy lifestyle changes that will improve your weight and health, as well as the weight and health of other members in your household.

Taking part in this research study is your choice. You can decide to refuse to participate in this study or to stop taking part in this study at any time for any reason. However, the purpose of the study is to compare the two weight loss programs including drop-outs over 2 years. Therefore, in order to enroll in the study you are required to continue the research measurements (body weight,

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health and questionnaires) for the full 2-year study even if you drop out of your weight loss group. Refusing to participate in the study or deciding to stop being in this research study or to stop coming to weight loss groups, will not affect your care or treatment outside this study, payment for your health care or your health care benefits.

We ask that you follow the directions to the best of your ability. If you are unable to do so, or the researchers feel it is best for you to leave the study, the researchers may end your participation in the study even though you might like to continue. The researchers may have to withdraw you from the study if you become ill or injured during the research. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate. The investigator will make the decision and let you know if it is not possible for you to continue. Your withdrawal will not jeopardize the relationship of you or your family members with US Government or military.

Please read all of the following information carefully. Ask Dr. Roberts or her representative, to explain any words, terms, or sections that are unclear to you. Ask any questions that you have about this research study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.

New things might be learned during this study that you should know about. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you are eligible to participate and agree to be in the study, the Principal Investigator, Dr. Roberts, may still choose to stop your participation in this study if she thinks it is in your best medical interest. You may be withdrawn from the study due to safety concerns. If the investigators see that the weight loss program is harmful to your health (ex: causes too much weight loss) you will be contacted immediately. If you separate from your AD or retired military sponsor and you choose to continue in the program, arrangements will be made for you to continue participation. If you relocate out of the area arrangements will be made so that you can continue participation in the study via telephone, internet meetings and/or email. You will also be provided with a Wi-Fi scale so that the study team can continue to track your weight measurements and since most of the questionnaires are online, you can do them using your computer from any location.

As a participant in this study, your identity, and data relating to this study will be kept confidential, except as required by law.

If you have questions about your rights as a research study subject, study complaints or any other related questions, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512 or contact the USARIEM Office of Research

Quality and Complianceat (508) 233-6306 or usarmy.natick.medcom-usariem.list.usariem-rqc@mail.mil. The IRB is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.

This research study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences and U.S Army Medical Research and Material Command Human Research Protection Office and the Headquarters U.S. Army Medical Research and Material Command (HQ USAMRMC) IRB.

CONFLICT OF INTEREST

Co-Investigator, Dr. Susan Roberts, is a part owner and the Chief Scientific Advisor of iDiet, a behavioral weight loss program. Some of the other researchers involved in this clinical trial have had in the past or have current employment affiliation with iDiet. Therefore, Dr. Roberts is making this disclosure and will not access or personally analyze the original data being collected in this study, and will not be responsible for any conclusions drawn regarding the effects of iDiet on weight change. iDiet does not receive direct monetary compensation in this trial.

PURPOSE OF STUDY

Obesity and overweight are important health concerns in the United States generally, including in AD or retired military personnel and their family members. This study will test the long-term effects of two weight loss programs, The Tufts Healthy Weight for Living program and the Current Best Practice program, in adult dependents of AD or retired military personnel.

You will be the primary person who participates in one of the weight loss programs that is being offered. However, we will also invite your AD or retired military personnel to some program meetings and to have measurements of body weight and health made to study the benefits of the programs for family members.

Both weight loss programs are made up of similar levels of participation and will involve group classes for education and support on food, activity and behavior changes that can help you lose weight and maintain weight loss. These will include menu planning, grocery shopping, making healthy choices and using recipes and menus provided by the study team. Self-monitoring of weight, diet and activity will also be part of the weight loss programs.

Both programs have the same goal of helping you lose weight and use a combination of recognized strategies to help you achieve this goal. In particular both programs help you achieve a balance between what you eat and how physically active you are. This balance allows for more calories expended than consumed, with the result that body fat and weight will be lost as you adhere to the recommendations. Both programs also set a recommended pace of weight loss of one to two pounds per week and ask you to weigh yourself regularly to achieve that. You will be taught healthy food guidelines, and provided with menus and recipes that you can use. You will also have a physical activity goal to reach and maintain two and half hours of moderate physical

activity (such as brisk walking) per week. Differences between the two programs will relate to types of carbohydrates recommended as part of your diet, dietary protein and fiber levels, and whether you are taught behavioral strategies such as mindful eating.

To assess how well the programs work we will measure your body weight at intervals, as well as take small blood samples and ask you to complete questionnaires on eating habits, activity, psychology and other factors relevant to weight control. It is anticipated that changes in your weight and health will also benefit the AD or retired military personnel and other family members who live with you.

The study will be done at the following locations:

- Natick Soldier Systems Center (NSSC), 15 Kansas Street, Natick, MA 017160
- U.S. Coast Guard First District, 427 Commercial Street, Boston, MA 02109
- U.S. Army Garrison Fort Devens, 31 Quebec Street, Devens MA 01434
- Hanscom Air Force Base, 20 Schilling Circle, Hanscom Air Force Base, MA 01731
- U.S. Coast Guard Cape Cod Area Units, 5215 East Hospital Road, Buzzards Bay MA 02542
- Fort Drum, Fort Drum New York, 13620
- Navy Recruiting District New England, 495 Summer Street, Boston, MA 02210
- Fort Carson MEDDAC 1650 Cochrane Circle, Fort Carson, CO 80913
- Fort Campbell, 2601 Indiana Ave., Fort Campbell, KY 42223
- Naval Submarine base New London, Box 00, BLDG 86, Suite 210 Groton, CT 06349-5000

290 adult dependents of active duty or retired military personnel will be recruited at the above locations. If more installations are added for enrollment, we will expand the study sites to these locations.

PROCEDURES TO BE FOLLOWED

You will be enrolled in this study as a participant for a period of 2 years (24 months). After the completion of the baseline (initial) visit, you will be randomly assigned to one of two weight loss programs for the next 24 months. By "random", using a procedure, like flipping a coin, a computer program assigns you to one of the groups. Neither you nor any of the study staff members (including Dr. Roberts) can select the group you will be in.

If you wish to be assigned to a group with your friend so that you both enter the same group, you should let the investigators know before the group assignments are made. For this option to be available to you, both you and your friend should enroll in the study at the same time so you can be in the same draw for the group to which you are assigned.

You may be able to continue participating in this study if you move away from one of the above listed locations after enrollment.

Weight Loss Program

Both weight loss programs have shown an average weight loss in studies done before, will consist of similar levels of participation, and will involve education and support on dietary and behavior changes that are required to help you lose and maintain weight. The main difference between the programs is what types of food are suggested: one diet is higher in protein and fiber, while the other diet focuses on low calorie foods. The two weight loss programs will be delivered as a group program by trained experts with experience in nutrition and weight loss counseling. The group meetings will be held at the military installations or via web conferencing at convenient times weekly initially, decreasing to every other week, and then monthly over time with additional booster sessions as needed and on a seasonal basis. Regular attendance is expected, each group session will take approximately one hour and there will be provided materials such as menus, recipes, handouts and activity monitors, and some food samples. You may also have a weekly check in with the counselor either in person or by email. You will be requested to weigh yourself daily throughout the study, as well as do food and activity logs for some study periods (see below), and send records to your counselor at specified intervals. These activities are expected to take about 35 minutes weekly in addition to the group meetings.

There is a small exercise component in both weight loss programs that will include recommendations to slowly increase your physical activity time up to 2.5 hours per week. Examples of physical activity include brisk walking, lifestyle changes, and resistance training. You will be asked to complete/obtain a provided physician clearance form that permits you to engage in exercise on your own in order to participate in the weight loss programs. Although we do not anticipate any safety concerns, if you do not complete this form, participation in the physical activity recommendations is at your own risk.

All group sessions in both weight loss programs will be audio- recorded. A random selection of recordings will be reviewed by a study investigator to ensure that the weight loss programs are being delivered as intended. All audio-recordings will be uploaded to a secure, password protected computer, which only study investigators will have access to.

In addition, the following measurements will be made by study staff at time points specified:

Body Weight: (Baseline, months 6, 12, 24) (No more than 5 minutes)
You will be asked to remove your shoes and outer-garments (jacket and uniform) to empty your pockets, and step on a calibrated scale to measure your weight at each time point. This will be done twice at each time point for accuracy. You will be asked to remain fasted for eight hours before the weight measurements. Fasting entails not consuming any food or liquid after midnight prior to your scheduled appointment. Consumption of water will be allowed. During the intervention you may be weighed at the beginning of each session by a study member, but will not need to be fasted for these measurements.

Body Fat: (Baseline, months 6, 12, 24) (5 minutes)
You will be asked to remove your shoes and outer-garments (jacket or heavy uniform) and to empty your pockets and step on a calibrated scale to measure your body fat at each time point. This will be done twice at each time point for accuracy. The scale uses a very low and harmless

electrical current to measure the opposition your body presents to its passage, and provides an estimate of body fat percentage. You will be asked to remain fasted for eight hours prior to body fat measurements. Fasting entails not consuming any food or liquid after midnight prior to your scheduled appointment. Consumption of water will be allowed.

Height: (Baseline) (5 minutes)
You will be asked to remove your shoes for measurement of your height using a vertical tape measure that is attached to a post. You will be asked to stand upright and the study staff may ensure that this position is accurate so that a good measurement of your height is obtained. This will be done twice at the baseline time point for accuracy.

Waist Circumference: (Baseline, months 6, 12, 24) (No more than 5 Minutes)
Using a tape measure the size around the middle of your waist will be taken by trained study staff. This will be done twice at each time point for accuracy.

24 hour food recalls: (Baseline, during months 3-6, and during months 18-24). (30-40 Minutes)
A study team member will call you to ask you what you ate in the past 24-hours. You will be asked to provide a detailed description of the type and amount of food eaten including the time at which the food item was consumed and related details. The dietitian will ask you many questions to make sure that the recall is complete and an accurate list of all foods eaten in the past day is recorded. This assessment will be repeated three times at each time point in the study for a total of 9 recalls.

Blood Tests: (Baseline, months 6, and 24) (15 minutes)
Blood will be drawn by trained personnel from the study team for measurements including cholesterol, triglyceride and blood glucose levels. These measurements will be taken to look at the weight loss programs effects on heart disease risk factors. About 2 tablespoons (30 ml) of blood will be drawn during each testing time period. You will be asked to remain fasted prior to blood tests, and refrain from physical activity for 24 hours prior to blood tests. Fasting entails not consuming any food or liquid after midnight prior to your scheduled blood test. Consumption of water will be allowed.

Blood Pressure: (Baseline, months 6, 12, and 24) (10 minutes)
Measurements of your blood pressure will be taken by trained personnel after fifteen minutes of quiet sitting. This will be done three times at each time point for accuracy, or more if needed to obtain a stable reading. These measurements will help us determine improvements in your health and bodily functions. You will be asked to remain fasted prior to blood pressure measurements.

***Food, Physical Activity and Weight Logging*:** (Self monitoring tool) (5 minutes daily)
You will be given a small step counter to monitor your activity levels, which you will be encouraged to wear regularly during the study, and a log book to record your steps. You will also be given a log book to record what food you eat. These activities are optional but you will be encouraged to complete them regularly throughout the study. In addition you will be given a log for recording your weight daily. The weight logs will either be sent or emailed to investigators

weekly so they can track your weight changes or you will store your de-identified data on the internet and allow investigators to access that data to monitor changes.

Questionnaires: (Up to 2 hours total at baseline, 6, 12 and 24 months, but can be done in parts) At the beginning of the study, you will be asked to do a questionnaire including questions on age, gender, your employment, AD military sponsor employment, family size and structure, race/ethnicity, and location of AD military sponsor, which will be updated as needed throughout the study. In addition you will be asked to complete questionnaires on eating behaviors, social support, stress, sleep, physical activity, general health, quality of life, depression, circadian rhythms and any adverse events you may experience. You will complete these questionnaires either on the web or a paper copy. You will be allowed to skip questions you are not comfortable answering. However, if you choose to skip certain questions, the researchers may not be able to score your responses. You will be asked to complete these questionnaires 2-3 hours after eating in the morning.

Supermarket receipts (Baseline, month 6, month 24): You will be asked to provide receipts for all purchased food for household (including supermarkets, convenience stores, restaurants) for a designated 2 week period at each time point. This will allow us to track changes in your food choices.

Permanent Change of Station & Relocating

If you move away from one of the above listed locations, you will be able to continue participation in your online group weight loss classes as normal. If your new location provides a challenge to meet with your regular weight loss class, please notify your counselor who will work with you to seek out possible accommodations.

If relocated, it will not be requested nor required of you to travel to your original military installation where you began the study for the 6, 12, and 24 month outcomes events as described above. At those designated time points, the study team will ask you to utilize your remote scale provided at the beginning of the study to provide your body weight. Additionally, it will be asked of you to complete all online questionnaires and dietary recalls.

If interested, you will have the opportunity to voluntarily submit your physical results obtained from your healthcare provider to the study team (body weight, blood pressure, and bloodwork) at the designated 6, 12, and 24 month events as part of the remote outcomes process. Bloodwork only needs to be submitted at 6 and 24 months, but body weight and blood pressure will be submitted at 6, 12, and 24 months. Please notify a member of the study team when you are aware of your relocation date and they will provide you with the possible options to stay involved in the study. The study team will provide you with an informational packet which outlines the instructions for this process. Included in this packet will be instructions on how you will submit information obtained through your healthcare provider back to our study team. Please contact a member of the study team if you have any questions on this process.
If you are unable to schedule an appointment with your provider within the date range requested,

then your information which would have been obtained at the healthcare provider's office for that outcomes timepoint will not be needed. Please be aware that you will incur all costs associated with having physical measurements performed by your healthcare provider. You will not receive reimbursement or additional stipends outside those that you receive for participation in the study as normal. If you choose not to seek out your healthcare provider, you will not be penalized in any fashion and will still be allowed to participate in your group weight loss class as normal.

RISKS

Although weight loss is expected on average for those who follow the programs, weight loss and prevention of weight regain are not guaranteed. If you choose to have blood tests performed, there is a slight chance that you may have pain, light-headedness, bleeding or bruising at the site of blood collection; however the staff will use proper technique while taking blood samples in order to reduce the risk of these unwanted effects. You may feel hungry or weak during the times you are required to fast before blood tests and weight measurements. You may experience temporary discomfort during blood pressure recordings due to the pressure of the cuff on your arm. In addition, bloating, intestinal gas, or diarrhea have occasionally been reported with a change to a very high fiber diet. There is risk of allergies or adverse reactions to changes in your food choices. Although it is not anticipated, there is a small risk of physical injury, shortness of breath and fatigue while participating in the recommended physical activity. However, these risks are minimal. Precautions will be followed by staff to reduce unwanted effects. Loss of confidentiality is a risk in a group weight loss setting if you share personal information in group sessions that is then shared by other group members. Group members are expected to not share the personal information of other people in their group. However, you should not share anything in the group setting that you would not want other group members or others outside the group to know.

Some questionnaires include questions related to eating behaviors, weight control strategies, mood and other similar topics. You may refuse to answer questions that cause you anxiety. Your responses to the research questions will not be linked to your identity and the information will be protected and kept confidential.

In addition to the risks listed above, you may experience a previously unknown risk or side effect. Continuous monitoring by the investigators will minimize potential risks and discomforts. If you are a woman, and miss a menstrual cycle (period) during the study, you should notify the investigator(s). If you are pregnant, or intend to become pregnant during the study, you should not participate in the study. You must notify the investigator(s) immediately if you learn you have become pregnant during the study. When you begin the study, you will be provided an adverse event log, in which you will track changes in health, occurrence of illness, hospitalizations, injuries, and any expected or unexpected medical events. Instructions for the log will be provided when you receive it. The log will be reviewed weekly by the study team and physician.

The major potential risk associated with the study is that the security of your identity may be exposed due to reasons beyond the control of the study staff and your confidentiality may no

longer be intact. Since all your information is stored without any identifiers and precautions are in place for data security, this risk is also minimal.

BENEFITS
Your participation in the study may help you lose weight and avoid weight regain. By participating in the study, you will also learn about healthy eating practices. Any resulting weight loss may also improve other health conditions like blood pressure, blood sugar levels, cholesterol levels etc. It is anticipated that other members of your family, including your AD or retired military sponsor, will also benefit from these programs via your direct participation. In addition, your participation will help researchers identify effective means for weight control in military personnel and their families.

ALTERNATIVES
The alternative to participation in this study is to not participate. Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time. There will be no penalty or loss of benefits to which you are otherwise entitled.

WHOM TO CONTACT
In case you have any problems or questions, you may contact the Principal Investigator or Co-Investigators. Their contact details are listed below

Susan Roberts, Principal Investigator
(617)556-3238
Susan.Roberts@tufts.edu

Edward Saltzman- Co-Investigator & Study Physician
(617) 556-3245
Edward.Saltzman@tufts.edu

LTC Asma Bukhari- Co-Investigator
(301) 400-2708
asma.s.bukhari.mil@mail.mil

LTC Renee Cole- Co-Investigator
(508) 233-5808
Renee.e.cole.mil@mail.mil

Adrienne Hatch- Co-Investigator
(508) 233-5648
Adrienne.m.hatch.civ@mail.mil

RESEARCH RELATED INJURY
There are no plans for Tufts to pay for your treatment if you get hurt or sick as part of this study. Tufts has not set aside any money to pay for a research-related injury or illness.

COSTS

There are no costs associated with participation. The weight loss program is offered free of charge to you. If you choose to participate in the remote outcomes process due to relocation, you will incur any costs associated with visiting your healthcare provider.

PAYMENT

A maximum of $400 will be given to you over the course of the study via check. You will get this amount as $50 for doing all baseline testing, $50 for doing 6 month testing, $100 for doing all the month 12 testing, and $200 for doing all the month 24 tests. These amounts will be divided proportionally and given to you based on completion of testing at each time point and if you withdraw, or are withdrawn from the study for any reason. However, if you are a federal employee participating in this study on government time, you will only receive compensation for blood draws ($50/draw). If you are a federal employee who participates on your own time, you are eligible for full payment.

PRIVACY AND CONFIDENTIALITY

All reasonable measures to protect the confidentiality of your records and your identity will be taken by JM USDA Human Nutrition Research Center on Aging at Tufts University to protect your information according to State and Federal Laws. There is always the possibility that your information could be shared in a way that would no longer be protected by law. However, all information that identifies you will be removed from the study results before data analysis and your identity will not be revealed in any publication or presentation that may result from this study.

Your participation in this intervention is for the purpose of research only. None of your personal records or the data collected for the study will be shared with your employer, and will remain at Tufts University Human Nutrition Research Center on Aging.

The research team will be permitted to use your data up until 10 years after closure of the study. At that time, unless an extension is approved by the Tufts Institutional Review Board, the research information in your records will be destroyed or information identifying you will be removed, making it impossible to link you to the study. Blood samples will be archived for a period of 10 years after closure of the study, or until their use and analysis is complete, whichever is earliest.

If you agree to take part in this research study, your personal information will not be given to anyone unless we get your permission in writing. It will only be given if the law requires it. It will also only be given for regular hospital treatment, payment, and hospital management activities.

Representatives of the Tufts University IRB, the U.S Army Medical Research and Material Command and the HQ USAMRMC IRB are authorized to review research records as part of their

responsibility to protect human research volunteers. Research records will be stored in a confidential manner so as to protect the confidentiality of your information.

We will make every effort to keep your information private, but it cannot be totally guaranteed. Certain government agencies (such as the DoD) and the IRB of Tufts Medical Center and Tufts University Health Sciences, the U.S Army Medical Research and Material Command Human Research Protection Office, and the HQ USAMRMC IRB may check records that identify you. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

Documentation of Consent

I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

_____ _____

Date Participant's Signature

I have fully explained to_____the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator or Representative's Signature