**Research Proposal**

**Title: Implementation of Intensive Weight Management Intervention Program for Army ROTC Cadets**

**Principal Investigator(s) and Contact Information:**

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1. **Potential Subjects**- The subjects will include the MS3 ROTC cadet class, all of whom are undergraduate students at Texas State University. The sample consists of 30 male and female cadets, ranging in age from 19-30 years. The sample was selected at the request of the ROTC program officers. These cadets must meet physical standards for Body Mass Index (BMI) and % body fat in order to be eligible for the Army’s Leadership Development and Assessment Course (LDAC) in the summer following their junior year. Preliminary data for current MS3 cadets reveal that 33% exceed the minimum military standards for BMI and 13% exceed body fat standards, which would potentially prevent them from entering the LDAC which is a requirement to becoming commissioned.
2. **Procedure for Recruitment of Subjects and Consent**-The subjects comprise a convenient sample of the entire junior class (MS3) of Army ROTC cadets at Texas State. All junior class cadets are required to participate in training to prepare them for the LDAC camp that occurs the summer after their junior year. At the request of the Texas State ROTC Program officers, we will include a wellness component to the program. Study investigators will provide verbal information about the study and written consent forms to the cadets at the initial meeting of the wellness course. The consent forms will provide the purpose, subject selection, procedures, funding source (a Research Enhancement Program Grant, if applicable) risks, benefits, researchers contact information and any other pertinent information related to the research.
3. **Methodology-** The study will be conducted from January until May 2009, totaling five months. Subjects will be randomly assigned to either a treatment or control group. Direct intervention strategies related to diet and behavior will be implemented with the treatment group while minimal contact will occur with the control group. All subjects will be measured for parameters assessing dietary changes, body composition, physical activity and performance, and behavior change, as well as biochemical parameters related to health status in January, March and May.

*Diet*: All subjects will be trained to correctly record serving sizes and maintain 3-day diet records by undergraduate nutrition students under the supervision of graduate nutrition students. Three-day diet records will be collected during the 3 testing periods in January, March, and May. Diet records will be analyzed and evaluated for nutrient content using *Nutrition Data System for Research* software modified to reflect military standards. This software is designed to collect, calculate, and analyze dietary data in the form of dietary recalls, written dietary records, record-assisted recalls, recipes and menus. Each week, each member of the treatment group will be weighed and receive a 45-minute individual or group nutritional counseling to promote weight loss or maintenance. The counseling sessions will be structured to provide a review of the previous week’s progress related to diet (food diary), physical activity, and psycho-social factors, as well as information about a particular weight management topic, such as portion control, importance of incidental physical activity, sources of nutrient dense foods, and other topics already identified through evidence based practice to promote weight loss/maintenance. Individual counseling will be provided by undergraduate or graduate nutrition students who are assigned to each cadet. The control group will only receive printed materials about healthy eating habits.

During the three data collection periods in January, March, and May, subjects will also be interviewed.

*Body Composition*: All subjects’ height, weight, 7-site skin folds, waist and hip circumferences will be measured during the 3 testing periods. Graduate students from the department of Health, Physical Education and Recreation will perform skin fold measurements on all the subjects. All other measurements will be conducted by the nutrition students. Body composition measurements will also be assessed using The Army’s Weight Control Program (AR 600-9) guidelines. Body fat will be determined using the formula specified in AR 600-9 and air-displacement plethysmography (ADP) technology using a BOD POD®. ADP is highly reliable and valid when compared with other body fat assessment techniques such as hydrostatic weighting and dual energy x-ray absorptionmetry (DXA). ADP will be used to verify validity and reliability of the physical measurements.

*Fitness and Physical Performance*: All subjects will perform exercise training prescribed by the ROTC officers and will be tested each month using the Army Physical Fitness Test (APFT) under the supervision of ROTC officers. Daily energy expenditure and cardiovascular activity will be monitored during the 3 testing periods using Advanced Polar heart rate watch monitors. Daily physical activity from the monitors will be downloaded to computers to analyze heart rate activity. Daily physical activity will be reviewed and analyzed by nutritional counselors. Activity will be assessed by the American College of Sports Medicine guidelines.

*Behavior change*: Subjects in the treatment group, but not the control group, will be counseled using motivational interviewing techniques to identify obstacles to making dietary changes. Subjects, along with their nutrition counselors will write a contract with specific goals. Goal attainment will be measured at the 3 testing periods using a Likert scale.

*Biochemical assessment*: Subjects in the treatment and control groups will have fasting blood samples drawn for analysis of blood lipoproteins and a basic metabolic panel during the initial and final testing periods to evaluate nutritionally related indicators of health status. The Texas State Student Health Center will provide these services at no cost to the participants.

*Statistical Analysis*: Weekly body weight and anthropometric measures (weight, skinfolds, waist circumference) at the 3 testing periods will be analyzed for differences between the treatment and control groups using ANOVA. Results of monthly APFT will be analyzed by ANOVA to detect any differences in physical performance between the control and experimental groups. Three day diet histories and other components of dietary habits will be completed by the subjects at the 3 testing periods and will be recorded and analyzed for nutrient content using *Nutrition Data System for Research.* ANOVA will be used to determine any differences in food intake, food behaviors and attitudes between the control and experimental groups. T-tests will be used to test for any differences in goal attainment among subjects in the experimental group based on data obtained from the Initial and Exit Interview Questionnaires. Results of biochemical testing done at the beginning and end of the project will be analyzed for differences between the control and experimental groups using t-tests.

1. **Potential Risks**- Potential risks are minimal. There will be some discomfort with the blood draws. The BOD POD chamber may cause discomfort for subjects with claustrophobia. ADP is considered a safe method of assessing body composition.
2. **Confidentiality**- Confidentiality Authorized persons from Texas State University and the Institutional Review Board have the legal right to review subjects’ research records and will protect the confidentiality of those records to the extent permitted by law. Research records will not be released without authorized consent from the subject unless required by law or a court order. All data will be de-identified and only the PIs will know the code. If the results of this research are published or presented at scientific meeting, the subject’s identity will not be disclosed. All research data and documents will be kept in a locked file cabinet in a locked room in the Family and Consumer Sciences Building. Only the identified researchers will have keys to the file cabinets. All digital data will be kept on secured computers located within the Family and Consumer Sciences Building and will require a password to access the information. Only the identified researchers will have passwords to access the digital data.
3. **Potential Benefits**- Subjects in the experimental group should receive benefits from the intensive individual counseling provided for weight loss/maintenance, increased muscle mass, and improved health. The control group will benefit from the general nutrition guidance provided by the handouts. All subjects will be given the results of all testing and general outcomes of the study. Participation may be helpful for the cadets to become eligible for the Army’s LDAC and become commissioned as an US Army officer.
4. **Compensation**- There is no compensation offered to subjects in the study.
5. **Risk in relation to anticipated benefits?**  With minimal risk in this study, the benefits of increased health knowledge, improved body composition and dietary habits greatly outweigh the risk presented by blood draws and body composition measurements.
6. **Specific sites/agencies** – All counseling and measurements will be conducted on the Texas State University campus with cadets from the Army ROTC unit.