**Statement of Need**

 As the prevalence of obesity remains high in the United States and poses a threat around the world, children and adolescents are not immune to the growing epidemic. The terms overweight and obese in the pediatric population are defined as excess body weight given a particular height while taking into consideration fat percentage, muscle and bone contribution, and water component.1 In short, obesity is defined as having excess body fat.1 In many studies, obesity is defined using body mass index (BMI). Although this does not directly measure fat percentage, it is a reliable measure for measuring body fat.1 This calculation considers an individual’s weight in relation to height. Obesity is defined as BMI greater than 95th percentile for children of the same age and sex.2 Overweight is defined as BMI greater than 85th percentile but less than the 95th percentile for children again with age and sex taken into consideration.2 In order to understand the importance of maintaining a healthy weight, one must consider the threat obesity poses not only to the individual but also the community, including health conditions, financial drain, and decreased functional status.

Efforts to decrease both childhood and adulthood obesity prevalence are largely founded on evidence supporting the harmful health issues associated with this condition. According to the Center of Disease Control and Prevention (CDC) obesity is associated with several chronic conditions including coronary heart disease, stroke, type two diabetes, and some cancers.3 A study by Danaei et al. found that approximately one tenth of all deaths in the United States can be linked to physical inactivity and overweight-obesity.4 Another study by Wolf et al. states that obesity has both direct and indirect costs related to health conditions including diabetes mellitus type two, coronary heart disease, hypertension, gall bladder disease, endometrial cancer, colon cancer, osteoarthritis, and low back pain.5 Although many of these conditions do not present in childhood or adolescence, Cali et al. found that childhood obesity can increase insulin resistance in children and is associated with cardiovascular complications even in earlier stages of life.2 Obesity in children and adolescents is also associated with early hypertension, dyslipidemia, fatty liver disease, and systemic low-grade inflammation leading to early morbidity.2

Unfortunately obesity does not resolve between childhood and adulthood. According to several studies, children and adolescents who are overweight or obese are more likely to be overweight or obese as adults.2,6 Approximately 80% of children who are obese or overweight will remain overweight or obese into adulthood.2 Given these statistics is becomes very apparent that early intervention for children and adolescents can change not only the prevalence of obesity in the selected population but also decreases prevalence among adults in the future.

Considering the associated health conditions and health related costs, the growing prevalence of obesity both globally and locally should be alarming. According to a study by Cali et al. conducted in 2008, there are approximately 110 million children in the world who are obese or overweight.2 In 2008 an estimated 16.3% of children or adolescents in the United States were classified as obese and 31.9% had a BMI greater than the 85th percentile.2 According to the CDC, obesity in adolescents has more than quadrupled in the past 30 years. In fact, in 2012 over one third of children and adolescents in the United States were overweight or obese.1

 At a more local level, North Carolina continues to have a high prevalence of obesity in children as well as adults. According to the Center of Disease Control and Prevention, in 2012 approximately 14.6% of adolescents in North Carolina were classified as overweight, with a BMI falling between the 85th and 95th percentile.3 Additionally, 13.4% of teenagers in North Carolina were obese (BMI >95th percentile).3 Approximately 50% of North Carolina counties have a childhood obesity rate greater than 15% in children between the ages of two and four.7 Several counties located in the eastern and western parts of the state have early childhood obesity rate greater than 20%.7 Looking specifically at Catawba County, North Carolina 38% of children between the ages of 2 and 18 were overweight or obese in 2008.8

Given the health issues associated with obesity, medical costs are driven higher as the prevalence rises. In fact, according to Cali et al., “excess body weight is the sixth most important risk factor contributing to the overall burden of disease worldwide.”2 A comprehensive study by Finkelstein et al. predicted the obesity related health costs to rise to 147 billion dollars per year in the United States by 2008.9 On average in 2006, obese individuals spent $1,429 more than normal-weight individuals on medically related expenses in the United States.9 A study by Wolf et al. stated that direct costs related to health conditions associated with obesity can be far more easily measured that indirect costs such as excessive physician visits, work days lost, and restricted activity, suggesting that actual obesity related costs may be higher than previously estimated.5 Given the changing health care system in the United States, finding ways to decrease the financial burden should include reducing the prevalence of obesity.

Physical activity is a form of preventative medicine that has been shown to reduce body fat as well as positively influence health in overweight and obese children. In a systematic review by Kelley et al. the effect of exercise on weight-loss was considered in children and adolescents. Aerobic exercise, strength training, or both were found to be effective for body fat reduction.10 In fact, “exercise reduces percent body fat in overweight and obese children and adolescents.”10 Exercise has also been shown to reduce both blood pressure and triglycerides in children, positively affecting the cardiovascular system.11,12

Even though research supports the health benefits of daily physical activity, many individuals in the United States receive far less than the optimal levels of exercise. A national survey by the CDC found that in 2013 only 29% of high school students participated in 60 minutes of physical activity daily.13 Less than half of high school students attended physical education classes in an average week.13 In fact, 15.2% of high school students did not participate in 60 minutes of physical activity even one day of the week.13 Interestingly, participation in physical activity continues to decrease with age.13

With less than half of adolescents participating in the recommended amounts of physical activity daily,13 the need for physical therapist designed, school-based intervention programs remains high. According to the American Physical Therapy Association, physical therapists play a role in weight-loss programs. Physical therapists can uniquely evaluation the patient and develop personal and safe exercise programs to incorporate strength, cardiovascular health, and flexibility while working to reduce any preexisting pain and monitoring health conditions.14 With extensive knowledge of associated conditions, physical therapists can work to modify behavior and encourage regular physical activity.14 An article by Kushner et al concluded that screening and treating obesity in primary care is necessary to underlying issues and impact overall health.15

Implementing this school-based weight-loss program is necessary to provide optimal care and preventative medicine to at risk youth by addressing multiple levels of a Socioecological Model (SEM) as described by McLeroy et al. The SEM outlines several layers of influence on health behaviors including the intrapersonal level, interpersonal level, the community level, and public policy level.16 Programs that target multiple layers are believed to have better outcomes in behavioral changes. This program will incorporate educational components to address the intrapersonal level. Each participant will also have access to individualized work out programs to address needs. At the interpersonal level, group exercise classes and peer accountability will encourage students to establish regular exercise habits. By using school facilities, this weight-loss program allows relationships to be built between health care providers and participants in a well-established school setting. This can create a supportive school environment to encourage weight loss at the community level. Not only will participants in the program benefit from the education and intervention, but the program could raise awareness in the community among health care providers, teachers, students, and parents to form a more exercise friendly town. Resources can be pooled and participants in a rural setting will have access to a fitness facility.16

Given the limited physical activity high school students participate in daily and the positive role of exercise on addressing both weight-loss and cardiovascular health in overweight and obese adolescents, there is a need for developing a school-based intervention program in Catawba County, NC. By establishing an appropriate program, obesity related health costs could decrease and the overall health of the community could be improved. Targeting adolescents allows for a direct reduction of childhood obesity and an indirect reduction of adult obesity.

**Background**

 Exercise and physical activity have been shown to be effective in weight loss. More specifically, exercise has been found to be an effective strategy for reducing body fat.10 When combined with diet, exercise can result in significant weight loss and metabolic changes in children and adolescents.17 There are several forms of exercise described in the literature as effective for weight loss including both high-intensity training and aerobic exercise.18 A systematic review by Lemura et al also found that exercise effectively reduces body weight obese children and adolescents, outlining the importance of behavioral interventions.19 Although it has long been accepted that physical activity can help in weight reduction, the types of exercise, duration of intervention programs, and impact of diet remain debated topics. More recently, the impact of psychological components such as motivational interviewing and behavioral models have also impacted weight-loss program designs. When considering a school-based intervention program, all of these topics must be considered to provide the best, evidence-based approach.

 To begin, the types of exercises performed may have an impact on weight reduction in obese children and adolescents. Although aerobic training has traditionally been proposed as the optimal form of exercise for weight-loss, recent studies have found high-intensity interval training to be effective as well. One study identified aerobic training as the optimal form of fat reduction and weight-loss in obese adolescents; however, this study goes on to indicate that further research is needed to determine the benefits of high-intensity training.18 It has also been found that the most favorable forms of exercise for altering body composition in obese or overweight children and adolescents are both low-intensity, long duration exercise as well as aerobic exercise coupled with high-intensity resistive activities.19 A study by Brandou et al expands upon the importance of high-intensity training, describing this form of exercise as a more superior approach for weight-loss in conjunction with dietary changes.20 Given these studies, both aerobic exercises and high-intensity activities appear to be effective in weight-loss. Incorporating both can allow for variety and adjust for personal preference.

 In addition to the types of exercises incorporated into weight-loss programs, the duration of intervention could impact amounts of weight reduction as well as long term outcomes. Kelley et al included studies with a minimum intervention duration of 4 weeks, finding significant results even in this short duration.10 Several systematic reviews found intervention programs to last approximately 6 months.17,18,21 There is little information regarding interventions with durations longer than 6 months in clinic-based interventions, however, school-based programs have been reported to extend to longer periods of time. A review by Zenzen et al found the average duration of school-based programs to be 10 months.29 As supported by previous school-based weight loss interventions, this program will take place over 10 months to follow the school calendar.

 The importance of nutrition and dietary changes in combination with exercise cannot be denied. A systematic review by Ho et al found that diet alone is effective in for weight loss; however diet in conjunction with exercise had additional benefits by improving levels of fasting glucose and insulin.17 Another review by Luckner et al found that in children, the most effective weight-loss intervention programs included exercise, health education, and nutritional components.22 By incorporating education about guidelines and recommendations in the program, weight-loss can be optimized.

 School-based weight-loss programs have been proposed as possible alternatives to clinic-based approaches. There are several theoretical benefits for implementing a school-based intervention program for children and adolescents. First, these programs can offer a more comprehensive approach including physical activity and nutrition. Secondly, the setting offers preexisting resources. School-based nutritional changes have been found to be effective in promoting health eating in young African American children and teenagers.23 By combining both nutritional interventions and physical activity, weight-loss can be achieved in obese children in the school setting.24 One study even found that although specific designs of school-based weight loss inventions vary, they are effective in treating childhood obesity, particularly when nutrition, physical activity, and family were incorporated into the program.25 Given this information, the proposed program will include educational sessions that will be open to family members to attend. These sessions will largely focus on making changes at home such as changes in diet, decreasing screen time, and increasing physical activity. The program will also allow for scheduled and organized fitness classes and exercise interventions.

 Another important component of weight-loss programs, particularly in the adolescent population, is the incorporation of behavioral models and psychological approaches. The Transtheoretical Model (TTM), specifically stages of change, has been suggested in literature as possible means for achieving desirable results especially when promoting lifestyle changes.26 Stages of change include pre-contemplation, contemplation, preparation, action, and maintenance. A Cochrane review by Mastellos et al found that when applying the TTM to weight-loss programs, increases in physical activity and dietary modifications could be observed for up to a year.26 These results, however, should be interpreted with caution due to the risk of bias and imprecision.26 Another study by Johnson et al found much stronger results, indicating that the TTM is effective in increasing physical activity and improving healthy eating.27 In this study, stages of change, the process of change, and self-efficacy were all addressed.27 By meeting participants where they are in the process of change, lasting effects can be promoted. Recognizing the stage of change will allow for more effective intervention.

 Expanding on psychological approaches, motivational interviewing is another important component of a weight-loss program. Motivation interviewing is a patient-centered approach that aims to build rapport with patients and encourage behaviors changes.28 A study by Armstrong et al found that motivational interviewing significantly improved weight-loss when compared to the control group.28 Using motivation interviewing in an exercise and diet based weight reduction intervention program may increase the positive results that could be achieved.

 By incorporating various forms of exercise including aerobic training and high-intensity training into this weight-loss program and incorporating nutrition into treatment, outcomes will be optimized. A school-based intervention provides numerous benefits, including a comprehensive setting with preexisting equipment. Including both aspects of the TTM and motivational interviewing will further promote weight-loss and long term changes.

**Program Description**

Objectives

The goal of this intervention is primarily weight reduction; however, it is important to assess many aspects of health including nutrition, cardiovascular health, and over-all well-being. Upon the conclusion of this program, the following goals should be met:

* + In 10 months, 90% of participants will decrease body weight by 10% from baseline.
	+ In 10 months, 90% of participants will improve SF-36 scores by 20%.
	+ In 10 months, 90% of participants will increase 6 minute walk test by 100 meters.
	+ In 10 months, 90% of participants will self-report consuming no more than 3 sugary drinks/week in nutrition journal.
	+ In 10 months, 90% of participants will have resting blood pressure (BP) and heart rate (HR) within the normal range.

Methods:

Participants

* 30 obese and overweight high school students in Catawba County, North Carolina as defined by a BMI greater than 85% of the population when controlling for age and sex. All participants will require medical clearing by a physician prior to beginning program.
* Exclusion criteria: physical or cognitive disabilities limiting program participation, inadequate transportation, and students involved in conflicting afterschool activities.
* Parents and/or guardians will be asked to join for educational components.

Program Administrators

* A physical therapist will design and manage individualized exercise programs that consist of aerobic training, high-intensity interval training, and stretching.
* A dietician will provide general nutrition information during educational components of the program.
* Both the physical therapist and dietician will implement motivational interviewing strategies during individual monthly meeting with participants.

Time

* The program will follow the academic calendar during the 2015-2016 school year (August-June).
* The program will take place immediately following school (3:30pm - 5:00pm) Monday through Friday to reduce transportation needs.

Location

* Fred T. Foard High School in Newton, North Carolina
* The program will use the following facilities:
	+ Track: rubber surface with 6 lanes. Stadium surrounding the track may also be used for stair climbing exercises.
	+ Gym: this location will only be available when not being used by sports teams throughout the school year.
	+ Aerobics room: private access will be granted for program participants. Equipment includes treadmills, ellipticals, and recumbent bicycles.
	+ Weight room: participants will have private access during scheduled times. Sports teams have access to a separate weight room after school. Weight room has both machines as well as free weights.
	+ Class rooms and school grounds: to complete exercises as well as educational components.

Interventions

* Monthly individual meetings will take place for each participant. These meetings will allow one on one discussion between the participant and program administrators. These meetings will allow measurements to be taken regularly. Initially, these meetings will be used to determine baseline in each of the following areas:
	+ Fitness: 6 minute walk test and resting vitals including HR and BP.
	+ Stage of change: the Godin Leisure-Time Exercise Questionnaire (GLTEQ) and Fred Hutchinson Food Frequency Questionnaire (FFQ) are two outcomes measures that have been used to asses TTM stage of change for physical activity and healthy eating, respectively.30 Once stage of change has been determined, participants will be broken into groups based on stage of change for educational components and materials. A study by Johnson et al found that by providing educational components based on stage of change, participants were able to make longer term physical activity and dietary behavioral changes better than without these stage tailored educational interventions.30
	+ Motivational factors: participants will be asked about likes and dislikes concerning exercise and fitness. Participants will also be asked if they feel like they would benefit from losing weight and why or why not. This will allow administrators to individualize training programs to include activities that each participants enjoys.
	+ Nutritional status: During the initial meeting, participants will be asked about their typical diet, including questions about number of fruits and vegetable servings eaten each day and the number of sugary drinks consumed per day. Participants will also be provided with a food journal and instructed on how to log daily food consumption.
* In addition to monthly meetings, participants will engage in an exercise program daily and an educational component twice a week as outlined below.

|  |  |
| --- | --- |
| **Day** | **Interventions** |
| Monday, Wednesday, Friday | 1. Warm-up (10 minutes)* 50% of maximum heart rate ((220 – age) X 0.5). All participants will wear a heart rate monitor during and immediately following exercise interventions to assess appropriate activity levels.
* Warm up will consist of walking or biking on a stationary bicycle

2. Stretching (10 minutes)* Stretching will target major muscle group, particularly in the lower extremities, including but not limited to hamstrings, quadriceps, calves, and hip flexors.
* Each stretch will be held for a minimum of 60 seconds.

3. Aerobic Exercise* Aerobic exercise will gradually progress towards 60 minutes. This is one area that will be individualized as participants will likely have different baseline fitness levels. Some may be able to participate in moderate aerobic activities for 60 minutes from the very beginning. Others will need breaks throughout but will progress towards exercising at a moderate level for the full 60 minutes.
* Moderate physical activity will be defined as performing exercise at 60-70% of maximum heart rate [((220-age) X 0.6) to ((220-age) X 0.7)].
* Activities will include walking, biking, and stair climbing among others based on personal preference. At least once a week, activities will include sports such as ultimate Frisbee, soccer, basketball, and dodgeball depending on participant feedback.

4. Cool Down (10 minutes)* 50% of maximum heart rate ((220 – age) X 0.5)
* Activities will consist of walking or biking.
 |
| Tuesday, Thursday | 1. Warm-up and stretching program as above2. High Intensity Interval Training (30 minutes)* High intensity interval training will consist of 1 minute of exercise performed at 80-90% of maximum heart rate [((220-age) X 0.8) to ((220-age) X 0.9)] followed by a recovery phase of 1 minute during which participants will exercise at 50% of maximum heart rate ((220 – age) X 0.5).
* Exercise may include walking, running, biking, stair climbing, jump roping, resistance training and other activities and will be tailored based on fitness level and personal preference.
* Participants will also complete interval training in pairs or small groups to help give feedback and encouragement. While one person completes the exercise, the other team member(s) can encourage and cheer them on. Relay races, shuttle runs, and other field day activities may be included based on participant preferences.

3. Cool Down as above4. Educational Component – 30 minutes* This session will occur twice a week and is designed to include both parents and participants. It will take place at the end of the session in order to allow parents to arrive a little early to picking up their child and participate in the educational opportunity.
* Nutrition topics will include know your portion sizes, reading nutrition labels, limit the sweets, protein to carbohydrate ratios, eating fresh fruits and vegetables, drinking water, don’t forget calcium, and all about whole grains.
* Other topics will include limiting screen time, eating as a family, and meals cooked in the home.
* Participants will also be asked to keep a food journal to track changes in nutritional intake and allow the dietician to make personal suggestions. The food journal will ask participants to write down foods consumed each day.
* Educational materials provided for each participant will be tailored towards stage of change. For example, for each of the topics mentioned above, there will be materials that focus on why the topic is important and how it influences health that will be distributed to individuals in the pre-contemplation and contemplations groups. These materials will raise awareness and help motivate participants to take action. The other half of the educational materials will focus on how to make changes (targeting the preparation and action stages). This will be the practical application. Both sections will be available and will be distributed based on current stage of change.
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**Program Evaluation**

 The Center for Disease Control and Prevention (CDC) provides a very extensive framework for evaluating a program that considers multiple aspects of the program including the merit, worth, and significance.31 First, to evaluate the merit of the program, there is a need to look at the quality of services provided.31 There will be two parts to this in the proposed weight-loss program. It will be vital to evaluate the dietary information provided to participants and determine whether or not educational materials are evidence based. The same holds true for all exercise components. These will be assessed and addressed prior to the start of the program but will need to be reassessed throughout the program to insure participants are receiving the most up to date information. All recommendations should adhere to the recommendations provided by the CDC. Secondly, the worth of the program needs to be determined. The question, “Is this program cost-effective and worth the trouble?” needs to be answered and hopefully has been answered in this proposal. Careful consideration has already been given to this factor as it is believed that using a school-setting and previously established facilities will lessen the cost of the program while still provided the best possible treatment. It will be important, however, to continue tracking expenses and determining whether the services provided are worth the cost. This will be reassess at the conclusion of the proposed program. Finally, the significance of the program needs to be objectively measured and tracked. This will be done in several ways, using both self-reported outcome measures and administrative measurements such as weight, blood pressure, and heart rate. These are detailed in greater detail below.

Weight Loss Measures:

Since the primary objective of this program is weight loss, there are several measurements that need to be taken prior to program involvement and throughout the program to track changes. We will focus on weight and body mass index (BMI).

* Weight: Currently, weight loss recommendations suggest losing approximately one to two pounds per week.32 It is recognized that even modest weight loss (5-10% overall) can have great health beliefs and reduce risk factors for chronic diseases related to obesity.32 In this program, weight will be measured in pounds every two weeks using a Seca Medical Column scale. Weight loss of 1-2 pounds per week will be considered optimal.
* BMI: Body mass index will be based off the participant’s height and weight (using pounds and inches, respectively). BMI will be calculated using the calculator provided by the CDC, which takes into consideration both age and sex norms.33 Ideally, participants will improve BMI by at least one category (i.e. from obese to overweight) upon complete of program.

Other Health Measures:

In addition to weight loss, this program will track changes in overall health. To do so, there will be an attempt to assess cardiovascular fitness, perceptions of health, and nutrition. Outcome measures will include a 6 minute walk test (6MWT) and the Short Form (36) Health Survey (SF-36). Other measures will include heart rate, blood pressure, and evaluation of nutrition log.

* 6MWT: The 6 MWT can be used to determine cardiovascular fitness.34 This measure have been validated on many different populations including children and adults with and without disabilities.34 It will, however, be important to use the same length of space from one test to the next as significant differences have been noted when using different lengths of track between trials.34 Participants will be asked to complete this test once per month to evaluate changes.
* SF-36: This measure has been validated in a variety of populations, including patients with disabilities. It measures 8 subgroups: physical functioning, role limitations due to physical problems, general health perceptions, vitality, social functioning, role limitations due to emotional problems, general mental health, and health transition.35 This measure will allow administrators to determine self-perceived health status of participants and changes that occur throughout the program. Participants will complete this outcome measure before beginning the program, once in December, and once at the completion of the program. Upon conclusion of the program, the goal is for 90% of participants to increase SF-36 scores by at least 20%.
* Heart Rate and Blood Pressure: These vitals will be taken with the patient seated to obtain resting vitals prior to any physical activity once every two week. The goal is to have a resting heart rate between 60 and 100 beats per minute and resting blood pressure around 120/80 mmHg.36 Heart rate monitors will also be warn during activity to determine appropriate levels of exercise.
* Nutrition Log: Participants will be asked to keep a daily nutrition log, detailing food and beverages consumed each day. These will be coded for fresh fruit and vegetable servings as well as sugary drinks consumed to track dietary changes. Upon conclusion, participants should report no more than 3 sugary drinks per week.

Program Feedback:

Participants will be asked to provide program feedback once per semester in the form of an anonymous survey. The survey will ask participants to rate how much they liked several parts of the program on a scale from 1 to 5. There will also be a section for comments. See example below.

Please rate the following activities from 1 to 5 based on how much you liked the activity, with 1 meaning “I hated it” and 5 meaning I absolutely loved it!”

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | I hated it | I disliked it | I neither liked or dislike it | I liked it | I absolutely loved it! |
| Educational components | 1 | 2 | 3 | 4 | 5 |
| Aerobic Exercises | 1 | 2 | 3 | 4 | 5 |
| High Intensity Interval Days | 1 | 2 | 3 | 4 | 5 |
| Group Sports Days | 1 | 2 | 3 | 4 | 5 |
| Nutrition Journal | 1 | 2 | 3 | 4 | 5 |

Comments:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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