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CRC IRB Proposal
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Title: H2GO! (Healthy Habits 2Go!) Teen Group Visits

A) Study Proposal and Rationale

According to the CDC, in the last 30 years childhood obesity has doubled and obesity in adolescents has quadrupled. Since the 1980s the percentage of obese adolescents has gone from 5% to almost 21%. Obesity has a lot of long term and short term harmful effects on health. Long term effects include: obesity into adulthood, increased risk of type 2 diabetes, high cholesterol, cardiovascular disease, hypertension, stroke, arthritis, an increased predisposition to cancers like breast and colon cancer, as well as psychological issues including depression. Short term effects include: obstructive sleep apnea, depression, low self-esteem, exercise intolerance and pre-diabetes.

Childhood obesity is a growing issue that has caught not only the attention of health care providers but even has political leaders trying to come up with public health campaigns to combat this growing problem. In February 2010, the Obama administration established the Task Force on Childhood Obesity which included the “Lets Move” initiative which promotes children to move more and eat healthier. One of the goals of this initiative is to improve access to health and affordable foods. According to a correlational study done by Tate et al in 2015, adolescents of lower SES had a higher consumption of food higher in calories and fat than did those from a higher SES. This could be due to lack of access to health food options.

Adolescence is a time of self-discovery as well as a transition into adulthood which requires independent thinking and making decisions including medical decisions. Since adolescence is an important time to learn independence and gain more autonomy in decision making it is a vital time to learn how to make good decisions especially those regarding one’s health. Since healthy eating allows for “optimal growth and development” it can reduce the long term effects that obesity can cause.

There are many health related illnesses that have group sessions that focus on motivation and acceptance, which help participants feel like they are not alone in their struggle to become healthy (i.e. Alcoholics Anonymous, Narcotics Anonymous, Cognitive behavioral therapy). According to Teoh et al social support can make an individual feel either loved, esteemed, accepted, valued or motivated. Likewise a study by Jebb et al, when referred to a weight loss program that had regular weighing, advice about diet and physical activity, group support and motivation, study participants lost twice as much weight as those who receive standard care by a care provider.

By providing teens with a safe place to learn about healthy choices as well as educate them on why these choices are important, we hope to motivate and encourage lifelong healthy habits.

B) Study Design and Statistical Analysis

1. Aim: The purpose of this study is to assess whether a Dietitian led group medical visit program can improve achievement of target goals in overweight and obese teens and lead to better screening of co-morbidities as compared to usual primary care visit.

Our aim is to create a four month adolescent weight management pilot program that improves the knowledge of healthy eating and physical activity amongst our patients at Audubon. Group visits will be held at Audubon for adolescents between the ages of 13-18 years old.

Hypothesis: Teens who attend at least 2 classes will have at least a 5lb weight loss over the course of 6 months as compared to teens who did not attend any classes.

2. Study procedures: Patients will be recruited in 2 groups, one group of girls 13-18 years who have a BMI above 85% and the second group of boys 13-18 years who have a BMI above 85%. The group visit will consist of 40-60 minute educational counseling held once a month for a four month period and will be led by a Dietitian and Pediatrician. A Dietitian will provide nutritional education and counseling and the Pediatrician will screen for co-morbidities and create a care plan.

a) Inclusion criteria: Teens aged between 13 and 18 years, with BMI >85th percentile, teen fluent in English, teen willing to participate in the program and completion of written informed consent and assent prior to any study-specific procedures.

b) Exclusion criteria: severe intellectual difficulties which would limit the ability to engage in group activity, obesity secondary to genetic condition, limitations to engaging in physical activity (for example, active musculoskeletal injury) or use of medication known to effect body weight, participation in another weight management program or medical reasons to restrict diet or physical activity.

3. Goals:

- 70% of patients will attend 100% of classes
- Patients who attend at least 2 classes will have a down-trending BMI, with at least a 5lb weight loss.

4. Statistical Analysis: Pts will be compared against a control group of other teens in the Audubon practice with a BMI >85% who were not participants in the course. An unpaired t-test will be performed to compare the mean difference in changes in weight between teens who attended at least 2 classes vs teens who attended no classes.

Assuming teens who attend at least 2 of 4 classes have an average weight loss of 5lbs, using a SD of 4, power of 0.8, α of 0.05 and a sample size of 16, we would be able to show statistical significance.

C. Potential Benefits: Participation will lead to improvement in knowledge of healthy eating

and physical activity and other health outcomes like quality of care.

D. Potential Risks: This is a minimal risk study. This is a group visit intended to improve the knowledge of healthy eating and physical activity amongst our patients and also appropriately screening them for obesity associated comorbidities. They will be provided with surveys. Some patients might find questions to be intrusive, but they can opt out of answering questions at any time. Group visit will be recorded in Allscripts SCM as part of medical record.

E. Alternatives: Participation in this study is voluntary. The alternative is to not participate in this study.

F. Costs to subjects: None

G. Compensation: Patients will be provided with a \$10 gift card once all 4 classes are completed.

H. Confidentiality and Consent: Patients will be provided with an information sheet regarding the research at first visit. This information sheet contains these elements:
--Voluntary status: A statement regarding the voluntary status will be included in the information sheet, including the choice not to participate in the group visit and ability to stop at any time.

References:

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CRC IRB Proposal

7/24/15

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