Wise Social Psychological Interventions to Improve Outcomes of Behavioral Weight Control in Children with Obesity

NCT04422951
April 30, 2023

1. PURPOSE OF THE STUDY

a. Brief Summary

Weight loss interventions for children and their families often have variable outcomes and are hindered by low attendance or relapse. We will test if brief social psychological interventions (termed “wise” interventions) designed to overcome psychological barriers may improve participants' efforts toward a weight management program, their attitudes about themselves and their weight, and their weight control.

b. Objectives

We seek to improve outcomes of pediatric weight control interventions by adding novel, yet brief (less than 20 minutes) activities to pediatric weight management for children with obesity.

These wise interventions have proven very successful in improving school performance in children but are only recently have been applied to health behavior change. If found to be effective, these activities can easily be added to standard weight control interventions to increase their effectiveness and would be a major contribution to improving immediate and long-term health and well being of children seeking treatment for obesity.

c. Rationale for Research in Humans

The purpose of the study is to test the efficacy of new strategies for enhancing weight management in children with obesity and their families.

2. STUDY PROCEDURES

a. Procedures

Recruitment and screening:
We intend to recruit 200 households of children ages 10 through 16 years with obesity who are enrolled in usual care pediatric weight management and their parents.

Pediatric weight management programs will be identified and asked to distribute a study recruitment flyer and/or email to their patients. All recruiting materials will direct potentially interested parents to our Stanford study website that describes the study and provides a REDCap screening survey to assess possible eligibility.

A copy of the approved consent and assent forms will also be available via a link on our Stanford study website.

To qualify, children must be enrolled in pediatric weight management and parents or legal guardians must complete an online eligibility screening questionnaire that is available on our study website in REDCap. At the start of the screening survey, they will read the waiver of documentation for recruitment and click continue to proceed to the screening questions. If a family meets preliminary eligibility criteria, they will be asked if they would like to schedule a baseline appointment (zoom video call). After they have scheduled an appointment, they will be emailed the consent and assent forms.

Baseline screening and measurement:
Parent(s) and child(ren) must attend an initial Zoom video call with a research coordinator. During this call and prior to collecting any data, we will explain all aspects of the study including data collection measures, intervention activities and randomization and obtain signed consent from the parent/guardian and signed assent from the child. All questions will be answered by study staff prior to families signing consent forms (parents/guardians) and assent forms(children). The consent/assent forms are on REDCap, which allows participants to use their mouse (desktop) or finger (mobile) to record signatures.

Measures in baseline appointment – part 1
After children and parents complete assent and consent forms, they will be asked to complete all survey measures including demographics, household composition, physical activity and eating habits, screen use, puberty stage, overconcern with weight or shape, school grades, and psychosocial measures. Children and parents will be encouraged to complete online REDCap surveys on separate devices. The research coordinator will review all surveys for completeness before ending the call. Parents will be asked to schedule a second zoom call within the upcoming 3 weeks. An electronic cellular-connected scale (BodyTrace), a tape measure to measure height, and a food portion size booklet to use during the dietary recall will be mailed to participants. Parents will be emailed a lab requisition for their child to have fasting blood tests collected at their local Quest labs.

Measures in baseline appointment – part 2
During the second Zoom video appointment, child’s and parent's heights and weights will be measured using the mailed tape measure and electronic scale, and children will complete a 24-hour dietary recall. Child weight measurements will be used to determine child’s eligibility into the study (>=95th BMI percentile for age and sex). After finalizing eligibility and completing all baseline measures, participants will be randomized.

Randomization:
Families will be randomized to treatment conditions after completing baseline measures, using Efron’s biased coin randomization stratified by location, sex, and race/ethnicity, to promote balance on key characteristics that may influence weight changes, and allow examination of sex as a biological variable. Investigators and all data collection staff will

remain blinded to treatment condition assignment until all participants have completed the final follow-up assessments.

Interventions:
The research activities will be delivered as online videos and activities sent 9 times throughout the program. Parents will be emailed REDCap surveys that link to Qualtrics activities; one with a parent video/activity and one with a child video/activity. The WISE interventions encourage values affirmations and a growth mindset. The control videos and activities reinforce diet and physical activity messages that are part of the weight control program.

Follow-up Assessments
Children and parents/guardians will complete data collection visits at 3 and 6 months post randomization. With the exception of demographic measures and a few baseline only measures, the 3- and 6-month visits will include measures previously collected at baseline. Fasting blood tests are included only at baseline and 6-month visits.

b. Procedure Risks

There are minimal risks in the research protocol. All research measures will be obtained by trained research assistants and phlebotomy by qualified phlebotomists at Quest Diagnostics, a nationwide commercial lab.

c. Use of Deception in the Study

There will be no deception used in the research.

d. Use of Audio and Video Recordings

No audio or video recording will occur by study staff.

As part of one of the intervention activities, children will be asked to upload a photo or a drawing to their individually assigned REDCap surveys. This image is similar to a profile image and designed to increase engagement. Children are instructed to not include photographs with faces.

Only qualified research staff will have access to images uploaded to REDCap.

e. Alternative Procedures or Courses of Treatment

No standard or alternative treatment will be withheld.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

No additional continuing treatment will be made available by the study after conclusion of the study.

g. Study Endpoint(s)

The main study endpoint is BMI change over 6 months, at the end of treatment. We do not plan to perform interim analyses of treatment
outcomes or terminate the study early for efficacy or futility because:

- Potential effects of the social psychological interventions are to
- mitigate drop out and increase perseverance with the treatment program over time.
- The interventions aim to affect weight gain trajectory and maintenance, intervention effects may not be observed over the short term.
- Alternatively, statistically significant short-term benefits may not reflect clinically significant health benefits over 6 months (the full length of the study).
- This study aims to calculate with some assurance the size of the

difference between treatment outcomes (effect size) within reasonable confidence intervals, and to avoid bias in the estimates of effect sizes (because random high values in treatment effect may be used to justify early stopping, but rarely would random low values).

- We should avoid interim analyses and unnecessary "alpha-spending," which reduces the power of the study.
- Study participants in both treatment groups are being provided with beneficial interventions.

The Safety Officer may request an interim analysis at any time during the study for purposes of assessing safety/harm.

The study will be terminated if there is clear evidence of harm or harmful side-effects of the treatment or participation in the study that outweighs evidence of the benefits of participation. Each Safety Officer report (approximately every six months) will conclude with a recommendation to continue or to terminate the study. A copy of this letter will be forwarded to the IRB and the NIH Program Officer. A termination recommendation may be made by the Safety Officer at any time during the study if deemed necessary.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Childhood obesity is a medical and public health priority. Pediatric obesity in the U.S. has more than tripled over the past 3 decades. Childhood obesity is associated with substantial medical, psychological, and social morbidities. Most treatments for children with obesity have produced modest, unsustained effects, and there remains a great need for new approaches to increase and sustain weight loss among children with obesity.

Existing weight control interventions may be limited in their success, in part, because of the many psychological barriers and threats that children and families face when attempting to manage their weights. Therefore, one potentially effective and efficient way to enhance the success of behavioral treatments and reduce variability in outcomes may be to focus on changing the attitudes and preparedness of the participants. One of the most formidable psychological barriers faced by people trying to control their weight is

the belief that they cannot succeed. The associated lack of self-efficacy results from the countless setbacks that are often encountered. Self-efficacy may also be damaged by the child's awareness of social-stereotypes about children with obesity, such as their lack of control and/or discipline, biologic/genetic propensity for obesity, lack of athleticism, etc., that may cause anxiety and stress. Thus, interventions designed to help children overcome the obstacle of low efficacy beliefs in the face of challenges and setbacks should be more successful in promoting long-term changes in health behaviors. We believe that certain brief and precisely targeted psychological interventions, termed "wise" interventions, can act as key levers in the behavior change process, aiding the success of more traditional behavioral interventions by increasing perceptions of efficacy. These wise interventions target beliefs about ability and performance and help buffer against psychological and social-environmental threats, making one more open to information regarding how to make changes, better able to cope with the psychological threats and setbacks they experience along the way and thus, better able to take advantage of the behavioral skills they are learning. When applied in a specifically timed way, wise interventions have proven effective at producing remarkably large and long-term improvements in children's academic performance. Based on our understanding of the barriers faced by children with obesity and families, and the very promising results of our pilot studies, these interventions are particularly well-suited to combine with behavioral interventions for pediatric obesity.

b. Findings from Past Animal Experiments

N/A

4. PARTICIPANT POPULATION

a. Planned Enrollment

(i) We expect to enroll approximately 200 families. Because multiple eligible children and parents may be enrolled from a single family, this is expected to include up to 240 eligible children and 240 eligible parents.
(ii) We are the only site involved in this research. Therefore, the total sample will be approximately 200 families.
(iii) Children aged 10-16 years with obesity and their parents/guardians. Children and their parents are included because this is a study to test a family-based approach to reduce weight gain in children with obesity using online methods.

b. Age, Gender, and Ethnic Background

Based on past experience in the existing pediatric weight control treatments, we anticipate participants to be approximately: 55% girls, 45% boys, 50% white, 3% African-American, 25% Latino/Hispanic, 1% Native American, 8% Asian/Pacific Islander and 13% other (including multi-ethnic).

c. Vulnerable Populations

Up to approximately 240 10-16 year-old children with obesity (in 200 families).

Rationale for Involvement of Potentially Vulnerable Subjects.

Children with obesity are at increased risk of related morbidities, including hypertension, dyslipidemias, diabetes, non-alcoholic fatty liver disease, and atherosclerosis, among others, and future risk of heart disease, stroke and many cancers. However, most available pediatric obesity treatment programs produce only limited and non-sustained effects. There is a great need for new, innovative approaches to improve and sustain weight control among overweight and obese children. In the proposed trial, we will test the addition of several promising and potentially generalizable social psychological strategies.

To minimize risks and chance of harm, assent will be obtained from all children and consent will be obtained from parents/guardians for their child's and their own participation, after full explanation of the study, via zoom video call. Parents/guardians will be required to accompany their child during participation in the study zoom calls.

Serious Adverse Events (medical problems where the study participant was hospitalized, had any problem resulting in a persistent or significant disability, had any problems that were life-threatening, or resulted in a birth defect in a newborn child) will be assessed at 3 and 6 months. Adverse events any medical illnesses or injuries requiring a visit to a medical care provider or institution) that the participant believes possibly related to their participation in the study will be assessed as part of the follow-up assessments at 3 and 6 months. A report form has been designed for this purpose to at least include a brief description, severity, resolution, potential relationship to study participation, and actions taken with respect to study participation. The PI will evaluate each event to determine if it meets the criteria of an Unanticipated Problem (UP) – which is unexpected, possibly related to participation in the study, and harmful. We will inform the IRB immediately of all Unanticipated Problems, and all adverse events, regardless of seriousness, will be reported to the IRB during annual reports/reviews.

Some also express concern that obesity treatment can increase the risk of unhealthful eating behaviors, although the bulk of available data do not support this, including a recent meta-analysis. Since the 1980's, our research group has studied risk and prevention of disordered eating behaviors among children and teens. As a result, we carefully consider the risks of disordered eating behaviors in all our obesity prevention and treatment research. A diagnosis of anorexia nervosa, bulimia nervosa or binge eating disorder, past or present, and any self-induced vomiting, or use of diuretics or laxatives for weight loss are exclusions for the study for the adult participant and any child living in the household.

The wise social psychological interventions proposed in this research have been found to be beneficial in multiple past studies in other domains (e.g., schools) and are designed to bolster self-integrity and focus on overall well-being, not specifically on weight.

d. Stanford Populations

We will not recruit from Stanford laboratory personnel, employees, or students.

e. Healthy Volunteers

Participants are children with obesity who are otherwise healthy and their parents/guardians who are also healthy.

This is a weight control study for otherwise healthy children and their parents/guardians. Pediatric obesity is associated with substantial medical, psychological, and social morbidities. For example, population-based data from Bogalusa, LA indicated that more than 60% of obese 5-10 year old children already suffered from at least one physiological risk factor for cardiovascular disease, such as hypertension, dyslipidemias, and/or hyperinsulinemia, and 25% had 2 or more risk factors. Increased childhood obesity has also led to a new epidemic of Type 2 diabetes in children and adolescents, a problem that was previously limited to adults, and now accounting for up to 45% of all newly diagnosed diabetes in children. Conditions associated with overweight, such as sleep apnea and gallbladder disease, tripled in children and adolescents between 1979–1981 and 1997–1999. Overweight children and adolescents also are much more likely to become overweight adults. Therefore, there is a compelling rationale to try to prevent and reduce obesity in children, for its immediate and future benefits. Targeting efforts at children may not only improve pediatric health, but potentially reduce and delay the incidence of chronic diseases in adults, such a heart disease, stroke, diabetes, and many cancers associated with obesity.

The measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included to protect participants' rights and and welfare are described above in 8c.

f. Recruitment Details

We intend to recruit 200 households of children aged 10-16 years with obesity and their parents. Pediatric weight management programs will be identified and asked to distribute a study recruitment flyer and/or email to their patients. All recruiting materials will direct potentially interested parents to our Stanford study website that describes the study and provides a REDCap screening survey to assess possible eligibility. A copy of the approved consent and assent forms will also be available via a link on our Stanford study website.

We will not be targeting children directly – only their interested parents/guardians. Other than distributing our study flyers/emails, weight management program staff will not participate in recruiting or providing information about the study.

g. Eligibility Criteria

i. Inclusion Criteria

10-16 year old children with obesity (BMI ≥ 95th %ile for age and sex).
Live in continental USA.
Internet access and Zoom video capability.
Interest in receiving Stanford online activities.

Completion of baseline data collection activities, including willingness to use the Stanford provided electronic scale and tape measure to measure weight and height during the assessment sessions.

As we are interested in testing generalizable strategies for weight control in diverse populations, the eligibility criteria are designed to be liberal, to maximize the generalizability of the results, but also maintain the internal validity of the test of the intervention.

ii. Exclusion Criteria

To enhance internal validity, children will not be eligible if they:

1) Diagnosed with a medical condition affecting growth (a genetic or metabolic disease/syndrome associated obesity, Type 1 diabetes, Type 2 diabetes taking medication, chronic gastrointestinal diseases, Chronic renal diseases, uncorrected structural heart disease, heart failure, heart transplant, AIDS or HIV infection, pregnancy); are taking medications affecting growth (systemic corticosteroids more than 2 weeks in the past year, insulin, oral hypoglycemics, thyroid hormone, growth hormone);

2) Child has had, or in next 6 months plans to have bariatric surgery;

3) Parent/guardian, or any child in the household has ever been diagnosed with an eating disorder such as anorexia nervosa, bulimia nervosa or binge eating disorder, or self-induce vomits or uses diuretics or laxatives for weight loss.

4) Child cannot fully participate in the interventions (e.g. be able to participate in routine physical activity)

5) Cannot fully participate in the assessments: child or primary caregiver not able to read surveys in English or Spanish, child not in mainstream classes at least70%

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h. Screening Procedures

On our study website, a link to an online screener in REDCap will be available. We will obtain a limited waiver of authorization for recruitment prior to asking potential participants to complete the online screener. (Section 15). After completing the waiver of documentation, the screening survey will assess inclusion and exclusion criteria listed above.

If the family is potentially eligible, based on their screening survey responses, and if they are potentially interested in volunteering and learning more about the study, they will schedule an initial Zoom video call (zoom #1) and will provide their name, email address and phone number to confirm the meeting and to receive links to the consent and assent forms.

During Zoom #1, the parent/guardian and child(ren) will meet with a research coordinator who will explain the study including data collection measures, intervention

activities and randomization and obtain signed consent from the parent/guardian and signed assent from the child. If the parent/guardian and child sign consent and assent and complete the survey measures they will schedule a second Zoom call (Zoom #2) and will be mailed an electronic cellular-connected scale, a tape measure, and a food portion size booklet to use during the dietary recall in Zoom #2. Parents will be emailed a lab requisition for their child to have fasting blood tests collected at their local Quest labs.

During Zoom call #2 the child's height and weight will be collected to determine if the child's BMI percentile meets study eligibility requirements.

After finalizing eligibility and completing baseline measures, participants will be randomized.

i. Participation in Multiple Protocols

Parents/guardians are asked if they or the participating child are participating in any other research studies during their first online Zoom meeting. We will allow participation in another study if it is not another weight control study or focused on changing diet, physical activity and/or screen time behaviors, and/or it does not increase risks to participants.

j. Payments to Participants

Parent/child family units will be compensated with a $30 gift card for their time and in appreciation at completion of the 3-month post-randomization assessments and a $50 gift card at the completion of the 6-month post-randomization assessment.

We will not include information about financial compensation for assessments in our recruitment materials because we do not want to entice families motivated by the financial compensation, but rather want to recruit families interested in the Stanford online activities.

In our previous research we have offered similar levels of compensation. Families have told us that financial compensation is not necessary or an important reason for joining the study but they do appreciate this expression that we value their time and participation in the measures. In our experience, these payments do not constitute undue pressure to participate in the study.

k. Costs to Participants

Participants are not charged for participation in the research study.

l. Planned Duration of the Study

Each child and parent/guardian will participate for a total of 6 months.

(i) Screening
Pre-screening online is estimated to take less than 15 minutes.

(ii) Active Participation in the Study

Baseline: Explanation of the study, confirmation of eligibility, completion of the consent/assent, and baseline measures will occur face-to-face via two Zoom calls. Estimated time = 90-120 minutes.

Intervention activities are sent to families by Qualtrics links via REDCap 9 times (throughout the 6 months study). Activities include short videos which range in length from 45 seconds to 5 minutes and/or a Qualtrics reading and writing activity that should take less than 15 minutes.

Follow-up Assessment Appointments: Face-to-face via Zoom follow-up assessments will occur approximately three months and six months after randomization. At the 3 and 6-month assessments, surveys will be administered, diet recalls collected, and height and weight will be measured. After six months, blood test requisitions will also be emailed. Estimated time for the 3- and 6-month Zoom appointments is 60 minutes.

(iii) Analysis of Participant Data
We anticipate keeping this protocol active for at least 10 years (5 years beyond the end of participant involvement) to complete data analysis and paper writing.

5. RISKS

a. Potential Risks

i. Investigational devices

N/A

ii. Investigational drugs

N/A

iii. Commercially available drugs, biologics, reagents or chemicals

N/A

iv. Procedures

Blood tests (venipuncture) are associated with transient local discomfort and possible bruising. Blood draws will occur at baseline and 6-month follow-up assessments. None of our measures have been associated with complications in our recent studies with hundreds of children in this same age group, using the similar measurement protocols.

v. Radioisotopes/radiation-producing machines

N/A

vi. Physical well-being

No evidence of risk to physical well-being.

vii. Psychological well-being

No evidence of risk to psychological well-being. Previous research using similar interventions have enhanced psychological well-being in both children and adults.

viii. Economic well-being

No evidence of risk to economic well-being.

ix. Social well-being

No evidence of risk to social well-being.

A breach of confidentiality might be considered a risk to social well-being, however this has not occurred in our studies to date.

x. Overall evaluation of risk

Low

b. International Research Risk Procedures

N/A

c. Procedures to Minimize Risk

A data collection/tracking system will provide confidentiality to all participants. All collected data are identified by study identification numbers but not names. No one except the research staff will have access to data. Electronic data will be kept in password protected files on password protected computers and all data forms and computers are kept in locked offices, to comply with Stanford Medical Center HIPAA policies. Consistent with Stanford University policy, all project staff will be required to complete the Human Subjects and HIPAA training modules for certification. These methods have proven successful at protecting confidentiality in our prior research.

Adverse events (any medical illnesses or injuries requiring a visit to a medical care provider or institution) will be assessed as part of the follow-up assessments. An adverse events recording form has been designed for this purpose, to systematically document all adverse events occurring during the course of the study (to at least include a brief description, severity, resolution, potential relationship to study participation, and action taken with respect to study participation). Intervention staff will also be trained to investigate and record adverse events continuously, between assessments, as they become aware of them.

Although the evidence suggests treatment does not cause disordered eating, overweight children and families seeking treatment are at increased risk irrespective of participating in treatment. Therefore, as noted above, diagnosis of anorexia nervosa, bulimia nervosa or binge eating disorder, past or present, as well as self-induced vomiting and use of diuretics or laxatives for weight loss are exclusions for the study for both children and parents.

A Safety Officer and the Stanford University Administrative Panel on Human Subjects in Medical Research (IRB) will be informed within 7 days of learning of all unanticipated

problems. With the exception of SAEs for otherwise healthy childbirth, all adverse events, regardless of seriousness, will be reported to the IRB during annual reports/reviews.

The Safety Officer is an independent physician who is designated to provide ongoing oversight to protect participant safety and make ongoing assessments of the balance between risks and benefits. The Safety Officer is a Stanford University faculty member who is not involved in this study or in the Principal Investigator's chain of command. They have relevant clinical and clinical trials experience and expertise. Confidentiality of participant data will be maintained throughout all Safety Officer reviews. The Safety Officer will act in an advisory capacity to NIH, the Principal Investigator, and Stanford University to monitor patient safety and the performance of the study.

Throughout the course of the study, while participants are enrolled, the Safety Officer will meet with the Principal Investigator to review study progress and safety, including all adverse events. An emergency meeting may be called at any time by the Principal Investigator, the Safety Officer or the study Statistician, should questions of participant safety arise. At meetings during the course of the trial, the Safety Officer's responsibilities are to:
• review plans for data safety and monitoring;
• evaluate the progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome;
• consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;
• protect the safety of the study participants;
• report on the safety and progress of the trial;
• make recommendations to the NIH, the PI, and the Stanford University Administrative Panel on Human Subjects in Medical Research (Institutional Review Board, IRB) concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study;
• ensure the confidentiality of the trial data and the results of monitoring; and,
• assist NIH by commenting on any problems with study conduct, enrollment, and sample size and/or data collection.

As an additional safety measure and potential benefit to participants, we will also screen participants for pre-existing or incident conditions that may pose a risk to their health, but are not expected to result from participation in the study. This represents an additional safety mechanism for study participants. Parents/guardians will be notified and referred to their primary medical care provider for further evaluation and care as needed, according to the appropriate current recommended cut-offs for abnormal measures of dyslipidemias, impaired fasting glucose/prediabetes, and diabetes. Notifications and referrals are made in writing, with a full explanation, and followed-up with subsequent phone calls.

d. Study Conclusion

The study will be terminated if there is clear evidence of harm or harmful side-effects of the treatment or participation in the study that outweighs evidence of the benefits of participation, if study progress (study accrual, participant retention, ability to implement the study) is judged to be insufficient to result in a valid study, or new information becomes available from other studies suggesting the risks of participation in this study outweigh the potential benefits.

Each Safety Officer report will conclude with a recommendation to continue or to terminate the study. A copy of this letter will be forwarded to the IRB and the NIH Program Officer. A termination recommendation may be made by the Safety Officer at any time during the study if deemed necessary.

We will not perform interim analyses of treatment outcomes or terminate the study early for efficacy or futility, for reasons related to the nature of the research question (see full explanation above). The Safety Officer may make a request for interim analyses at any time during the study for purposes of assessing safety/harm.

e. Data Safety Monitoring Plan (DSMC)

i. Data and/or events subject to review

The database manager and statistician will compile and report: recruitment and retention, quality control of measurements, fidelity of the of intervention implementation, participant progress in the study, and all AE, SAEs, and UPs.

ii. Person(s) responsible for Data and Safety Monitoring

The Principal Investigator and the Co-Investigators have primary responsibility. In addition, we have appointed an independent and qualified Stanford Investigator, Dr. Anisha Patel, as a Safety Officer, who has been approved by the sponsor (NIDDK, NIH).

iii. DSMB Reporting

We will report unexpected deaths or life-threatening experiences related to the research to the IRB within 5 working days from the PD learning of the event. An unanticipated problem (UP) will be reported to the IRB within 10 working days from receiving assessment from the Safety Officer. All other adverse events will be documented monthly and reported to the Safety Officer semi-annually and to the IRB annually.

iv. Will the Protocol Director be the only monitoring entity? (Y/N)

No

v. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)

Yes

6. BENEFITS

Potential Benefits of the Proposed Research to the Subjects and Others: Participants may benefit from reduced weight gain and reduced physical, psychological and social morbidities and mortality associated with excess weight, the potential psychological and social benefits of participating in a treatment program, and the potential health benefits of improved diet and activity behaviors. Other children and the public may benefit from the potential scientific and public health impact of the knowledge that may result from this study. The potential benefits to the subject and to others outweigh the potential risks.

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.