

**UCSD Human Research Protections Program
New Biomedical Application
RESEARCH PLAN**

Version Date 3/30/2004

(Enter text in the **white space areas** below each numbered heading bar. **Expand the size of table cells as needed** – to multiple pages if needed.
See accompanying Instructions for explanation of headings and information to be provided)

1. PROJECT TITLE

Parents as the Agent of Change for Childhood Obesity (PAAC)

2. PRINCIPAL INVESTIGATOR

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3. FACILITIES

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4. ESTIMATED DURATION OF THE STUDY

5 years

5. SPECIFIC AIMS

Parents play a major role in the development and maintenance of obesity in children, and logically should be considered the agent of change for the treatment of childhood obesity. One potential opportunity for improving childhood obesity treatment is to intervene with the parents, without child involvement, focusing on changing the behaviors and home environment. No study to date has evaluated an appropriately powered, empirically designed and delivered parent-only intervention for childhood obesity. Due to the rising rates of obesity in children and adults, a parent-only intervention could prove incredibly useful to clinicians, researchers and public health personnel to intervene on the childhood obesity epidemic.

The long-term goal of this program of research is to ultimately improve the treatment for childhood obesity, to prevent adult obesity. The objective of this application, which is a first step in pursuit of this program of research, is to pilot test and evaluate the efficacy of a parent-only treatment for childhood obesity. The central working hypothesis is that the parent-only treatment will result in greater weight loss for the overweight child as compared to the parent + child treatment. The specific aims of this application focus on comparing a behavioral parent-only intervention to a parent + child intervention for childhood obesity.

The primary aim of the proposed study is to compare the efficacy of the parent-only treatment to the parent + child treatment for childhood obesity.

The secondary aim is to compare treatment groups on the child and parent diet and exercise behavior, parent weight post-treatment, at 6-month, 12-month and 18-month follow up.

This line of research will provide critical information for clinicians and researchers regarding changes in the standard treatment protocol for childhood obesity, and has the potential to improve treatment outcomes.

6. BACKGROUND AND SIGNIFICANCE

Family based interventions are effective ways in which parents can improve nutrition and activity behaviors within the home, and thus influence a child's weight. Traditionally, behavioral therapy interventions combine nutrition education and exercise with behavior therapy techniques¹. Research has shown that a behavioral treatment approach is superior to no treatment for childhood obesity and control groups. The long-term efficacy of this treatment protocol has been well documented. Ten-year longitudinal data show that 1/3 of children treated by this modality are no longer overweight in adulthood, which is a significant improvement as compared to interventions for adult obesity. However, 2/3 of overweight children who have completed treatment continue to struggle with their weight into adulthood and more research is clearly needed. Parent-only interventions for childhood obesity offer developmental appropriateness for children, improved generalizability, decreased risk of disordered eating for the child, and decreased treatment costs.

Very few studies have manipulated the attendance of parents in childhood obesity treatment. Moria Golan and colleagues have published the only recent studies evaluating a parent-only intervention for childhood obesity. In all of these studies, the parent-only treatment has been shown to be superior to the comparison group. However, there are a series of methodological issues that make it difficult to generalize from this research; including lack of a true comparison group and small numbers of participants. These data suggest that a parent-only intervention is promising, but further research is needed.

7. PROGRESS REPORT/PRELIMINARY STUDIES

Pilot data on the same protocol was collected at University of Minnesota and UCSD. These data were published in 2011.

8. RESEARCH DESIGN AND METHODS

Three cohorts of 50 families will be recruited each year in the San Diego Metropolitan area with an overweight child. The families will be recruited through online ads, flyers to pediatricians, direct mailings to families and advertising on car magnets, as well as through our Facebook page that can be “liked” by participants, members of the community and health organizations. Children and their parents will be randomized by gender of the child to treatment group (parent-only or parent + child). Inclusion criteria for this study include a) An overweight 8-12 year old child (>95th); b) A parent willing to participate and attend all treatment meetings c) Parent who can read at an 8th grade reading level; d) Family willing to commit to 5 months of treatment attendance, and follow-up for 18 months post treatment. Exclusion criteria for this study include: a) Child psychiatric disorder diagnoses (based on MINI and KSADS interview), b) Child diagnoses of a serious current physical disease (such as diabetes) for which physician supervision of diet and exercise prescription are needed, c) Family with restrictions on types of food, such as food allergies, or religious or ethnic practices that limit the foods available in the home, d) Child with physical difficulties that limit the ability to exercise, and e) Child with an active eating disorder (based on EDE interview). f) Families where children or parents are involved in swimming or weight training for most than 5 hours per week; G) Major parent psychiatric disorder. Efforts will be made to recruit a diverse sample, by sending flyers to pediatricians who have a high minority patient base, as large proportions of children who are Hispanic or African American are overweight.

Those who meet the eligibility criteria will be scheduled for a baseline assessment session where both the parent and the child will have their height and weight measured, will complete the assessment packets, give a saliva sample, the parent will complete a consent form and the child will complete an assent form approved by the Institutional Review Board of UCSD. Efforts will be focused on maximizing participant retention. Phone calls will be used for missed treatment groups and to remind participants of upcoming assessments.

Families will be paid \$50 for completing baseline assessment, \$100 for post-treatment follow-up, \$150 for completing 6 month follow-up and \$200 for completing the 18-month follow-up. We will also offer \$25 for a 4-5 year follow-up assessment where only height and weight data will be collected for both parent and child.

The treatment length is set for both groups at 16 weekly meetings, followed by bi-monthly meetings during months 5 and 6. Information for parents and children is presented using standardized treatment manuals that are at the 3rd grade reading level for children and the 5th grade level for adults.

Intervention Description

The intervention will be a state-of-the-art behavioral therapy program for child weight loss, based on the empirical literature. Cognitive-behavioral treatment to change eating and activity behaviors is a standard component in the treatment of childhood obesity. Treatment includes three main components: dietary therapy, physical activity, and behavioral therapy. The topics covered in the parent and child groups will be similar, and the child information will be delivered in a developmentally appropriate manner. Additionally, we will offer a facebook page for families who are part of the FRESH study. We will post messages on the FB page regarding new research on components of childhood obesity treatment (i.e. new research on drinking water, studies on physical activity, etc. Families will be offered the opportunity to “like” the FB page, however, it is not required. All of the intervention is routine care for childhood obesity. The experimental manipulation in this study is whether the child comes to treatment (parent-only group).

Parent Only Group

The parent only group will meet once weekly for 60 minutes with a 30-minute behavior coaching visit.

Parent + Child Group

The parent + child condition will consist of 2 simultaneous groups (parent group and child group). Each group will be 60 minutes one evening per week with a 30-minute behavior coaching visit.

Trained staff will lead the parent and child groups in the parent only and parent + child arm.

All interventionists in the study will be graduate level psychology students or professionals with Masters or a Ph.D. in psychology, exercise science, nutrition or other related field. Dr. Denise Wilfley, consultant on the project from Washington University, St. Louis, Dr. Epstein, consultant on the project from SUNY Buffalo, and Dr. Boutelle will train the study interventionists in a 2-day training during the first year of the project, prior to intervention. Dr. Boutelle along with Dr. Wilfley's and Dr. Epstein's staff will review study audio/video tapes to assure treatment fidelity. In addition, Dr. Boutelle will meet with all interventionists each week for supervision during the treatment phases of the study. All study staff will have completed the Research Aspects of HIPAA course and the online CITI training module at UCSD.

Measures

Many of the questionnaire measures listed below will be assessed using Survey Monkey in the assessment office. Survey Monkey allows participants to answer surveys on the computer, and the data is directly downloaded to an excel spreadsheet. No identifying information will be included on the surveymonkey assessment. All participants will complete identifying information (name, age, birthdate etc) on paper and they will be assigned a deidentified ID number. The ID number will be used on the SurveyMonkey website.

Parent and Child Measures:

- a) *Anthropometry.*** Both child and parent will have their body size measured. Height will be measured using a portable Schorr height board in duplicate; body weight will be measured on a Tanita Digital Scale (model WB-110A) in duplicate. The average of the two values will be used for analysis and will be translated for children to BMI for age percentile score using the CDC growth charts and to Body Mass Index(BMI) in parents ($BMI=[kg/m^2]$).
- b) *Dietary intake.*** Dietary intake of the child and parent will be assessed with 3 24-hour dietary recalls at each assessment point on 3 non-consecutive days, via telephone interview.
- c) *Physical activity.*** Physical activity of the child and parent will be assessed using Actigraph accelerometers. Actigraph accelerometer (model GT1M, www.theactigraph.com) is a small (3.8 x 3.7 x 1.8 cm), lightweight (27 g), uni-axial accelerometer that is worn on a belt snugly around the waist. The GT1M records time varying accelerations ranging in magnitude from approximately .05 to 2 G's. We plan to ask participating children to wear the Actigraph for 7 consecutive days so that we may be able to assess within-person variation more precisely than if we collected data for only 4 days. Trained staff will instruct participating children and their parents on the proper procedure for attaching the Actigraph to their waistband and completing a log to record the times they did not wear the Actigraph (they'll be asked to remove the actigraph during sleeping time).
- d) *Sedentary behaviors & recreational media use.*** Sedentary behaviors and media use will be assessed using an instrument developed in the PACE+ Adolescent trial¹⁷⁹. Both child and parent will complete this measure. This 8-item survey was based on a survey developed by Robinson¹⁸⁰ and measures hours spent doing various sedentary behaviors during a typical school day and non school day. Analysis of the survey indicated that 3 factors account for 58% of the variance. The three factors were "Idle" (TV, computer/video games, listening to music, talking on the phone), "Intellectual" (homework, reading), and "Creative" (playing musical instrument, arts and crafts).
- e) *Activity logs.*** In addition to wearing the actigraph for 7 consecutive days, children and parents will complete activity logs that include physical activity and sedentary activity. Children will record their activity, television usage and computer usage on specific activity logs for the assessment. When children and parents receive instructions on using the actigraph, they will also receive instructions on completing activity logs. Actigraphs's and activity logs will be returned to project staff at the first treatment session.
- f) *Demographics characteristics and Weight History (Baseline only).*** Parent and child will complete separate demographic questionnaires that includes items on personal weight history, types of weight management strategies, dieting, weight fluctuation, health history, and parents will complete a locator information for assistance in tracking individuals.
- g) *Genetics.*** Parent and child will each give a saliva sample which will be collected using the Oragene•DNA saliva collection system. Samples will be collected before the first FRESH treatment session. Saliva will be stored at room temperature using the deidentification number assigned to each patient, and no other identifying information
- h) *Parenting Style.*** Parents and children will be presented with four situational vignettes to act out in front of a study video camera. These vignettes will address problem-solving and planning skills of the parent and child. Tapes will later be coded for positive and negative parenting styles by project staff who were not present at the taping.
- i) *Body Composition.*** Parents and children will be given the option to participate in a BODPOD measurement of body mass index and body composition. If the family elects to participate in this extra measure, parent and child will enter the FDA-approved BODPOD separately wearing their own swimsuits or similar clothing. This will provide the parent and child with increased accuracy of body mass index in addition to body fat and lean body mass percentage and overall mass.

Measures specific for the CHILD:

- a) *Psychiatric Disorders.*** The Schedule for Affective Disorders and Schizophrenia for School-Age Children (KSADS 181) is a reliable and valid semi-structured diagnostic interview with good inter-rater reliability¹⁸¹ that assesses childhood and adolescent diagnoses included in the DSM-IV. A clinical psychologist or a trained graduate student in clinical psychology will administer the child portion of the KSADS, and interrater reliability will be 0.9 or higher before initiating research. The KSADS interview will be used to determine the presence of a psychiatric disorder warranting study exclusion, or development over the study period.
- b) *Eating disorders.*** The Eating Disorder Examination version 12.0D/C.2182(EDE) has been described as the "gold standard" of eating disorder assessment¹⁸³ and will be used to assess eating disorders with the children. The EDE assesses disordered attitudes and behaviors related to eating, body-shape and weight, and diagnoses specific Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) eating disorders. The EDE interview will be used to exclude those children meeting criteria for bulimia nervosa, and to determine the presence and number of episodes of binge eating. Trained research assistants, graduate students and post-doctoral fellows will administer the EDE. Twenty percent of EDE interviews will be taped and co-rated by an independent rater to verify the accuracy of the interview. The EDE interview will be used to determine the presence of a bulimia nervosa (warranting exclusion), development of eating disorders over the study period,

and changes in binge eating over the study period

- c) *Parenting style.* Children will complete the Child Report of Parental Behavior Inventory (CRBPI).¹⁸⁹ The original CRBPI has 26 factors that measure parenting as perceived by the child, and each of the 26 factors is measured by 10 questions.
- d) *Quality of life.* The IWQOLKids¹⁹¹ is an obesity-specific measure consisting of 27-items distributed into four scales (physical comfort, body esteem, social life, and family relations).
- e) *Puberty.* Children will complete a self-report measure of pubertal development on the Pubertal Development Scale

Measures specific for the PARENT:

- a) *Medical history.* Parents will be asked to complete a medications and medical history questionnaire to report information about current and history of medical conditions for parents and the identified child. Parents will be asked to provide information on their child's current and previous medication use and to bring to the clinic visit any prescription or over-the-counter medications that are currently being used (including vitamins or other supplements). The names of these medications will be recorded and the medications will be assigned a general pharmacy index number for later classification into groups. Family and personal history of medical co-morbidities associated with obesity, including diabetes, cardiovascular disease, joint difficulties etc. will be assessed.
- b) *Home food environment.* A Food Shelf Inventory will be used to assess the types of foods that are available in the home. This 43-item inventory has been validated by Crockett¹⁹⁴ with good validity (correlation between reported and observed assessment of foods in the home was 0.86). The Food Shelf Inventory will be used to assess changes in the home food environment over the study period.
- c) *Family eating environment.* Parents will complete questions regarding time of meals, number of meals eaten together as a family, source of meals (cooked at home or take-out) and where meals and snack are eaten. Parents will also complete questions regarding practices that pertain to social interactions during meal time, including rules about family meal time, food choices during meals, rules about snacking, television viewing during mealtime, and adult reinforcement of healthy food choices. We will adapt questions from our PAAC pilot survey, to assess changes in the family eating environment over the study period.
- d) *Physical activity/sedentary behavior family environment.* Parents will complete questions regarding opportunities for physical activity in the home environment, including family physical activities, encouragement of physical activity, and encouragement of sedentary family activities. We will adapt questions from our PAAC pilot survey, to assess changes in the physical activity environment over the study period.
- e) *Parent psychopathology screener.* The Symptom Checklist-90-R (SCL-90-R) is considered a reliable and valid self-report inventory of psychopathology.¹⁹⁵ The SCL-90-R provides a Global Severity Index, and 9 symptom scales, including somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, psychoticism. The SCL-90-R scores will be converted to T scores based on norms for non-clinical samples.¹⁹⁵ The scale has been well demonstrated to be both reliable and valid.^{196, 197} The SCL-90_R will be used to determine the presence of a psychiatric disorder warranting study exclusion (such as schizophrenia, unmanaged anxiety disorder, major depression), or development over the study period.
- f) *Eating disorders.* The Eating Disorder Diagnostic Scale (EDDS)¹⁹⁸ is a 22 item self-report scale, created to be a brief screen for eating disorders. Research shows that the EDDS has good reliability (mean kappa = .80) and criterion validity (with interview diagnoses; mean kappa = .83). test-retest reliability ($r = .87$), internal consistency (mean alpha = .89), and convergent validity with other eating-pathology scales.¹⁹⁸ The EDDS will be used to determine the presence of anorexia nervosa or bulimia nervosa warranting study exclusion, or development over the study period.
- g) *Binge Eating.* The Binge Eating Scale (BES).¹⁹⁹ is a 16-item questionnaire developed to assess the severity of binge eating. Published data support its internal consistency and concurrent validity¹⁹⁹ and BES severity scores have been found to correlate with independent measures of binge eating in published studies.^{200, 201} The BES will be used to measure changes in parent binge eating over the study period.
- h) *Parenting style.* The Parenting Style Dimensions survey (PSD) to assess parenting style.²⁰² This survey can be completed by the mother or the father and assesses parenting style; authoritative, authoritarian, and permissive typologies for parents of pre-adolescent children. The survey is 62 items and these 3 factors have been useful in predicting differential developmental outcomes.²⁰² The PSD will be used to measure changes in parenting style over the study period.
- i) *Child behavioral disorders.* The Child Behavior Checklist (CBCL6-18) parent report²⁰³ will be used to screen for child internalizing and externalizing behavioral disorders, and has been updated to incorporate new normative data, include new DSM-oriented scales. The CBCL/6-18 has 118 items that describe specific behavioral and emotional problems, plus 2 open-ended items for reporting additional problems. Parents rate their child for how true each item is now or within the past 6 months. The CBCL profile provides scores for 3 competence scales (Activities, Social, and School), Total Competence, 8 cross-informant syndromes, and Internalizing, Externalizing, and Total Problems. The CBCL's validity and psychometric strengths have been well documented.^{203, 204} Cutoffs used to establish clinical criteria will be $T \geq 67$ for the behavior problem scale, and $T \geq 60$ for the internalizing and externalizing subscales and Total Problem subscales. The CBCL will be used to screen for child behavioral disorders that warrant study exclusion (severe anxiety, oppositional disorder, major

depression) at the baseline assessment, and will be used to detect any changes in behavioral disorders throughout the follow-up period.

- j) Socioeconomic status.* Family socioeconomic status will be assessed using the Hollingshead Four Factor Index of Social Status.²⁰⁵ Parents provide information about their own and their partner's educational level and employment assessment. The Hollingshead index is widely used and allows for calculation of socioeconomic status (SES) scores for both one- and two-parent families.
- k) Parent reading ability.* Wide Range Achievement Test-3 (WRAT-3) Reading subtest will be used at baseline to assess reading ability.²⁰⁶ The WRAT-3 is widely used in educational and research settings, is considered to be a good screening device for academic achievement, and is used with subjects in age 5 and older. Median test coefficient alphas for the nine tests of WRAT-3 range from .82 to .95. The alternate form correlations for the reading subtest are 0.92, and there is high correlation with measures of overall intelligence.
- l) Quality of Life* The Impact of Weight Quality of Life Questionnaire is a 31-item instrument consisting of five scales: (physical functioning, self-esteem, sexual life, public distress, and work). ²⁰⁷⁻²¹² The IWQOL-Lite questionnaire provides reliable and valid information on the functional impairment related to obesity as perceived by the person living with obesity. In a community sample, internal consistency ranged from 0.82 to 0.94 for IWQOL-Lite scales and was 0.96 for total score. Test-retest reliability ranged from 0.81 to 0.88 for scales and for the total score equaled 0.94. Internal consistency and test-retest results for overweight/obese subjects were similar to those obtained for the total sample. There is strong evidence to suggest that the IWQOL-Lite is a reliable and valid measure for treatment seeking and non-treatment seeking overweight/obese persons.²¹³
- m) Treatment utilization.* The Treatment Experience Diary will be used to collect medical utilization for each child and parent participating in the study during the period of treatment and follow up. The Diary will collect both medical utilization data and medication usage and is a revised and simplified version of a form used successfully to collect such data in previous studies of obese binge eaters (R01 DK 61912) and bulimia nervosa (R01 MH 59234) and are proposed in the TODAY study.¹²⁶

Process measures for BOTH parent and child:

- a)* Data will be collected on process variables that could contribute to the success of the childhood obesity treatment program. Attendance at treatment sessions will be collected, as well as weekly weight. Parent and child habit books will be collected, and daily self-monitoring will be scored by two independent raters on completeness, similar to other published studies that have evaluated self-monitoring
- b)* To assess set shifting, flexibility and problem solving, we will use the Wisconsin Card Sort Test (WCST). The WCST is a neuropsychological test of "set-shifting", i.e. the ability to display flexibility in the face of changing schedules of reinforcement. It has been considered a measure of executive function because of its reported sensitivity to frontal lobe dysfunction. As such, the WCST allows an assessment the following "frontal" lobe functions: strategic planning, organized searching, utilizing environmental feedback to shift cognitive sets, directing behavior toward achieving a goal, and modulating impulsive responding. Initially, a number of stimulus cards are presented to the child. The shapes on the cards are different in color, quantity, and design. The research assistant will make decisions regarding whether the cards are to be matched by color, design or quantity. The child is then given a stack of additional cards and asked to match each one to one of the stimulus cards, thereby forming separate piles of cards for each. The child is not told how to match the cards; however, he or she is told whether a particular match is right or wrong. During the course of the test the matching rules are changed and the time taken for the child to learn the new rules, and the mistakes made during this learning process are analysed to arrive at a score. The test takes approximately 12–20 minutes to administer and generates a number of psychometric scores, including numbers, percentages, and percentiles of: categories achieved, trials, errors, and perseverative errors. The test takes approximately 12–20 minutes to administer and generates a number of psychometric scores, including numbers, percentages, and percentiles of: categories achieved, trials, errors, and perseverative errors. The test can be administered to those 6.5 years to 89 years of age.⁽¹²⁸⁾
- c)* The *stop signal task*, designed to measure disinhibition, was copied from Logan, Schachar, & Tannock (1997). This task has been related to impulsivity (Logan et al., 1997) and impulsive disorders like ADHD (Schachar et al., 1995 R. Schachar, R. Tannock, M. Marriot and G. Logan, Deficient inhibitory control in attention deficit hyperactivity disorder, The stop signal task involves two concurrent tasks, a go task, which is a choice reaction time task, and a stop task, occurring on 25% of the trials and involving a stop signal that tells subjects to inhibit their responses to the go task. The task consists of five blocks, each containing 64 trials. During the go trials, the letters O or X are presented for 1500 ms on the centre of a PC computer screen, preceded by a 500 ms fixation point. The subject had to press a right button with his right hand when an X was on the screen and a left button with his left hand when an O was on the screen. Between trials, the screen was blank for 1000 ms. The subject was instructed to press the buttons as fast as possible. The stop signal was a 100 ms, 1000 Hz tone, produced by the computer. Initially, the stop signal delay was set at 250 ms after the presentation of the go signal (the O or the X) and then adjusted dynamically dependent on the responses of the subject. When the subject failed to inhibit the response, the delay was decreased by 50 ms, thereby making it easier to inhibit the next stop signal

trial. When the subject succeeded in inhibiting the response, the delay was increased by 50 ms, thereby making it more difficult to inhibit the next stop signal trial. The two variables measured in this task are reaction time (RT) and stop delay. The stop signal reaction time (SSRT) is calculated by subtracting the stop delay from the reaction time. Higher stop signal reaction times means less inhibitory control.

- d) Digit Span is a subtest from the Wechsler Intelligence Scale for Children to assess working memory in children. Includes both digit span forward and backward. Children are orally given sequences of numbers and asked to repeat them, either as heard or in reverse order.
- e) To assess parenting style and behaviors and parent-child problem-solving skills, parent-child pairs are given four different scenarios or vignettes of situations. They are instructed to pretend to have to plan one day's worth of meals and have to generate solutions for what to do at a party with many high calorie foods. Participants are given 5 minutes for each vignette. Parent-child interactions are video-taped (after parents confirm their consent and children confirm their assent to be video-taped). Parenting behaviors and parent-child interactions will be coded and analyzed qualitatively.

Please see Table I in Appendix A for Assessment measures for child and parent.

The goal of Primary Aim 1 is to evaluate the effectiveness of a behavioral parent-only intervention for childhood obesity on the target child's weight, compared to the parent + child group. We hypothesize that the parent-only treatment will produce child weight loss (BMI-P, BMI_Z) that is not inferior to the parent + child treatment group immediately following treatment and at 6-, 12-, and 18- months post-treatment.

The goal of Secondary Aim 1 is to compare effect of the treatment groups on child and parent diet and exercise behavior, quality of life, psychosocial measures, parents adherence (as measured by group attendance, adherence to behavior recommendations), parenting style, and parent weight loss (as measured by BMI) immediately following treatment and at 6-, 12-, and 18-months post-treatment.

The goal of Primary Aim 2 is to evaluate the cost effectiveness of a parent-only group, as compared to the parent + child group.

The goal of Secondary Aim 2 is to evaluate predictors of success in childhood obesity treatments, by evaluating change in weight by parent and child, compliance (as measured by group attendance, adherence to behavior recommendations), changes in household food environment, parenting style, parent and child psychosocial functioning, and parent weight loss.

9. HUMAN SUBJECTS

For this study, we will recruit up to 174 parent/child dyads. As stated in the text above, the inclusion criteria for this study are a) An overweight 8-12 year old child (99th%>eligible>85th%); b) An overweight parent willing to participate and attend all treatment meetings) who can also read at a 5th grade reading level; d) family willing to commit to 6 months of treatment attendance, and follow up for 18 months post treatment.. Exclusion criteria for this study include: a) Child psychiatric disorder diagnoses (based on parent report or diagnostic interview), b) Child diagnoses of a serious current physical disease (such as diabetes) for which physician supervision of diet and exercise prescription are needed, c) Family with restrictions on types of food, such as food allergies, or religious or ethnic practices that limit the foods available in the home, d) Child with physical difficulties that limit the ability to exercise, and e) Child with an active eating disorder based on EDE interview f) families where children or parents are involved in swimming or weight training for more than 5 hours per week; g) major parent psychiatric disorder. Our experience has been that most of the parents who attend treatment with their child are mothers. Efforts will be made to recruit a diverse sample, by sending flyers to pediatricians who have a high minority patient base, as large proportions of children who are Hispanic or African American are overweight. Considering the high Hispanic population in San Diego, we will make efforts to assure that at least 1/3 of the children in the study are of Hispanic descent.

10. RECRUITMENT

One-hundred-fifty families in the San Diego Metropolitan area with an overweight child will be recruited through online ads (Craigslist), flyers to pediatricians, flyers posting on campus, direct mailings to families, ResearchMatch, and the Facebook page. Direct mailings to families have been used at the University of Minnesota and University of New York, Buffalo to recruit families for these studies. Dr. Boutelle will buy a list of families with 8-12 year old children, and mail or email an IRB approved flyer to those families. Please see attached recruitment materials. All families who call and are interested will be contacted by the research staff and screened over the phone for eligibility and to describe the study. If participants meet criteria, they will be scheduled for an evaluation in clinic.

11. INFORMED CONSENT (Note: provide information in Section 28 on Surrogate Consent and Decisional Capacity Assessment, if applicable)

Consent will be obtained from parents and assent will be obtained from their children. The study will be described to them in detail. They will be asked if they have any questions regarding the study, after having had it described to

them plus having a chance to review the consent/assent form. Participants will then be asked to describe the study briefly, in order to ascertain that the subject comprehends the procedure to which he/she is being asked to give consent. Dr. Boutelle, or other study staff that have completed HIPAA training will obtain consent.

12. THERAPEUTIC ALTERNATIVES (therapeutic studies only)

The alternatives to participation in this study are to not participate and to seek treatment with another therapist or community program. We will offer all families who are not interested or who disqualify a list of alternate options for weight loss for children.

13. POTENTIAL RISKS

Potential risk of loss of confidentiality: Risk associated with breach of confidentiality of behavioral research data. Since this study includes psychological assessments as well as height and weight, there is the potential that this information might not be kept confidential (for instance by theft of study material). Risk of confidentiality of participation in research may be heightened by a participant "Liking" the study Facebook page, however this risk is voluntary and is in no way linked to participant study data.

Risks of psychological assessments: The main risks are that the psychological assessments and questionnaires may be considered sensitive to the parent or child. In addition, both parent and child will have their weight and height measured at the 5 assessment sessions, which may be considered sensitive to certain parents and children. However, we do not feel that these assessments pose any significant psychological risk for the patients.

14. RISK MANAGEMENT PROCEDURES

Potential risk of loss of confidentiality: The research team will make every effort to keep any information confidential. Any study material will be stored in locked cabinets in UCSD sponsored facilities. Furthermore, a unique identification number will be used for each person in data sets and spreadsheets that do not readily identify a name. The identifying name information containing material will be locked.

Risks of psychological assessments: Parents and children will receive consistent support from the behavioral therapist throughout the study. Participants (both parents and children) will be told that they are free to choose not to answer any questions that may cause them distress if they wish.

For any unidentified/unreported psychiatric concerns identified during assessments for this project, we will execute the following protocol:

- 1) Parents will be notified of concerns identified.
- 2) Family will be given a list of referrals in the community. Dr. Boutelle is the training director for the UCSD Eating Disorder clinic, and will be able to refer patients directly there and to a number of providers in the community. In terms of other psychiatric issues previously unidentified, we will refer to providers in the UCSD Pediatrics department, in the UCSD Psychiatry department, or in the community.
- 3) If significant concern is warranted (child reports suicidal ideation, significant bingeing and purging), Dr. Boutelle will call the family the following week to determine whether they have followed through on referrals. If a family has not followed through, they will be encouraged and will be offered help with following through (offer to make calls for the participant and family) if they choose to accept the assistance.

15. POTENTIAL BENEFITS

Although we do not guarantee any benefits from this study it is possible that there will be substantial benefit to overweight children and their parents that may occur through this study. Children and parents may lose weight, and/or improve their dietary intake, increase their physical activity, decrease their sedentary behavior, and improve their home food environment. Their relationship may be strengthened by working together to achieve a common goal. Children and parents may find the groups supportive. Through research such as this, the protocol for treating overweight children may change from requiring both parent and child to attend treatment, to only requiring parent attendance at treatment sessions. If the parent-only treatment is efficacious, dissemination to other treatment sites, such as primary care offices or worksites, could be more feasible

16. RISK/BENEFIT RATIO

The benefits greatly outweigh the risks involved in this study. The significant potential benefits to families include weight loss, improved dietary intake, increased physical activity, and strengthened relationships and support. Parents and children will receive consistent support from the therapist to address any concerns or distress.

17. EXPENSE TO SUBJECT

None.

18. PAYMENT FOR PARTICIPATION

Participants will be compensated \$50 for completing the baseline assessment, an additional \$100 for completing surveys immediately following treatment, \$150 for completing the follow-up assessment at 6 months post-treatment and \$200 for completing the 18-month follow-up assessment. We will offer a \$25 for a 4-5 year follow-up assessment where only height and weight data will be collected for both parent and child. This compensation is intended to offset any travel expenses and/or time taken from work, and to decrease risk of lost data.

19. PRIVILEGES/CERTIFICATIONS AND LICENSES

Dr. Boutelle is a licensed clinical psychologist.

20. BIBLIOGRAPHY

Epstein LH, Roemmich JN, Raynor HA. Behavioral therapy in the treatment of pediatric obesity. *Pediatr Clin North Am.* Aug 2001;48(4):981-993.

Epstein LH. Family-based behavioural intervention for obese children. *Int J Obes Relat Metab Disord.* Feb 1996;20 Suppl 1:S14-21.

Epstein LH, Myers MD, Raynor HA, Saelens BE. Treatment of pediatric obesity. *Pediatrics.* Mar 1998;101(3 Pt 2):554-570.

Golan M, Weizman A, Apter A, Fainaru M. Parents as the exclusive agents of change in the treatment of childhood obesity. *Am J Clin Nutr.* Jun 1998;67(6):1130-1135.

Golan M, Kaufman V, Shahar DR. Childhood obesity treatment: targeting parents exclusively v. parents and children. *Br J Nutr.* May 2006;95(5):1008-1015.

21. INDUSTRY STUDIES

NA

22. FUNDING SUPPORT FOR THIS STUDY

NIH 5R01DK075861

23. BIOLOGICAL MATERIALS TRANSFER AGREEMENT

NA

24. INVESTIGATIONAL DRUG FACT SHEET

NA

25. IMPACT ON NURSING STAFF

NA

26. CONFLICT OF INTEREST

None of the investigators or any of the study personnel has any financial interest in this study. This includes any financial relationships, service on advisory boards, company officer and stock option ownership. All investigators will complete a 700U form on file with Grants and Contracts.

27. CANCER-RELATED STUDIES

NA

28. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

NA

Version date 3-30-2004

Note: Supplemental form pages follow. **Delete them** if not appropriate to this project

Appendix A

Table 1. Assessment Measures for Parent and Child

Domain	Instrument	Abbrev	Child or Parent	Mins Child	Mins Parent	Timepoint					Format/Method
						BL	Day1	6	12	24	
FIRST ASSESSMENT VISIT											
Anthropometry	Height/Weight		C, P	5	5	X	X	X	X	X	Staff
Energy Balance Behaviors	YBRFSS (Dietary behavior and physical activity)	YBRFSS	C	10		X		X	X	X	C = Self-report
	Diet History Questionnaire	DHQ II	P		20	X		X	X	X	P = Self-report (take home)
	Project EAST measure (sedentary activity)		P		3	X		X	X	X	P = Self-report
	GODIN Leisure-time exercise questionnaire	GODIN	P		2	X		X	X	X	P = Self-report
Screening (at 1st assessment visit)	PRIME MD Screen		P		5	X					P = Self-report
	Eating Disorder Examination Questionnaire: YEDE-P, YEDE-C, & EDEQ-P	EDEQ-P, YEDE-P, YEDE-C	P, Pc, C	5	10	X		X	X	X	P, Pc, C = Self-report
	Medical history questions		P, Pc		5	X					P,Pc = Self-report
	Child Behavior Checklist	CBCL	Pc		15	X				X	Pc = Self-report
	ChEDE interview -overeating module (+questions on secretive eating/LOC)	ChEDE	C		25	X		X	X	X	C = Interview
	MINI/KASADS	MINI	C		20	X					C = interview
Demographics	Age, gender, ethnicity, grade in school (for child)		C, P	5	5	X					C,P = Self-report
	SES - Barratt Simplified Measure of Social Status (Hollingshead Modified)		P		5	X					P = Self-report
	Reading ability - WRAT-4		P		5	X					Staff admin test
Psychosocial functioning	Child Dietary Self-efficacy / Self-efficacy Scale for Children's Physical Activity	CDSS, SESCOA	C	5		X		X	X	X	C = Self-report
	Eating in the Absence of Hunger	EAH	C, P, Pc	5	10	X		X	X	X	C,P,Pc = Self-report
	Child Eating Behavior Questionnaire	CEBQ	C, P	5	5	X		X	X	X	C,P = Self-report
	Emotional Eating Scale - Child version	EES-C	C	5		X		X	X	X	C = Self-report
	Brief Symptom Inventory	BSI	P		15	X				X	P = Self-report
	Center for Epidemiologic Studies Depression Scale for Children (added after wave 1 BL)	CESD-C	C		5	X		X	X	X	C = Self-report
	Loss of Control Eating	LOC-ED	C		5	X		X	X	X	C = Self-report
	Teasing questions from Sizing Me Up/Them Up and from PAAC		C		5	X		X	X	X	C = Self-report
	Sizing Me Up/Sizing Them Up (quality of life related to obesity)	SMU/STU	C, P		5	5	X		X	X	X
Pediatric Quality of Life Inventory	PEDSQL	C, P		5	5	X		X	X	X	C,P = Self-report
Estimated time for 1st visit				115	120						
SECOND ASSESSMENT VISIT											
Energy Balance Behaviors cont.	24-hour recall (+sleep questions) (missing by design)	24hr recall	C, P			X		X	X	X	Interview
	Accelerometers (missing by design)	ACC	C, P			X		X	X	X	Electronic
	Eating Patterns	EP	C, P	5	5	X		X	X	X	C,P = Self-report
Parenting	Child Report of Parent Behavior Inventory	CRBPI	C, P	20	20	X		X	X	X	C,P = Self-report
	Parent Motivation Inventory	PMI	P		5	X		X	X	X	P = Self-report
	Parent Consideration of Future Consequences	PCFC	P		5	X		X	X	X	P = Self-report
	Birch Child Feeding Questionnaire	CFQ	P		10	X					P = Self-report
	CHAOS - Daily Life At Our House	CHAOS	P		5	X		X	X	X	P = Self-report
	Raising Children Checklist	RCC	P		5	X		X	X	X	P = Self-report

	Family Assessment Device (family functioning)	FAD	P		5	X		X	X	X	P = Self-report
	Healthy Lifestyle Family Responsibility Questionnaire	HLFRQ	P		5	X		X	X	X	P = Self-report
	Family meal - video taped		C, P			X		X			Staff, video
	Vignettes pre and post - video taped		C, P	15	15	X		X			Staff, video
Socio-environment	Home Food Inventory (Gorin's modification of Raynor's measure)	HFI	P			X		X	X	X	P = Self-report (take home)
	Exercise Environment Questionnaire	EEQ	P		5	X		X	X	X	P = Self-report
Treatment and Adherence	Attendance (weekly assessment)						X	X			Staff
	Adherence measure (behavioral changes and implement at home), pre & post		C, P	2	5	X		X	X	X	C,P = Self-report
	Self-monitoring in habit books (weekly assessment)						X	X			Staff
Nutrition Knowledge	Knowledge Questionnaire		C, P	5	5		X	X			C,P = Self-report
Cost-effectiveness	Travel information form: mileage/time travel, cost of childcare (weekly assess)		P			X	X	X			P = Self-report
	Health care diary (aka Treatment Experience Diary) (monthly assessment)		P			X	X	X	X	X	P = Self-report
	Track: # of parent only visits and # of parent/child visits (weekly assessment)		C, P				X	X			Staff
Behavioral phenotypes	Inhibition/Impulsivity - Stop Task	Stop	C, P	20	20	X		X			Staff admin task
	Planning/problem-solving - Wisconsin Card Sort Test	WCST	C, P	20	20	X		X			Staff admin task
	Working memory - WISC-IV Digit Span	WISC-IV, WAIS-IV DS	C, P	10	10	X		X			Staff admin task
Genetic	Saliva samples	SAL	C, P			X					Saliva kits
Estimated time for 2nd visit				92	140						
TOTAL ESTIMATED TIME (minutes) TO COMPLETE Note: Time estimates do not include 24-hr recall, accelerometer data, and home video taping. DHQ and HFI are given to parents to complete after the first assessment and to bring back at second assessment.				207	260						