Connect 4 Health Detailed Protocol
Study PI: Elsie Taveras, MD, MPH

Connect 4 Health
Detailed Protocol
Version Date 9/28/16

Study PI: Dr. Elsie Taveras
Chief, Division of General Academic Pediatrics, Department of Pediatrics
Massachusetts General Hospital for Children

Co-Investigators and Study Staff

- Dr. Mona Sharifi (Co-I)
  General Pediatrics Faculty, Massachusetts General Hospital for Children
- Dr. Richard Marshall (Co-I)
  Pediatrician, Harvard Vanguard Medical Associates
- Dr. Dan Slater (Co-I)
  Pediatrician, Harvard Vanguard Medical Associates
- Dr. Thomas Sequist (Co-I)
  Physician, Brigham and Women’s Hospital
- Dr. E. John Orav (Co-I)
  Statistician, Brigham and Women’s Hospital
- Dr. Lauren Fiechtner (Co-I)
  Research Fellow in the Division of General Academic Pediatrics, Massachusetts General Hospital for Children and Fellow in Pediatric Gastroenterology and Nutrition Boston Children’s Hospital
- Christine Horan, MPH
  Project Manager, Massachusetts General Hospital for Children
- Sarah Price, MPH
  Senior Health Educator, Massachusetts General Hospital for Children
- Leilani Hernandez, MPH
  Data Analyst, Harvard Vanguard Medical Associates
- Jonathan Watson
  Project Manager, Harvard Vanguard Medical Associates,

I. Specific Aims:
Connect 4 Health Detailed Protocol
Study PI: Elsie Taveras, MD, MPH

Health care system (HCS)-based interventions have been limited by their inattention to social and environmental barriers that impede improvement in obesity-related behaviors. Additionally, current pediatric obesity care delivery relies on an outdated provider:patient paradigm which is ill-suited for a problem as prevalent as obesity. HCSs often lack the organizational structure to provide longitudinal care for children with chronic illnesses, the clinicians to manage and support patients with chronic illnesses outside of clinic, and/or the health information systems that support the use of evidence-based practices at the point-of-care. Thus, the research question this study is designed to address is whether a novel approach to care delivery that leverages delivery system and community resources and addresses socio-contextual factors will improve family-centered childhood obesity outcomes.

The primary specific aims are to examine the extent to which the intervention, compared to the control condition, results in:

a. A smaller age-associated increase in BMI over a 12-month period.
b. Improved parental and child ratings of pediatric health-related quality of life.

The secondary aims are:

a. To examine parental ratings of quality and family-centeredness of pediatric obesity care and compare outcomes among participants in the intervention with the control condition.
b. To assess change in weight-related behaviors and compare outcomes among participants in the intervention with the control condition.
c. To assess the following process measures:
   a. Reach
   b. Extent of implementation
   c. Fidelity to protocol
   d. Parent satisfaction.
d. To examine the extent to which neighborhood environments modify observed intervention effects.
e. To assess the documentation of Healthcare Effectiveness Data and Information Set (HEDIS) measures in participant medical records.

II. Background and Significance
**Connect 4 Health Detailed Protocol**

**Study PI: Elsie Taveras, MD, MPH**

**Childhood obesity is highly prevalent and of consequence.** In the past three decades, obesity rates among adults and children have substantially increased worldwide. Healthy People 2020 has declared obesity a national health priority. In the US, approximately 32% of children ages 2 - 19 years are overweight (age- and sex-specific body mass index [BMI] 85th to 94th percentile) or obese (BMI ≥ 95th percentile). Childhood obesity is associated with both short- and long-term adverse outcomes and with higher morbidity and mortality in adulthood. Obesity is also associated with several “silent co-morbidities” that are deeply experienced by children including social marginalization, relational victimization, bullying, and poor health-related quality of life.

**Substantial racial/ethnic and socioeconomic disparities exist in childhood obesity.** In the US, obesity rates in some population subgroups, such as whites and those of higher socioeconomic status, appear to have peaked. However, overall rates remain stubbornly high and racial/ethnic disparities appear to be widening. Racial/ethnic disparities in obesity prevalence emerge in cohorts as young as 2-years of age, e.g. prevalence of obesity is 9.2% among non-Hispanic white children, 16.2% among Hispanic children and 18.9% in non-Hispanic black children. Research has also shown that racial/ethnic and socioeconomic disparities exist across most known risk factors for obesity starting early in childhood.

**Health care systems (HCS) are well-positioned to have an impact on childhood obesity.** The primary care setting offers unique opportunities for detection of elevated BMI levels and for offering interventions to alter the subsequent course of health and disease for children at risk for obesity. HCS-based interventions to reduce childhood obesity have been particularly effective among low-income children. New recommendations from the United States Preventive Services Task Force (USPSTF) offer comparative effectiveness research evidence on the management of obesity in children. The recommendations, based on over 15 good-quality weight management interventions among children 4 to 18 years of age, support that 1) screening and evaluation of children for obesity is an important prelude to effective treatment and 2) behavioral management techniques to make and sustain lifestyle changes are important intervention components.

**Despite their advantages, HCS-based interventions have not realized their full potential in obesity management.** Providers do not routinely identify overweight or obese children. Even when identified, children do not receive adequate counseling and parent satisfaction with obesity care is low. The interventions recommended by the USPSTF are not readily available due to strained resources and a shortage of staff with behavioral expertise. Approaches that rely on primary care providers to deliver the bulk of treatment are often unsustainable because of the intensity required for effective behavior change. HCS interventions are also often limited in their effectiveness due to the myriad social and environmental factors that impede
improvement in obesity-related behaviors. To maximize effectiveness in improving obesity and reducing disparities, interventions must address the non-medical but health-critical factors, should be structured and scalable within a large HCS and should extend outside of the clinic to settings where children and families spend most of their time, chiefly, their homes and communities.

Understanding families’ social and environmental context could improve obesity management. Neighborhood socioeconomic characteristics and built environment factors including the food and physical activity environments can significantly influence health behaviors. Understanding community levels of poverty and unemployment as well as individual, health-related social problems such as poor health literacy and food insecurity could assist health practitioners in providing targeted resources and selecting referrals for local health and social service agencies. Sophisticated geographic information systems (GIS) analyses can provide community-level data on access to and distribution of food establishments including supermarkets and fast food restaurants that could assist in meal planning discussions with families. GIS methods can also provide information about recreational spaces and playgrounds as well as traffic patterns, crime distribution, and transportation availability that might influence parents’ decision-making regarding their child’s physical activity options. Thus, characterizing the environment can assist in developing the best, flexible, clinical-community intervention that could be adapted to an individual’s personal and environmental setting.

Novel approaches to care delivery that leverage clinical and community resources and address socio-contextual factors could improve family-centered outcomes for high-risk, overweight and obese children. Our proposed intervention will draw from two conceptual frameworks. The first is the Chronic Care Model (CCM) developed by Wagner et al, which will guide our approach to improving the HCS for childhood obesity management. The CCM identifies the essential elements of a HCS that encourage high-quality care for chronic conditions such as obesity. The second conceptual framework that will guide our approach is the Social Contextual Framework. This framework takes account of the multi-level influences on excess weight gain. It draws from several disciplines to help identify key constructs to address within an intervention, and suggests important social contextual factors to be taken into account when creating intervention strategies. The Social Contextual Framework will augment our CCM clinical approach by guiding us in addressing the social and environmental factors that mediate and moderate obesity-related behaviors.

III. Study Populations and Recruitment
Connect 4 Health Detailed Protocol
Study PI: Elsie Taveras, MD, MPH

Setting and Study Population
This trial will be conducted at the 6 Harvard Vanguard Medical Associates (HVMA) pediatric health centers that care for children from neighborhoods with the highest prevalence of overweight or obesity: Braintree, Chelmsford, Kenmore, Medford, Quincy, and West Roxbury. Our goal is to recruit 750 children between the ages of 2-12 years at the time of enrollment.

Inclusion Criteria
Eligibility criteria will be assessed by both the referring primary care provider and research staff and will include:

1. child is age 2.0 through 12.9 years at baseline primary care visit,
2. child’s BMI is equal to or exceeds the 85th percentile for age and sex at baseline primary care visit,
3. at least 1 parent has an active email address,
4. at least one parent is comfortable reading and speaking in English.

Justification for Inclusion Criteria
1. The purpose of this study is to implement an obesity management intervention among pre-school and school-aged children. We will recruit children age 2.0 through 12.9 years to cover children in this age group.
2. Our intervention is targeted at addressing overweight and obese children. Thus, study participation will be limited to those children with a BMI percentile greater than or equal to the 85th percentile.
3. An active email address for one parent is a requirement to enable participants in both the usual care and intervention groups to complete the parent survey. Email will be an important means of communication for survey data collection as well as communication between participants and health coaches for those in that intervention group.
4. Comfort speaking and reading English is required because the survey and health coaching intervention will be administered only in English. Participants will also be screened and enrolled only in English.

Exclusion Criteria
We will exclude:

1. children who do not have at least one parent/legal guardian who is able to follow study procedures for 1 year,
2. families who plan to leave HVMA within the study time frame,
3. families for whom the primary care clinician thinks the intervention is inappropriate, e.g., emotional or cognitive difficulties,
4. children who have a sibling already enrolled in the study,
5. children who are part of the youth advisory group, or have parents who are members of the parent advisory group,
6. children with chronic conditions or on medications that substantially interfere with growth or physical activity participation.

Justification for Exclusion Criteria

1. Enrollment of children in our target age group requires the informed consent of at least one parent/legal guardian. Additionally, since parents are also the health and healthcare decision makers for children this age, all study communication and activities will require their participation.
2. To minimize loss to follow up, we will exclude families who know at the time of recruitment that they will not stay at HVMA for the next year, the duration of the intervention.
3. The study requires clinicians to activate a referral in the patient’s electronic health record to indicate they approve the family’s involvement in the study. Clinicians may know of circumstances that make this study inappropriate for some families and the referral will ensure that is accounted for in the recruitment process.
4. We must enroll only one child per family to avoid the risk of randomizing siblings to different intervention groups. Since a parent’s involvement is required, having children in different intervention groups could result in the modification of the interventions effects.
5. Some children and their parents who participated in the Secrets of Success focus group and interviews have been invited to participate in the parent and youth advisory boards. We specify later in the protocol that parents and children participating in our advisory boards will not be research participants.
6. To assess if our study activities can affect BMI percentile among children, we want to eliminate the risk that change is due to a pre-existing condition or medication that may affect the child’s normal growth and development.
Recruitment
We will recruit eligible participants from the 6 practices at Harvard Vanguard Medical Associates that care for children from neighborhoods with the highest prevalence of overweight or obesity. These 6 practices are: Braintree, Chelmsford, Kenmore, Medford, Quincy and West Roxbury.

We will recruit all eligible children who are scheduled for a visit in primary care from the time the intervention begins in approximately June 2014 and will continue for 12 months or until we have reached our enrollment goal of 750 children. We request a waiver of consent and authorization to obtain names, basic demographics, contact information and weight-related data from Harvard Vanguard Medical Associates for recruitment purposes for the intervention. We will also request a waiver of authorization for a to collect pediatric obesity HEDIS measures documented at this 1 year visit as well as healthcare utilization data for the child within approximately the last year at the 9 HVMA pediatric offices that are not participating in the intervention. We will also collect the practice site and child’s date of birth, race/ethnicity BMI and BMI percentile. This will be part of a quality improvement evaluation at HVMA. This data will also be collected from consented participants, as well as other eligible children at the intervention sites and is further discussed under Study Close Out/Data from HVMA. We request this research be reviewed by Partners IRB on behalf of Harvard Vanguard Medical Associates, Inc. under the IRB Authorization Agreement entered into by BWH, MGH and Harvard Vanguard in October, 2012 (the “IAA”). Under the IAA, Partners constitutes the IRB/privacy board for Harvard Vanguard with respect to the covered studies. This research involves the protected health information of Harvard Vanguard patients. Harvard Vanguard submits a review request for each project that it wishes to have reviewed under the IAA. Harvard Vanguard’s review request for the research is submitted with this application. The request includes a request for waiver of informed consent and authorization on behalf of Harvard Vanguard to permit use and disclosure of the protected health information of Harvard Vanguard patients for purposes of study recruitment and quality improvement activities.

Research staff at HVMA will provide MGH weekly data pulls of children age 1.5-12.9 with a BMI ≥ 85th percentile with a scheduled upcoming primary care visit. This weekly data pull will include:

- the child’s name
- gender
- date of birth
Connect 4 Health Detailed Protocol

Study PI: Elsie Taveras, MD, MPH

- most recent height weight, BMI and BMI percentile from a visit within the last 15 months; for children under 2 years – most recent length, weight, weight for length and weight for length percentile within the last 9 months.
- address
- parent telephone numbers
- name of the clinician
- appointment site
- date/time of the scheduled visit.

The study team will receive the weekly data pulls for the duration of the recruitment period. Patient data for recruitment purposes will be transferred from the HVMA to Partners secure servers by the approved research staff. A secure file transfer protocol (SFTP) site will also be set-up for data transfer between HVMA and MGH to electronically transfer the data. After all contracts and approvals are in place at MGH, the MGH Clinical Project Manager will access and download the data file from the secure FTP site to a secure, access restricted Shared File Area (SFA) on MGH’s server. The Project Manager will manage access to this area through MGH’s IT Department. Only approved study staff at HVMA will be given access to this area. The file itself will also be password protected. No data will be transferred via email or saved on the hard drive of a computer.

Approximately 1-2 weeks before their scheduled visit, study staff at MGH will send a note card (Appendix 2 Recruitment note card) to potentially eligible families encouraging them to ask their clinician if their child is eligible for the Connect 4 Health study. A child may still be referred to the study by their clinician even if they did not receive a note card prior to the visit (i.e., a child who increased their BMI percentile since their last visit from <85th percentile at their previous visit to ≥85th percentile at the current visit).

At the patient’s visit, the clinician will receive a Best Practice Alert (BPA) (Appendix 20 – BPA draft) in the patient’s electronic health record (EHR) if the child is weighed and measured and the calculated BMI is ≥ 85th percentile. The BPA will include a referral to the Connect 4 Health study. The clinician will discuss the study briefly with the parent and if the parent and clinician agree, will refer the family to the study. Research staff will also provide HVMA clinicians with a one-page handout (Appendix 3 Fact Sheet) to provide parents with more information about the study, including next steps and a phone number parents can call to begin the enrollment process if they are interested.
Following the child’s appointment, MGH staff will be informed if a patient received a referral to the study from his/her clinician. The referral will be sent from the HVMA office to the MGH project manager or clinical research coordinator. These referrals will include:

- patient’s name
- date of birth
- gender
- Ethnic group
- address
- parents’ names
- parents’ phone numbers
- name of the clinician
- appointment site
- date/time of the completed WCC visit
- height, weight, BMI and BMI percentile and blood pressure from visit

The referral will be sent one of the following ways:
- automatically via secure email or an sftp site to the MGH project manager and CCing the HVMA data analyst or project manager or
- faxed by HVMA support staff to the MGH project manager.

The MGH project manager will share the referral with the clinical research coordinator, who will update the patient’s record in the study database, stored in a restricted SFA. Research staff responsible for study recruitment will access this data to identify who to contact. In case the parent did not receive a fact sheet at the child’s visit, research staff will mail all parents the fact sheet after updating their information (Appendix 3.1 Fact Sheet Intro Letter). Approximately 5 days after the fact sheet is mailed, research staff at MGH will call the parent of every child who has received a referral from his/her clinician. (Appendix 4 Eligibility and Consent phone script). Several attempts will be made each week (up to approximately 4 weeks) with a message left only on every third call attempt (Appendix 5 Voicemail script). If we cannot reach a participant by phone, and we have an email address available, we will send an email requesting to schedule an appointment to conduct the call (Appendix 6 Email to schedule recruitment call). Approximately 2 weeks after the calls begin for a patient, parents who have not yet been reached will receive a follow up mailing to encourage them to speak to a research team member during one of these call attempts or to contact us via the designated study line phone number (Appendix 7 Recruitment reminder mailing).
Connect 4 Health Detailed Protocol
Study PI: Elsie Taveras, MD, MPH

During the recruitment call we will explain that we are conducting a research study to examine strategies to improve childhood obesity prevention. Research staff will briefly describe the study and, if parents are interested in participation, confirm eligibility criteria. If the parent requests we resend the fact sheet, we may offer the option to email the fact sheet to the parent. (Appendix 29 Fact Sheet Email Template).

Consent
Eligible individuals will be consented over the phone immediately after screening. Study staff will review the fact sheet with subjects, answer all questions, and ask subjects to provide verbal consent. Verbal consent will be recorded and the date, time, and initials of the research staff member who conducted the consenting process noted. We believe verbal consent is warranted as this is a minimal risk study. The fact sheet will inform parents about the study before having an opportunity to discuss and ask questions to a study team member.

Child participation in this study involves minimal risk and the child will not be asked to do anything the parent has not already consented to. Children will be invited to participate in any activities their parents would like them to be involved in, but the child’s participation is voluntary. Additionally, since we are consenting parents by phone, we will not have an opportunity to review an assent form with the child in person. Half of our eligible sample will not be capable of providing assent based on age and maturity. For those children 7-12 years old, we do not feel the child should be asked to sign an assent form without a study staff member available to explain the form to him/her. Therefore, we will address a child’s willingness to participate by acknowledging the voluntariness of their participation and when applicable, asking them verbally if they want to take part in the activity (i.e., health coaching visit).

Once consented, parents will be asked to complete the baseline survey by phone. (Appendix 9.1 Combined Parent Baseline survey).

After we complete the baseline phone survey with the parent, we will send him/her an email with a link to an electronic gift card worth $25 from Amazon (Appendix 19 Email template for e-gift cards). We will also send him/her an enrollment letter that outlines the parent’s and child’s roles in the study (Appendix 12a, 12b Enrollment letters (UC and Ix). For parents with an enrolled child between the ages of 8-12 years, we will also include a short survey to be completed by the child (Appendix 14 Child Survey, Appendix 15 Child Survey Intro Letter). Instructions for the child survey will be included in the letter to the parent (Appendix 13a and 13b (UC and Ix) Enrollment letter w/ child survey). We will attach a $2 bill to the survey as an incentive for the child to complete the survey. We will also include a postage-paid business
reply envelope for the return of the child survey. If the survey is not returned 10 business days after it was mailed, we will make a reminder call to the parent. If the parent is not reached at this time, a reminder email will also be sent. If the survey still has not been received one week later, we will make a second reminder call (Appendix 16 Child Survey Reminder Phone Script). If a child has not returned his/her survey approximately 2 weeks after the last reminder call is made, we will send the family one more reminder mailing (Appendix 64 –Child Survey Reminder Letter). In this reminder, we will offer children who return their survey by a designated date, an entry in a prize drawing for a $25 gift card to a local trampoline park. We will also send a text message reminder, or email for those who requested not to receive text messages, to the parent asking them to encourage their child to return the survey. After all participants have been sent the child survey, and have had the allotted time to return it, approximately 1 month after recruitment ends, we will conduct the drawing and select one winner. Children will be instructed to return the completed survey along with the bottom portion of the reminder letter signed by the parent. This signature will acknowledge the parent’s consent to enter the child in the drawing upon return of the survey. We will put the IDs for all eligible contestants in a hat and randomly draw the winner. We will contact the parent of the winner by phone shortly after the drawing.

We will send the child survey at baseline and send a similar survey again at 1 Year, as a means to assess quality of life, as reported directly by the child (Appendix 25- Child Year 1 Survey Under development). We will survey only 8-12 year old children. We will administer a written survey, and younger children may not be able to read and complete a survey on their own.

All participants will be sent a “birthday card” on or around their birthday that occurs while enrolled in the study. The birthday card will be emailed to the parent’s email address provided and will ask the parent to share the “card” with their child (Appendix 30 Birthday Card Email Template).

Remuneration
Parents in both intervention groups will receive a total of $50 for their participation.
- $25 Amazon gift card for the completion of the baseline survey
- $25 Amazon gift card for the completion of the follow-up survey

Parents with children enrolled in the intervention group will be eligible to receive an additional $20 in Amazon gift cards for completing at least 80% of the health coaching contacts by the 6 month contact point. Parents will receive a $10 gift card for completing Contact #2 (the 1-2 month visit), the first true coaching visit. They will receive another $10 gift card if they complete at least 4 of the first 5 contacts (80%).
Connect 4 Health Detailed Protocol
Study PI: Elsie Taveras, MD, MPH

Children 8-12 years old will receive $4 to encourage them to complete study surveys. They will receive:

- $2 to encourage them to complete the baseline survey
- $2 to encourage them to complete the follow-up survey

Randomization
Once the parent provides verbal consent and completes the phone survey, participants will be randomized into one of two groups. Study participants will be randomized from 6 centralized randomization lists, one for each of the 6 pediatric practices, generated by the study statistician and maintained by the study project manager. The lists will be organized into blocks of size 4 in order to maintain balance between the two study arms in each of the practices. Patients will be randomized according to the order in which their consent was obtained. No one except the study project manager and study statistician will have access to the randomization lists: the study project manager in order to implement the proper intervention; the study statistician in order to provide blinded reports of study progress and safety data. Unblinding will not occur until after the general portion of the final parent survey is completed.

IV. Study Visits and Data Collection

Intervention Group The intervention for this study will consist of three elements: visits with a health coach, connection to community resources and an interactive text messaging program.

1. Health coach visits

Parent/child duos enrolled in the intervention group will be invited to participate in a total of six visits with a trained health coach. Approximately 1-2 weeks after enrollment, parents will be contacted by the health coach by phone for their first visit. Health coaches will call parents until they are reached to schedule the in-person visit and will not leave voicemails more than once every other day (Appendix 33 Health Coach Voicemail Script #1). If a parent cannot be reached after approximately 1 week, a letter or email will be sent to the parent asking them get in touch with us via phone or email (Appendix 40 HC Call 1 Letter/Email Template). At the end of this call the next visit will be scheduled for approximately 4-6 weeks later. We will encourage this visit to be in-person, but also offer a video call option, if scheduling the in-person visit is difficult. In-person visits will be held at HVMA offices. Subsequent visits will take place by telephone calls, video calls and in-person visits, according to the parents’ preference. We will send parents an email to confirm the visit after it is scheduled (Appendix 43a and 43b Email templates for health coach meeting
confirmation) and send a text message reminder about 1-2 days before the appointment date. Health coaches may check in with parents intermittently by email.

The schedule for the visits will be approximately as follows: (Appendix 17)

1. 1-2 weeks after enrollment (initial phone call)
2. 1-2-mos after enrollment
3. 3-mos after enrollment
4. 4-mos after enrollment
5. 6-mos after enrollment
6. 10-mos after enrollment

During these visits, the health coach will coach the parent/child duos on improving obesity-related behaviors (Appendix 22- Outline of Health Coach visits). These contacts will be structured to
1) review a tailored map that highlights resources available in their community that support healthy behavior change;
2) direct them to appropriate resources and community partners as desired, using a study-specific community resource guide for reference;
3) review social contextual and motivational factors affecting behavior change;
4) set behavioral goals; and
5) share educational materials.

If the parent misses or cancels a visit, the health coach will attempt to reschedule the visit by calling, emailing and/or texting the parent (Appendix 48 HC email text VM phone script scheduling templates). If the visit is not rescheduled, it will be documented as a missed visit.

If after approximately 3 months or more of attempted contacts we are unable to complete the first study visit, we will send an email including the “Our health coaches are here to support you” message shown in Appendix 65, and include previously approved health coaching participant documents as attachments. In addition, we will mail the participant a packet of previously approved health coaching materials, as well as a hard copy of the card shown in Appendix 65. About 10-14 days after this mailing has been sent, the health coach will attempt to contact the participant for approximately 2 weeks to try to schedule a subsequent health coaching visit.

After approximately 6 months have passed since enrollment, or 3 months or more since contact attempts began for visits 3-6, we will send an email including the “We miss you”
message shown in Appendix 65, and include previously approved health coaching participant documents as attachments. About 10-14 days after this email has been sent, the health coach will attempt to contact the participant for approximately 2 weeks to try to schedule a subsequent health coaching visit.

Approximately 9 months after enrollment or 3 months after the last “no-show email”, an email will be sent (Appendix 65) with previously approved participant handouts attached.

Quality Assurance Review
We will implement a quality assurance review to assure consistency across health coaches and fidelity to the health coaching protocol. To do this, health coaches will each audio-record 10 health coaching visits, with permission from each of the participants. Parent participation in the audio recording is entirely voluntary and visits will only be recorded if participant consent is granted at the beginning of the health coach visit (Appendix 22 Outline of health coaching visits). If the participant says no, the visit will proceed but not be recorded.

Audio recordings will be identified by participant ID. A designated research staff member will review the recordings using the QA checklist (Appendix 91) to assess consistency across the health coaches and fidelity to the protocol, and to note any areas for improvement. These checklists and notes will subsequently be reviewed with the health coaches.

2. Connection to community resources

The health coach will also help the family identify supports to assist with behavior change; discuss family health habits and the home environment; and review and encourage use of materials related to both specific target behaviors and available resources in the community. To further support families in making contact with the recommended community resources, we will offer to connect them to community partners by providing contacts or reaching out on their behalf. For example, if during a health coaching visit or call, a family expresses interest in learning about their local YMCA, the health coach could call the Connect 4 Health YMCA liaison to initiate that contact. If the liaison is reached, the health coach will turn the call over to the parent to speak to the liaison directly. No message will be left if the liaison is not reached at that time. The health coach will also give parents who are interested in the YMCA a letter offering a free 1-month family membership to a local YMCA (Appendix 39 YMCA Membership letter). Families can later take the letter to the Y to redeem the membership. The Y may provide study staff with information about
whether or not the free membership was used, how frequently the family used the facility and if the parent extended their membership beyond the free-trial period. Parents will be informed the YMCA may share this information in the Fact Sheet. If the parent/child is already enrolled in the study and in the Intervention group, they will be asked permission to share their data about use of the Y at the health coaching visit when the trial membership is offered. This consent will be documented in the study database. If a parent does not consent to allow the Y to share this information, the family will still be allowed to take advantage of the free 1 month membership. Study staff will not share any health information about the participants with the YMCA.

Parents will also receive a general handout about Cooking Matters at the Store with a prompt to ask their health coach for more information (Appendix 38 Cooking Matters at the Store Introductory page). Cooking Matters at the Store is a grocery store tour with an emphasis on healthy eating and we would like to encourage parents to attend when it is offered in their community. Cooking Matters also offers a Healthy Shopping Workshop, with similar content to the Cooking Matters at the Store tours, but offered at other locations within communities. Participants will be sent an invitation to attend Healthy Shopping Workshops in their communities that they can take part in voluntarily (Appendix 38a). Study staff will reach out to parents to encourage participation and remind them of upcoming event dates (Appendix 86 Healthy Shopping program outreach).

3. Text message program

Following the first call with the health coach, parents will receive semi-weekly text messages designed by the study team (Appendix 18 Text Message Library). The messages will alternate in structure between 2 types of messages; 1) skills training messages will deliver tips and motivational messages to help their child practice the study’s goals and 2) self monitoring messages will ask parents to respond to the message and track health behaviors important to this study. In the week prior to the coaching calls and visits, participants will receive a 3rd text message reminding them about the upcoming appointment with their health coach. Although owning a cell phone will not be a criteria for eligibility for this study, participants will be informed of the possibility that if selected for this intervention group, they will be sent and be asked to respond to text messages. Participants will be informed that cell phones will not be provided and normal text messaging rates will apply. If participants do not have a cell phone that supports text messaging or choose not to receive text messages, they will be offered the opportunity to
receive the messages by email. The content and frequency of the email messages will be the same as the text messages.

Enhanced Primary Care Group (Control) We will provide current “best practice” to the control arm. We will encourage providers to schedule a follow up visit for weight management or make a referral to HVMA nutritionists for children in this arm. We will also provide this group with a community resource guide (Appendix 26 Community Resource Guide – under development). The guide will be a general listing of resources that support healthy living in their region with contact information to learn more about them. Following the receipt of the participant’s consent, participants in this arm of the intervention will be enrolled in a limited text message campaign. This campaign will include text messages every 1-2 months to keep them engaged in the study for the duration of 1 year. We will not encourage this group to do self-monitoring, send them any individualized feedback, or offer any other tailored or direct support.

Disenrollment If at any time during the study a participant requests to change participation, we will take the following steps to document the participant’s change in study involvement:

- If the participant requests to disenroll while on the phone, when possible, the participant will be transferred to speak with the study project manager. The project manager, or study staff if the project manager is not available, will discuss participation alternatives with the parent.
- The project manager or study staff who completed the call will document in the database the parent’s request to change their involvement in Connect 4 Health.
- The project manager or study staff will send the parent the Disenrollment Letter and Disenrollment Reply from Participant (Appendix 44 Disenrollment Letter and Appendix 45 Disenrollment Reply from Participant), along with self-addressed business reply envelope.
- Responses will be documented and saved with study files. Any changes to study involvement from the previous phone call will updated in the study database.

VII. Study Technology

Text Messaging The text messages will be administered through a software platform developed by an outside vendor, Mobile Commons. Once parents agree to be sent text messages, we will register the participants’ phone numbers and unique IDs in Mobile Commons. Text messages will be sent out on a schedule based on the completion of the phone calls/meetings with the study health coaches. The text messages will be sent for approximately 12 months, the
duration of the intervention. Participant responses will be stored on a secure site accessible only by approved study staff with a login and password.

**Video Conferencing** Patients will be given the option to “meet” with their health coach at their 1-2, 3, 4, 6 and 10 month visits via Vidyo. Vidyo is a videoconferencing platform where clinicians and patients can use personal computers, tablets, and smart phones to communicate easily and securely using real time video and audio. This technology is preferred over Skype as it is more secure. There is a multitude of information readily available on the internet on how to “hack” in to Skype and steal user information such as names, addresses, credit card, and even phone numbers. This is not an issue with Vidyo.

The technology uses a virtual waiting room that is specific to each patient encounter. This mitigates the risk of two patients accidentally calling into the same session simultaneously. This method also avoids an issue where the patient could inadvertently call another clinician without clinician involvement.

We will send parents a letter with instructions regarding setting up the program on their personal devices. We will also send emails to the parent with the video conference link and login information (Appendix 31a Vidyo Welcome Letter, Appendix 31b Vidyo set-up email template, Appendix 31c Vidyo PIN # email template).

**VIII. Clinician Decisions Support Tools**

Standard work-flow for primary care visits at each HVMA site involves the medical assistant measuring the height and weight of the child, entering those data into the EMR, and notifying the clinician that the patient is in the examination room. Clinicians routinely access the EMR in the examination room during the visit. We will collaborate with Harvard Vanguard to improve upon an existing pediatric obesity best practice alert (Appendix 20a). This alert will be implemented in all HVMA pediatric practices, including those not part of the intervention. The alert will include brief educational content to prompt clinicians to document BMI percentile, document a diagnosis of overweight/obesity, discuss and document counseling on nutrition and physical activity, and provide educational materials to help manage childhood obesity. As part of a Quality Improvement initiative at HVMA, we will collect utilization and patient outcomes data at the non-study sites to evaluate the use of the Best Practice Alert.
Connect 4 Health Detailed Protocol
Study PI: Elsie Taveras, MD, MPH

A second, new alert will be developed for the 6 participating intervention sites and will include the referral to the Connect 4 Health study (Appendix 20). We will still encourage clinicians to make a referral to appropriate weight management programs or resources, as is part of their normal patient care. We will adapt the existing Pediatric Obesity SmartSets and ask clinicians to use these to document their overweight and obese patients’ visits.

For participants in both arms, we will design parent/child educational materials highlighting evidence-based obesity prevention behaviors (Appendix 23 Participant Educational Materials – under development). The materials will be based on expert recommendations around diet, physical activity and sleep behaviors, as well as household routines, environmental changes, and social/emotional wellbeing as it impacts healthy behaviors. These are behaviors related to obesity in children and behaviors that clinicians can assess rapidly during visits. The materials will serve as an aid to discussion between the primary care provider and the parent/child. A plain text summary of the Connect 4 Health study messages will be available for the clinician to include in the patient’s after visit summary (Appendix 21 AVS).

IX. Training and Clinician Communications

We will meet with the clinicians at each of the 6 practices sites before the study begins to review the study design and specifically the BPA and SmartSet. We will instruct clinicians to discuss the study with patients and their parents when making a referral. We will provide them with copies of the Fact Sheet to provide parents with more information about the study, including next steps and a phone number that parents can call to begin the enrollment process if they are interested. Study staff will also be available to meet with the clinicians to review these functions once the study begins. The clinicians from the non-study sites will not receive any training from study staff on the Best Practice Alert implemented at their sites.

Health coaches will provide clinicians up to 2 updates during each participant’s intervention year to keep the clinicians apprised of their patients’ progress. Health coaches will fax the updates to a secure folder overseen by the HVMA Medical Records department who will then send an Epic message to the clinician with the update attached. Study staff will send a final report to clinicians for usual care and intervention participants using the same method to summarize the patient’s involvement in the study (Appendix 90_Final Participant Summary Report for Clinicians).

Study staff will send monthly communications to clinicians with tips and resources about how to address barriers to improving weight and identify connections in their community to suggest to their patients.
X. Parent and Youth Advisory Group

We have worked for over 18 months with Mr. and Mrs. Danilo and Earlene Avalon, parents of two young children who receive their primary care at HVMA, on several initiatives within HVMA to help children with chronic diseases including Shared Medical Appointments for children with obesity and asthma and bringing farmer’s markets into the health centers. Mr. and Mrs. Avalon will serve as Co-Chairs of a Parent and Youth Advisory Board at HVMA to guide all planned research activities. Our Board will consist of 7–10 parents and their children, ages 6 to 12 years, from the panels of primary care providers on the study team. We have identified positive outlier parents and children from focus groups and interviews in a preliminary study (Protocol # 2013P002383) who appear, from their focus group and interview comments, that they could provide more in-depth information about successful strategies that can be generalized and promoted to improve the outcomes of other families. These parents and children will be invited to participate as Board members. The Board will advise the research team on the perspectives of potential trial participants and on the specifics of the proposed RCT. The Board will meet 1-2 times a year in each study year to discuss proposed study methods, including recruitment, informed consent, data collection, incentives, retention, and intervention design. Feedback on items such as participant materials may be sought by email in between meetings. Board members will not be study participants nor will their contributions in the Board meetings be considered research data. Parents and youth participating on the Advisory Board will receive a stipend for their participation. Parents will receive up to $80 per parent/child dyad for participation in each advisory board meeting.

Study Close Out/Shut-Down

At the end of the one-year intervention period parents will be contacted to complete a follow-up survey by phone (Appendix 24a Parent Year 1 Survey WTP 10-100, Appendix 24b Parent Year 1 Survey WTP 100-10). We will also offer to complete the survey with the participant in-person, either at their home or at a public place that is convenient for them, if they prefer this option. We will call parents several times a week and leave a voicemail every third attempt (Appendix 76 Year 1 Survey Voicemail Script). If we cannot reach a participant by phone after 1 week, we will email them to let them know we are trying to complete the Year 1 survey and try to schedule a time to speak by phone (Appendix 75 Year 1 Survey Scheduling Email Template). If we cannot reach the parent after 1 month, we will send a reminder note card (Appendix 83 Year 1 Survey Reminder Notecard). We will attempt to reach parents for about 3 months. If a participant is unable to complete the survey by phone after approximately 3 months, we will mail them a shorter, modified version of the survey to be completed on paper and mailed back.
to us in a postage-paid envelope (Appendix 85 Year 1 Mailed Parent Survey). If the parent has not returned the survey by the date requested, we will send the parent another copy of the survey (Appendix 96 Parent Survey Prize Drawing Letter). In the reminder, we will offer parents who return their survey by a designated date, an entry in a prize drawing for a $50 Amazon gift card. We may also contact the parent by email, text and phone to remind them about the survey and prize drawing deadline (Appendix 97 Mailed Survey Prize Drawing Reminders).

Also at the end of this period, we will also administer a follow-up child survey. After we complete the parent survey by phone, we will ask the parent if s/he prefer we administer the child survey by mail or over the phone. If s/he chooses to have his/her child complete the survey by phone, we will obtain the child’s assent before administering the survey (Appendix 84 Child Survey Phone Script and Phone Survey). We will send the $2 bill in the mail after the child completes the survey by phone along with a thank you letter (Appendix 94 Child Survey Thank You Letter). If the parent or child prefers a written copy of the survey, we will mail the child a follow-up survey with a $2 bill attached as a thank you (Appendix 25a Child Year 1 Survey Usual care, Appendix 25b Child Survey Intervention). The mailing will be addressed to the parent so they can ultimately approve the child’s participation in the survey. The mailing will also include a letter to the parent thanking them for completing the parent survey and giving instructions about the child survey, a letter to the child with survey instruction and a postage-paid business reply envelope for the survey’s return (Appendix 82 Year 1 Survey Thank You Letter and Appendix 79 Child Survey Intro Letter). This thank you letter will also be sent to parents not receiving a child survey to reaffirm the end of the family’s study participation. If the survey is not received by the return date on the on enclosed letters study staff will call the parent to remind him/her about the Child Survey and request its return (Appendix 81 Child Survey Reminder Phone Script). During this call, study staff will also offer to administer the child survey over the phone in place of the mailed version. If the parent agrees to have the child complete the survey by phone, the child will be made aware that their participation is completely voluntary and also be asked for their assent to complete the survey (Appendix 84 Child Survey Phone Script and Phone Survey). If we do not administer the survey over the phone and do not receive the survey by mail approximately 1 week from the call date, we will send a reminder email to the parent (Appendix 80 Child Survey Email Reminder Template). If the survey is not received approximately one week from the email date, 2 additional reminder calls will be made (Appendix 81 Child Survey Reminder Phone Script). If a child has not returned his/her survey approximately 2 weeks after the last reminder call is made, we will send the family one more reminder mailing (Appendix 98-Year 1 Child Survey Prize Drawing Letter). In this reminder, we will offer children who return their survey by a designated date, an entry in a prize drawing for a $25 gift card to a local trampoline park. We may also contact the parent by email, text and
phone to remind them about the survey and prize drawing deadline (Appendix 99 Child Survey Prize Drawing Reminders).

Data from HVMA
To identify when enrolled participants have upcoming primary care visits to obtain their final outcome measures, we will receive weekly data pulls from HVMA. Research staff at HVMA will provide MGH weekly data pulls of enrolled participants with a scheduled upcoming visit. This weekly data pull will include:

- the child’s name
- gender
- date of birth
- address
- parent telephone numbers
- name of the clinician
- appointment site
- date/time of the scheduled visit
- visit type

We will also receive a list of visit types from the baseline visits, so we can identify if the child is due for an annual well child care visit or if we might need to propose alternatives for collecting height and weight at approximately 1 year.

The address and phone number are needed to ensure up to date contact information for follow-up assessments. If a child does not have a primary care visit scheduled approximately 9 months after their baseline visit date, we will mail participants a postcard reminding them to schedule their next primary care visit or growth check (Appendix 77 Year 1 Visit Reminder Postcard). We will also email a reminder to the parent (Appendix 74 Year 1 Visit Reminder Email Template). If the parent has been receiving study text messages, we will also send a text message to the parent (Appendix 18 Text Message Library). If the participant still does not have a visit scheduled approximately 1 year after their baseline visit date, we will call the parent to remind them to schedule their child’s appointment (Appendix 72 Scheduling Year 1 Check-up Phone Script and Appendix 71 Year 1 Visit Scheduling Reminder Voicemail Scripts) and continue calling the parent until approximately 15 months after their child’s baseline visit date, or until a visit is completed. If the visit has not been completed at the time the parent completes the 1 year follow-up survey, the research assistant will remind them to schedule this appointment at this time as well. The research assistant may also offer to assist the parent in scheduling the appointment by calling the HVMA site and connecting the parent to the site’s reception desk to schedule the appointment. If the child is not due for a well child visit, study staff will also inform the parent about the option for a growth check, a short visit at Harvard Vanguard just to take the child’s height and weight measurements, and assist the parent with setting that up instead.
If the parent informs the research assistant that her child has left her original Harvard Vanguard practice, we will ask for permission to contact the child’s new provider for the child’s most recent height, weight and blood pressure. We will send the parent a letter and ask her to sign and return it to authorize the contact of her child’s new provider (Appendix 68 Authorization to Release Medical Record Intro Letter to Parent, Appendix 67 Authorization to Release Medical Record Consent Form). We will also email this letter and attach the Authorization form, with instructions to print, sign and return the authorization form to Connect 4 Health study staff (Appendix 68a Authorization to Release Medical Record Email Template). After we receive the signed Authorization form, we will send or fax a letter to the provider requesting the child’s height, weight and blood pressure data (Appendix 73 Outside Provider Record Request Memo) along with a description of the study and the signed Authorization form. If the parent can access the requested data from their health care provider themselves (i.e., via a patient portal), we will accept the data directly from the parent if they agree to that option.

If the parent does not intend to schedule a primary care visit or complete a growth check at HVMA before the end of the study, we will offer to come to the participant’s home to measure the child’s height and weight (Appendix 70 Home Visit Scheduling Voicemail). As BMI is a primary outcome of this intervention, collecting this data for all participants is important for the validity of the study. Trained and approved study staff will conduct these home visits. If the parent agrees to schedule a home visit, we will send a letter and email to confirm the details of the visit (Appendix 69 Home Visit Letter, Appendix 78 Home Visit Email Template).

HVMA will provide a second weekly data pull to identify those participants who completed their follow-up primary care visit. This second weekly data pull will include the following:

- the child’s name
- gender
- date of birth
- name of the clinician
- appointment site
- date/time of the completed primary care visit
- visit type
- height, weight, BMI, BMI percentile and blood pressure at visit.

At the end of the study, we will receive an additional data pull from HVMA which will include visit information from up to approximately 15 months prior to the baseline visit and up to approximately 15 months after the follow-up visit. The data pull will include:
Connect 4 Health Detailed Protocol  
Study PI: Elsie Taveras, MD, MPH

- the child’s name  
- gender  
- date of birth  
- name of the clinician  
- appointment site  
- date/time of the completed primary care visit  
- visit type  
- height, weight, BMI and BMI percentile and blood pressure at visit

The data will allow us to assess the trajectory of BMI change before and after the study intervention and improve our ability to examine the primary specific aim of the study.

After all participants are enrolled in the study, HVMA will provide MGH with data on the pediatric obesity HEDIS measures documented at these visits for all participants. HVMA will also provide documented obesity HEDIS measures and obesity-related health care outcomes for other patients who meet the age and BMI criteria and had a visit at their HVMA practice during the same timeframe as the enrollment period. At the end of the study, after all participants have completed their 1 year primary care visit and follow-up Parent Survey, HVMA will again provide MGH with data on the pediatric obesity HEDIS and obesity-related health care outcomes documented at this 1 year visit. HVMA will also provide HEDIS and obesity-related health care outcomes documented in the EHR for any other visit that occurred to assess healthcare utilization of the child within approximately the last year. We will request the same data, excluding names, for patients from the non-study sites and from eligible patients from the study sites not enrolled in the intervention to evaluate the impact of the Best Practice Alert. As mentioned earlier, we would like to collect the name of the practice site and child’s date of birth, race/ethnicity, BMI and BMI percentile as part of this quality improvement initiative. We request a waiver of consent and authorization to obtain this data for patients at the study sites who are not enrolled in the intervention and patients at the HVMA practices that are not participating in the Connect 4 Health intervention. These sites are Burlington, Cambridge, Concord, Copley, Harvard, Peabody, Somerville, Watertown and Wellesley.

V. Outcomes

Primary Outcomes
Connect 4 Health Detailed Protocol

Study PI: Elsie Taveras, MD, MPH

A. Height, Weight, and BMI. Height and weight will be measured by the medical assistants at each site using standard protocols. We use accepted definitions of obesity and overweight. BMI measures will be obtained from the EHR as provided through usual care. BMI measures will be converted to z-scores using CDC age and sex-specific normative data for children between 2 and 20 years old. This will allow us to combine data across children of different ages.

B. Quality of Life – Parent and Child Reported. We will ask parents to complete the PedsQL-4.0 for their child. The PedsQL is an extensively validated, widely used, 23-item measure of health-related quality of life in children. It has been used to assess quality of life of children with chronic conditions such as obesity. We will ask parents to complete 4 subscales: physical health, school, social, and emotional functioning which exists for parental report of children as young as 2 years of age. In addition, we will assess child-report of quality of life using the child version of the PedsQL validated among children ages 8 and over. We will also assess frequency of bullying and teasing, exercise intolerance, and satisfaction with clothing size.

Secondary Outcomes

A. Quality and Family-Centeredness of Pediatric Obesity Care.
B. Pediatric Obesity Healthcare Effectiveness Data and Information Set (HEDIS) measures from the participants’ EHRs for all visits conducted between (and including) the baseline and year 1 follow up visits. Obesity-related health care outcomes will include: diagnosis codes for BMI percentile/weight status, nutrition counseling, physical activity counseling; orders and results for recommended labs and orders and completion of related referrals.
C. Specified behavioral outcomes
   - Screentime
   - Physical Activity
   - Sleep Duration
   - Diet
     - Sugar-sweetened beverage intake
     - Fruits and Vegetables
     - Snacks and treat foods
     - Fast food intake
D. Process measures. To understand more fully the intervention effect, we will collect information on the acceptability, feasibility, uptake of components of the intervention, and family engagement in the study from the parents’ perspectives. We will measure the following implementation domains at 12 months: a) reach, b) extent of implementation, c) fidelity to protocol, and d) parent satisfaction with multiple dimensions of care.
E. Socioeconomic and Geographic Variables. We will measure variables that can act as effect modifiers or confounders of intervention effects including: (a) Indicators of socioeconomic status and (b) parental characteristics: age, height and weight, and marital status. We will also examine the extent to which neighborhood environments modify any observed intervention effects. Using residential addresses we will obtain geocoded information about neighborhood socioeconomic characteristics by linking participants’ addresses to 2010 American Community
Survey Census Data. We will also use GIS tools to characterize the food, physical activity, and built environments in each neighborhood. To characterize the built and socio-environment of children 2-12 years who live in eastern Massachusetts, we will collaborate with the Center for Geographic Analysis to map the distance from the children's residential address to built environment variables. Using publicly available databases we will geocode children’s nearest resources such as trails, parks, playgrounds, open spaces, gyms, exercise programs, schools, pools, recreation centers, sidewalk coverage, weight management centers, boys and girls clubs, farmers markets, food establishments, and public transportation. Using ArcGIS and StreetMap USA detailed streets (ESRI, Redlands CA), we will calculate distances along the street network from each participant’s residence to these places. We will also examine distance from their residential addresses to the places they report going to. This analysis will allow us to determine if these places were beneficial or detrimental in the child's improvement in weight.

VI. Data Analysis
The analyses will be carried out with the child as the unit of analysis, and our primary analyses will be based on the principle of intent-to-treat so that all patients who are randomized will be included. Missing data will be imputed using standard Monte Carlo Markov Chain procedures. All data will be carefully reviewed for correctness and logical consistency before formal analyses commence. The primary specific aims are:

To examine the extent to which the intervention, compared to the control condition, results in:

a. A smaller age-associated increase in BMI z-score over a 12-month period.
b. Improved parental and child ratings of pediatric health-related quality of life.

For each of these dual primary outcomes we will assess changes during the 12 month period following the start of the intervention. For the analysis of BMI, the follow-up BMI measure will be the first one that is recoded at least 9 months after the baseline value. A primary challenge in assessing our study outcome is that BMI increases naturally from ages 5 to 12 years. Therefore, measuring change in BMI between baseline and follow-up may introduce bias in analyzing our intervention effect if the time between the measurements is systematically different in the intervention and control groups.

Therefore, we will calculate the change in BMI z-score and then divide by the number of months between the baseline and follow-up measures to produce a more comparable “monthly change” in BMI z-score (referred to as the 12-month change in BMI). The distribution of the 12-month changes in BMI z-scores will be examined for normality and then an initial comparison between the intervention and control groups will be carried out using either a t-test or Wilcoxon rank sum test as appropriate to the normality diagnostics. We will then examine the balance of covariates between the randomized arms with respect to age, gender, baseline BMI, and other variables using Student’s t-tests for continuous variables and chi-square tests for binary variables. Any covariates which show a difference between arms at \( p < 0.10 \) will be introduced into a regression model and retained as confounders if the effect
estimate for the intervention changes by more than 20%. If the change in BMI z-scores are determined to be normally distributed, then a simple linear regression model will be used; if the BMI z-score changes are non-normal, then a median regression model will be used. Regardless of the confounding diagnostics, our regression model will include indicator variables for the study clinics and also for the three health coaches. Ideally, the model would include random effects for the health coaches, which would also allow for adjustment for correlation between patients seen by the same coach. However, with only three coaches, statistically, the estimates would be unstable. Therefore, our model will include only the fixed effects for coaches, but we will add interaction terms between coaches and the intervention to investigate whether the benefit was consistent across the coaches. All results will be reported using point estimates, 95% confidence intervals and p-values. All analyses will use SAS statistical software.

We will also perform the following additional analyses to address the study Aims:

1. Evaluate the effect on the intervention on pediatric quality of life as measured by the PedsQL.
2. Evaluate the effect of the intervention on the parental rating of the quality and family-centeredness of their child’s obesity related care;
3. Evaluate the effect of the intervention on improving obesity-related quality of care as measured by the presence of HEDIS codes in the EHR.

For the continuous scales from the surveys, we will follow the analysis plan above and develop linear regression models. For binary outcomes such as inclusion of obesity-related HEDIS measures, we will start with Fisher exact tests and develop logistic regression models.

**Subgroup Analyses.** We will perform sub-group analyses by intervention compliance, patient age, gender, race/ethnicity, baseline BMI (85-95th percentile and >95th percentile), family income, and neighborhood built environment characteristics. We will employ interaction terms in the linear regression analyses to determine if the effect of the intervention varies according to compliance, patient age, gender, baseline BMI, clinic, health coach, family income, and neighborhood built environment characteristics as potential effect modifiers.

**VII. Monitoring and Quality Assurance**

Data security & privacy will be maintained through:

- Paper data collection forms will be stored in a locked and secure facility only accessible by research staff at MGH in the Division of General Pediatrics at 100 Cambridge St, 15th Floor, Boston, MA 02114. All data collected and recorded on paper forms will be entered into a Partners supported REDCap database. Only approved study staff will have access to identifiable information and the linking code. Research staff will track all communication made with parents this database including when the parent was contacted about the study,
if the child was eligible and interested in participating or reasons for ineligibility, and demographic information (age, gender, parent contact info). We will also use this database to keep track of all technical difficulties encountered by study participants. This database will be housed on the Partners network and accessible to only IRB approved study staff.

- All HVMA patient information will be transferred from the HVMA to Partners secure servers by the approved research staff. A secure SFTP site or Syncplicity account will also be set-up for data transfer between HVMA and MGH to electronically transfer the data. After all contracts and approvals are in place at MGH, the MGH Clinical Project Manager will access and download the data file from the secure FTP site or Syncplicity account to a secure, access restricted Shared File Area (SFA) on MGH’s server. The Project Manager will manage access to this area through MGH’s IT Department. Only approved study staff at HVMA will be given access to this area. The file itself will also be password protected.

- Mobile Commons is hosted in a SAS-70 Type II compliant data center. Access to the servers is highly restricted via public key encryption and available only to select Mobile Commons system administrators. Background checks are performed on all system Administrators with access to the servers. Physical access is restricted via cage, biometrics, and human guard. Approved research staff access their account through a web interface with a username and password using best practices for web authentication. API access uses HTTP basic-auth with the same credentials. 256-bit SSL is automatically enforced for all Internet connections. Partners has executed a Business Associates Agreement with Mobile Commons.

- Vidyo is HIPAA compliant as it provides 256AES encryption form end to end. All usernames and passwords are stored securely behind a protected firewall within an externally hosted and Partners approved location. Partners has executed a Business Associate Agreement with the managed service company IDS, limiting our liability in these matters.

- To safeguard confidentiality, access to all collected data will be limited to only the IRB approved study staff. The web developers, web hosting company and text messaging company have appropriate BAA’s with MGH, and have accepted to maintain HIPAA compliance as applicable.

Maintaining the integrity of the technology

- Research assistants and health educators will be ready to assist participants if they encounter any technical problems during the study. A support telephone number and email address will be made available to participants.

- Log of all technical difficulties will be maintained on the study database.

Maintaining the integrity/validity of study documentation/materials

- The project manager, under direction of the Principal Investigator will monitor the study data regularly. The study staff will be appropriately trained, and the project manager will supervise data collection, storage and maintenance. The project manager will also regularly
Connect 4 Health Detailed Protocol
Study PI: Elsie Taveras, MD, MPH

- Review of the accuracy and completeness of case report form entries, source documents, and informed consent.
- Research staff will evaluate weekly data pulls from HVMA to ensure that they are complete. Research staff will also evaluate the completeness of signed consent forms and questionnaires.
- The research assistant will take primary lead on troubleshooting but the web developer will also play a minor role with troubleshooting any problems encountered on study website.
- The project manager will ensure that all paperwork is securely stored. The PI will ascertain appropriateness of security of all documents on a monthly basis.

Use of data
- Data collected will only be used for research purposes. Participants’ anonymity will be protected in any publication of findings.
- Patient contact information and EHR data will be shared with Partners research staff by HVMA. We are seeking a waiver of consent and authorization from Partners to obtain this data for recruitment from HVMA. All additional data shared will be done so with the participant’s consent.
- The Center for Geographic Analysis (CGA) will have access to participant addresses and the addresses of the establishments they report going to in order to geocode these addresses. Home addresses will be mapped to the child’s nearby recreation and food establishments, including trails, parks, playgrounds, open spaces, gyms, exercise programs, schools, pools, recreation centers, sidewalk coverage, weight management centers, boys and girls clubs, farmers markets, supermarkets, restaurants, and public transportation. All PHI will be sent from MGH to CGA using a Partners secure SFTP site. CGA will store the data in a password protected computer. In addition, files will be password protected. The computer will be stored in a locked office space. CGA will delete the PHI once the addresses have been geocoded.
- Participant study IDs and phone numbers will be sent to Mobile Commons to facilitate the programming of the text messages to be sent to participants. Mobile Commons will maintain all transaction records for 7 years for billing, verification and auditing purposes, after which time the data will be purged from their systems.
- Collaborators at the Harvard School of Public Health and the University of Albany will be sent deidentified data for analysis and to prepare a peer-reviewed publication. Data elements will include BMI/BMI percentile at baseline and follow-up, participant demographics and the baseline and follow-up survey responses. The data will be coded with a random study ID number, but the collaborators at the Harvard School of Public Health and University of Albany will not receive the code per a data agreement between the institutions.
Connect 4 Health Detailed Protocol
Study PI: Elsie Taveras, MD, MPH

- Collaborators at Boston Children’s Hospital will be sent deidentified data for analysis and to prepare a peer-reviewed publication. Data elements will include participant demographics and descriptive data, intervention process data, baseline and follow-up BMI/BMI z-score/BMI percentiles and baseline and follow-up survey responses. The data will be coded with a random study ID number, but the collaborators at Boston Children’s Hospital will not receive the code per a data agreement between the institutions.

VIII. Risks and Benefits

Risk and Discomforts
We do not foresee any significant risks for study participants: Participants may experience discomfort answering questions and discussing weight-related behaviors, as it may be a sensitive subject for some.
A breach in participant privacy and confidentiality is also a possible risk. To minimize this risk, we will use the minimum amount of PHI necessary for the proposed research. Participants are given an artificial study ID number that is linked through separate coding. Only study staff can link participant study ID numbers to PHI. All paper data is secured in locked file cabinets. All electronic data is secured in password protected files on computers with virus software enabled, with minimum necessary access.

Any time participant data will be transferred between MGH and a collaborator or vendor, it will be sent through an account set up on the Partners Secure File Transfer Protocol (SFTP) server.

Benefits
Potential Benefits to participants:
Participants may benefit from increased information about health or knowledge of resources. Participants may also benefit from improved health outcomes such as increased physical activity or improved dietary habits, possibly resulting in improved BMI.

Potential Benefit to Society:
In addition, this study may offer new insight into the role of a health coach and innovative methods employed for the improvement in weight status among children.