

ID: IH-1304-6739

Connect 4 Health: An Intervention to Improve Childhood Obesity Outcomes

NCT02124460

## Protocol Registration and Results Preview

### Connect 4 Health: An Intervention to Improve Childhood Obesity Outcomes

**This study has been completed.**

**Sponsor:**

Massachusetts General Hospital

**Collaborators:**

Harvard Vanguard Medical Associates

Brigham and Women's Hospital

**Information provided by (Responsible Party):**

Elsie Taveras, MD, Massachusetts General Hospital

**ClinicalTrials.gov Identifier:**

NCT02124460

First received: April 14, 2014

Last updated: January 5, 2017

Last verified: October 2016

#### Purpose

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 Additionally, current pediatric obesity care delivery relies on an outdated provider:patient paradigm which is ill-suited for a problem as prevalent as obesity.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:
  - o Reach
  - o Extent of implementation
  - o Fidelity to protocol

- 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

Condition	Intervention	Phase
Overweight Obesity	Behavioral: Health Coaching	N/A

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Single Blind (Outcomes Assessor), Randomized, Efficacy Study

Official Title: Improving Childhood Obesity Outcomes: Testing Best Practices of Positive Outliers

**Further study details as provided by Elsie Taveras, MD, Massachusetts General Hospital:**

Primary Outcome Measure:

- Change in BMI z Score [Time Frame: baseline and one year] [Designated as safety issue: No]
 

Height and weight will be measured by the medical assistants at each site using standard protocols. BMI measures will be obtained from the electronic health record (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 the research team to combine data across children of different ages.
- Change in Quality of Life [Time Frame: baseline and one year] [Designated as safety issue: No]
 

The PedsQL is an extensively validated, widely used, 23-item measure of health-related quality of life in children with chronic conditions such as obesity. Parents will be asked 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. Items are reverse-scored and linearly transformed to a 0-100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), so that higher scores indicate better HRQOL. Scale Scores are computed as the sum of the items divided by the number of items answered (this accounts for missing data). If more than 50% of the items in the scale are missing, the Scale Score is not computed.
- Change in Parent Resource Empowerment [Time Frame: Baseline to one-year follow-up] [Designated as safety issue: No]
 

The five items in the scale assessed parents' perceived knowledge of resources, ability to access resources, comfort with accessing resources, knowledge of how to find resources, and ability to acquire resources related to child weight management. For each question, parents responded strongly disagree, disagree, agree, or strongly agree, which were worth 1 to 4 points, respectively. Items were averaged to create a summary parental resource empowerment score (range= 1-4). Cronbach's  $\alpha$  for this score was 0.87.

**Secondary Outcome Measures:**

- **Change in Screen Time** [Time Frame: baseline and one year] [Designated as safety issue: No]  
Average hours/day spent watching television, videos, or playing games displayed on media such as television, desktop computers, laptops, portable DVD players, iPads or smartphones.
- **Change in Sleep** [Time Frame: baseline and 1 year] [Designated as safety issue: No]  
Average hours/day spent sleeping
- **Change in Physical Activity** [Time Frame: baseline and 1 year] [Designated as safety issue: No]  
In the past week, how many days the child was physically active for a total of at least 60 minutes per day.
- **Change in Fruit and Vegetable Consumption** [Time Frame: baseline and 1 year] [Designated as safety issue: No]  
Number of times the child consumed of vegetables and fruits yesterday
- **Change in Consumption of Sugar-sweetened Beverages and Juice** [Time Frame: baseline and 1 year] [Designated as safety issue: No]  
Number of servings of juice (e.g., orange juice, apple juice, or grape juice), fruit-flavored drinks (e.g., Kool-Aid, sports drinks, Goya juice, etc.), regular soda, soft drinks, or Malta consumed yesterday.

Enrollment: 721

Study Start Date: June 2014

Study Completion Date: November 2016

Primary Completion Date: June 2016

Arms	Assigned Interventions
<p><b>No Intervention: Enhanced Primary Care</b> We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.</p>	
<p><b>Experimental: Health Coaching</b> The intervention for this study will consist of the same best practices received by the</p>	<p><b>Behavioral: Health Coaching</b> Parent/child duos enrolled in the intervention group will participate in</p>

enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.

a total of six visits with a trained health coach. During these visits, the health coach will coach the parent/child duos on improving obesity-related behaviors .

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.

Following the first call with the health coach, parents will receive semi-weekly text messages designed by the study team. 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.

## Eligibility

Ages Eligible for Study: 2 Years to 12 Years

Genders Eligible for Study: Both

Inclusion Criteria:

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

Exclusion Criteria:

- children who do not have at least one parent/legal guardian who is able to follow study procedures for 1 year,
- families who plan to leave HVMA within the study time frame,
- families for whom the primary care clinician thinks the intervention is inappropriate, e.g., emotional or cognitive difficulties,
- children who have a sibling already enrolled in the study,
- children with chronic conditions that substantially interfere with growth or physical activity

participation.

**▶ Contacts and Locations**

**Locations**

**United States, Massachusetts**

Harvard Vanguard Medical Associates  
 Boston, Massachusetts, United States, 02215

**Investigators**

Principal Investigator: Elsie M Taveras, MD, MPH      Massachusetts General Hospital

**▶ More Information**

Responsible Party: Elsie Taveras, MD, Chief, Division of General Academic Pediatrics, Massachusetts General Hospital

Study ID Numbers: IH-1304-6739

Health Authority: United States: Patient Centered Outcomes Research Institute

## Study Results

**▶ Participant Flow**

Recruitment Details	
Pre-Assignment Details	

Arm/Group Title	Enhanced Primary Care	Health Coaching	Total (Not public)
▼ Arm/Group Description	We will provide current "best practice" to the enhanced primary care arm. We will encourage providers use clinical decision support tools and to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	The intervention group will receive the same components as the enhanced primary care group for this study plus the following elements: visits with a health coach, individualized connection to community resources and an interactive text messaging program. Parent/child duos enrolled in the intervention group will participate in a total of six visits with a trained health coach. The health coach will coach the parent/child duos on improving obesity-related behaviors and help	

		<p>the family identify supports to assist with behavior change and encourage use of materials related to both specific target behaviors and available resources in the community.</p> <p>Parents will receive semi-weekly text messages. The messages will alternate in structure between 1) skills training messages will deliver tips to help their child practice the study's goals and 2) self monitoring messages will ask parents to respond and track health behaviors important to this study.</p>	
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Period Title: **Overall Study**

Started	361	360	721
Completed	328	336	664
Not Completed	33	24	57

 **Baseline Characteristics**

Arm/Group Title	Enhanced Primary Care	Health Coaching	Total
<ul style="list-style-type: none"> <li>▼ Arm/Group Description</li> </ul>	<p>Arm: No Intervention: Enhanced Primary Care 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 Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational</p>	<p>Arm: Experimental: Health Coaching 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.</p>	

		text messages.		
<b>Overall Number of Baseline Participants</b>		361	360	721
▼ Baseline Analysis Population Description [Not specified]				
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	361 participants	360 participants	721 participants
	<=18 years	361 100%	360 100%	721 100%
	Between 18 and 65 years	0 0%	0 0%	0 0%
	>=65 years	0 0%	0 0%	0 0%
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	361 participants	360 participants	721 participants
		8.0 (3.0)	8.1 (3.0)	8.0 (3.0)
Gender, Male/Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	361 participants	360 participants	721 participants
	Female	188 52.08%	180 50%	368 51.04%
	Male	173 47.92%	180 50%	353 48.96%
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	361 participants	360 participants	721 participants
		361	360	721
BMI z score Mean (Standard Deviation) Unit of measure: BMI z score units	Number Analyzed	361 participants	360 participants	721 participants
		1.90 (0.51)	1.86 (0.52)	1.88 (0.52)
Pediatric Quality of Life (PedsQL) Summary Score [1] Mean (Standard Deviation)	Number Analyzed	361 participants	360 participants	721 participants
		86.0 (10.8)	85.4 (11.4)	85.7 (11.1)

Unit of measure: units on a scale				
		<p>[1] Measure Description: Items are reverse-scored and linearly transformed to a 0-100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), so that higher scores indicate better HRQOL. Scale Scores are computed as the sum of the items divided by the number of items answered (this accounts for missing data). If more than 50% of the items in the scale are missing, the Scale Score is not computed.</p>		
Parent Resource Empowerment Mean (Standard Deviation)	Number Analyzed	361 participants	360 participants	721 participants
		2.93 (0.59)	2.96 (0.53)	2.95 (0.56)
Unit of measure: units on a scale				

 **Outcome Measures**

1. Primary Outcome

Title:	Change in BMI z Score
▼ Description:	Height and weight will be measured by the medical assistants at each site using standard protocols. BMI measures will be obtained from the electronic health record (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 the research team to combine data across children of different ages.
Time Frame:	baseline and one year
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged by in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.

	encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	
Number of Participants Analyzed	361	360
Mean (95% Confidence Interval) Unit of measure: BMI z score units	-0.06 (-0.10 to -0.02)	-0.09 (-0.13 to -0.05)

▼ Statistical Analysis 1 

Statistical Analysis	Comparison Groups	Enhanced Primary Care, Health Coaching
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Overview	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3928
	Comments	[Not specified]
	Method	Other [Linear repeated measures]
	Comments	Multiple imputation was used for missing follow-up data.
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.02
	Confidence Interval	(2-Sided) 95% -0.08 to 0.03
	Estimation Comments	Health Coaching group compared to Enhanced Primary Care

## 2. Primary Outcome

Title:	Change in Quality of Life
▼ Description:	The PedsQL is an extensively validated, widely used, 23-item measure of health-related quality of life in children with chronic conditions such as obesity. Parents will be asked 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. Items are reverse-scored and linearly transformed to a 0-100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), so that higher scores indicate better HRQOL. Scale Scores are computed as the sum of the items divided by the number of items answered (this accounts for missing data). If more than 50% of the items in the scale are missing, the Scale Score is not computed.
Time Frame:	baseline and one year
Safety Issue?	No

### ▼ Outcome Measure Data

#### ▼ Analysis Population Description

[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged by in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.
Number of Participants Analyzed	361	360
Mean (95% Confidence Interval) Unit of measure: units on a scale	0.65 (-0.38 to 1.67)	1.53 (0.51 to 2.56)

▼ Statistical Analysis 1 

Statistical Analysis Overview	Comparison Groups	Enhanced Primary Care, Health Coaching
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.2306
	Comments	[Not specified]
	Method	Other [Linear repeated measures]
	Comments	Multiple imputation used for missing data at follow-up
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	0.89
	Confidence Interval	(2-Sided) 95% -0.56 to 2.33
	Estimation Comments	Health Coaching group compared to Enhanced Primary Care

3. Primary Outcome

Title:	Change in Parent Resource Empowerment
▼ Description:	The five items in the scale assessed parents' perceived knowledge of resources, ability to access resources, comfort with accessing resources, knowledge of how to find resources, and ability to acquire resources related to child weight management. For each question, parents responded strongly disagree, disagree, agree, or strongly agree, which were worth 1 to 4 points, respectively. Items were averaged to create a summary parental resource empowerment score (range= 1-4). Cronbach's $\alpha$ for this score was 0.87.
Time Frame:	Baseline to one-year follow-up
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

[Not specified]



Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged by in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.
Number of Participants Analyzed	361	360
Mean (95% Confidence Interval) Unit of measure: units on a scale	0.29 (0.22 to 0.35)	0.22 (0.15 to 0.29)

▼ Statistical Analysis 1 



Statistical Analysis Overview	Comparison Groups	Enhanced Primary Care, Health Coaching
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	.14
	Comments	[Not specified]
	Method	Other [Linear repeated measures]
	Comments	Multiple imputation used for missing data at follow-up
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	0.07
	Confidence Interval	(2-Sided) 95% -0.02 to 0.16
	Estimation Comments	Health Coaching group compared to Enhanced Primary Care.

#### 4. Secondary Outcome

Title:	Change in Screen Time
▼ Description:	Average hours/day spent watching television, videos, or playing games displayed on media such as television, desktop computers, laptops, portable DVD players, iPads or smartphones.
Time Frame:	baseline and one year
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description
[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th	The intervention for this study will consist of the same best practices received by the enhanced primary care group

	percentile will be flagged by in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.
Number of Participants Analyzed	361	360
Mean (95% Confidence Interval) Unit of measure: hours/day	-0.06 (-0.12 to 0.00)	-0.56 (-0.78 to -0.34)

▼ Statistical Analysis 1 

Statistical Analysis Overview	Comparison Groups	Enhanced Primary Care, Health Coaching
	Comments	[Not specified]
	Non-Inferiority	No

	or Equivalence Analysis?	
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0016
	Comments	[Not specified]
	Method	Other [Linear repeated measures]
	Comments	Multiple imputation used for missing data at follow-up.
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.50
	Confidence Interval	(2-Sided) 95% -0.81 to -0.19
	Estimation Comments	[Not specified]

### 5. Secondary Outcome

Title:	Change in Sleep
▼ Description:	Average hours/day spent sleeping
Time Frame:	baseline and 1 year
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description  
[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.

	a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	
Number of Participants Analyzed	361	360
Mean (95% Confidence Interval) Unit of measure: hours/day	-0.02 (-0.16 to 0.12)	0.40 (0.25 to 0.55)

▼ Statistical Analysis 1 

Statistical Analysis Overview	Comparison Groups	Enhanced Primary Care, Health Coaching
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<.0001
	Comments	Multiple imputation used for missing data at follow-up.
	Method	Other [Linear repeated measures]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	0.42
	Confidence Interval	(2-Sided) 95% 0.22 to 0.62
	Estimation Comments	[Not specified]

## 6. Secondary Outcome

Title:	Change in Physical Activity
▼ Description:	In the past week, how many days the child was physically active for a total of at least 60 minutes per day.
Time Frame:	baseline and 1 year
Safety Issue?	No

### ▼ Outcome Measure Data

#### ▼ Analysis Population Description

[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.

	Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	
Number of Participants Analyzed	361	360
Mean (95% Confidence Interval) Unit of measure: days/week	0.15 (-0.10 to 0.40)	0.33 (0.09 to 0.58)

▼ Statistical Analysis 1 

Statistical Analysis Overview	Comparison Groups	Enhanced Primary Care, Health Coaching
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3043
	Comments	[Not specified]
	Method	Other [Linear repeated measures]
	Comments	Multiple imputation used for missing data at follow-up.
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	0.18
	Confidence Interval	(2-Sided) 95% -0.16 to 0.53
	Estimation Comments	[Not specified]

### 7. Secondary Outcome

Title:	Change in Fruit and Vegetable Consumption
▼ Description:	Number of times the child consumed of vegetables and fruits yesterday
Time Frame:	baseline and 1 year
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description
[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.

	Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	
Number of Participants Analyzed	361	360
Mean (95% Confidence Interval) Unit of measure: times/day	0.19 (0.01 to 0.36)	0.50 (0.33 to 0.68)

▼ Statistical Analysis 1 

Statistical Analysis Overview	Comparison Groups	Enhanced Primary Care, Health Coaching
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0113
	Comments	[Not specified]
	Method	Other [Linear repeated measures]
	Comments	Multiple imputation used for missing data at follow-up.
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.32
	Confidence Interval	(2-Sided) 95% 0.07 to 0.56
	Estimation Comments	[Not specified]

### 8. Secondary Outcome

Title:	Change in Consumption of Sugar-sweetened Beverages and Juice
▼ Description:	Number of servings of juice (e.g., orange juice, apple juice, or grape juice), fruit-flavored drinks (e.g., Kool-Aid, sports drinks, Goya juice, etc.), regular soda, soft drinks, or Malta consumed yesterday.
Time Frame:	baseline and 1 year
Safety Issue?	No

#### ▼ Outcome Measure Data

▼ Analysis Population Description
[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.

	a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	
Number of Participants Analyzed	361	360
Mean (95% Confidence Interval) Unit of measure: times/day	-0.03 (-0.20 to 0.14)	-0.25 (-0.41 to -0.08)

▼ Statistical Analysis 1 

Statistical Analysis Overview	Comparison Groups	Enhanced Primary Care, Health Coaching
	Comments	[Not specified]
	Non-Inferiority	No

	or Equivalence Analysis?	
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0792
	Comments	[Not specified]
	Method	Other [Linear repeated measures]
	Comments	Multiple imputation used for missing data at follow-up.
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.21
	Confidence Interval	(2-Sided) 95% -0.45 to 0.03
	Estimation Comments	[Not specified]

### 9. Post-Hoc Outcome

Title:	Increased Satisfaction With Care at Harvard Vanguard Medical Associates (HVMA)
▼ Description:	This is a feasibility and acceptability measure from the study. <span style="color: blue;">◆ NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.</span>
Time Frame:	1 year
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description
[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.

	encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.		
Number of Participants Analyzed	321		315
Measure Type: Count of Participants Unit of measure: participants	153	47.66%	199 63.17%

10. Post-Hoc Outcome

Title:	Parent Very Satisfied With Content of Connect 4 Health Text Messages or Emails.
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▼ Description:	This is a feasibility and acceptability measure from the study. <span style="color: blue;">◆ NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.</span>
Time Frame:	1 year
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description
[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.
Number of Participants Analyzed	292	313
Measure Type: Count of Participants Unit of measure: participants	156      53.42%	226      72.2%

11. Post-Hoc Outcome

Title:	Received Information From Connect 4 Health About Resources in the Community
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▼ Description:	This is a feasibility and acceptability measure from the study. <span style="color: blue;">◆ NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.</span>
Time Frame:	1 year
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description
[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.
Number of Participants Analyzed	323	315
Measure Type: Count of Participants Unit of measure: participants	195      60.37%	301      95.56%

12. Post-Hoc Outcome

Title:	Received Text Messages or Emails From Connect 4 Health
▼ Description:	This is a feasibility and acceptability measure from the study.

Time Frame: 1 year

Safety Issue? No

▼ Outcome Measure Data 

▼ Analysis Population Description

[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.
Number of Participants Analyzed	323	315
Measure Type: Count of Participants Unit of measure: participants	295 91.33%	314 99.68%

13. Post-Hoc Outcome

Title:	Parent Very Satisfied With Information he/She Received About Resources in the Community
▼ Description:	This is a feasibility and acceptability measure from the study.  NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.

Time Frame:	1 year
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description
[Not specified]

Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description:	We will provide current "best practice" to the control arm. Patients with a BMI greater than or equal to the 85th percentile will be flagged in the electronic health record. Clinicians are also provided with clinical decision support tools for pediatric weight management. We will encourage providers to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.	The intervention for this study will consist of the same best practices received by the enhanced primary care group well as the following three elements: visits with a health coach, connection to community resources and an interactive text messaging program.
Number of Participants Analyzed	195	301
Measure Type: Count of Participants Unit of measure: participants	128 65.64%	228 75.75%

 Adverse Events

Time Frame
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Additional Description		
Source Vocabulary Name	[Not specified]	
Assessment Type	[Not specified]	
Arm/Group Title	Enhanced Primary Care	Health Coaching
▼ Arm/Group Description	<p>We will provide current "best practice" to the enhanced primary care arm. We will encourage providers use clinical decision support tools and to schedule a follow up visit for weight management or make a referral to Harvard Vanguard Medical Associates nutritionists for children in this arm. We will also provide this group with a community resource guide and educational text messages.</p>	<p>The intervention group will receive the same components as the enhanced primary care group for this study plus the following elements: visits with a health coach, individualized connection to community resources and an interactive text messaging program. Parent/child duos enrolled in the intervention group will participate in a total of six visits with a trained health coach. The health coach will coach the parent/child duos on improving obesity-related behaviors and help the family identify supports to assist with behavior change and encourage use of materials related to both specific target behaviors and available resources in the community. Parents will receive semi-weekly text messages. The messages will alternate in structure between 1) skills training messages will deliver tips to help their child practice the study's goals and 2) self monitoring messages will ask parents to respond and track health behaviors important to this study.</p>
▼ Serious Adverse Events		
	<b>Enhanced Primary Care</b>	<b>Health Coaching</b>
	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/361 (0%)	0/360 (0%)
▼ Other (Not Including Serious) Adverse Events		

Frequency Threshold for Reporting Other Adverse Events	0%	
	<b>Enhanced Primary Care</b>	<b>Health Coaching</b>
	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/361 (0%)	0/360 (0%)

## ▶ Limitations and Caveats

[Not Specified]

## ▶ More Information

### Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study. There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

### Results Point of Contact

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