Randomized Trial of a Family-Based, Automated, Conversational Obesity Treatment Program for Underserved Populations

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Objective: To evaluate the acceptability and feasibility of a scalable obesity treatment program integrated with pediatric primary care (PC) and delivered using interactive voice technology (IVR) to families from underserved populations.

Design and Methods: Fifty parent-child dyads (child 9-12 yrs, BMI > 95th percentile) were recruited from a pediatric PC clinic and randomized to either an IVR or a wait-list control (WLC) group. The majority were lower-income, African-American (72%) families. Dyads received IVR calls for 12 weeks. Call content was informed by two evidence-based interventions. Anthropometric and behavioral variables were assessed at baseline and 3-month follow-up.

Results: Forty-three dyads completed the study. IVR parents ate one cup more fruit than WLC (P < 0.05). No other group differences were found. Children classified as high users of the IVR decreased weight, BMI, and BMI z-score compared to low users (P < 0.05). Mean number of calls for parents and children were 9.1 (5.2 SD) and 9.0 (5.7 SD), respectively. Of those who made calls, >75% agreed that the calls were useful, made for people like them, credible, and helped them eat healthy foods.

Conclusion: An obesity treatment program delivered via IVR may be an acceptable and feasible resource for families from underserved populations.

Introduction

The prevalence of childhood obesity has been increasing for the last four decades and the problem affects children from all socioeconomic levels, genders, and ethnic groups (1). Minority children are particularly affected; the combination of a higher prevalence of severe obesity, higher severity of overweight (2), and possibly stronger tracking of BMI (3) also indicate that these characteristics may have considerable negative impact on the health, productivity, and quality of life of minority populations. The racial/ethnic disparities in incidence of severe obesity underscore the importance of developing interventions to treat this problem. The most effective obesity treatment programs for children have been family-based (4). Data suggest that parents should be considered key players in weight management interventions (5-10). Effective, evidence-based weight management interventions have high attrition rates and reach a small number of children. Reasons for this may include the program not meeting expectations, child engagement, costs, and scheduling conflicts with school and work (11).

There is a pressing need for effective and affordable treatments delivered outside clinical settings for overweight children. Automated home-based programs that are linked to primary care (PC) and delivered to children and their caregiver at home may be effective, affordable, and scalable. The use of automated interactive voice response (IVR) systems to deliver health interventions (12,13) has been found to be feasible, well-accepted, and effective in managing a variety of chronic conditions (12-16). To date, two studies have evaluated the use of IVR for treating overweight children (15,17).

The aim of this pilot study was to evaluate an integrated information system, Healthy Eating and Activity Today (HEAT), for promoting self-care in 9-12-year-old obese children. The primary aims were to
test initial efficacy, acceptability, and feasibility of the intervention. The primary hypothesis was that children in families who used the HEAT system would have a reduced rate of BMI increase at the end of the intervention compared to WLC children. A secondary aim was to evaluate whether use of the HEAT system was associated with (1) lower consumption of kilocalories (kcal/wk), (2) lower consumption of fat (total fat and saturated fat grams), (3) greater consumption of fruits and vegetables (servings/day), and (4) and fewer number of hours per week of television time.

Methods

Study design

The HEAT study was a randomized trial using a WLC group conducted at Boston University Medical Center (Boston, MA, USA). The study was approved by the Boston University Medical Campus Institutional Review Board.

Participants

Participants were 9-12-year-old obese children and their parents recruited from an urban pediatric outpatient clinic between October 2008 and October 2009. Patients were eligible to participate if they were (1) between 9 and 12 years old, (2) had a BMI 0-5 BMI points above the 95th percentile for age and gender, (3) attended a pediatric visit within the last year, and (4) were due for an annual well-child exam in the next 4 months. Exclusion criteria included cognitive impairment, terminal illness, eating disorder, special diet restrictions, participation in another weight treatment program, or spoke limited English. A HIPAA-approved staff member identified a list of potentially eligible pediatric patients through the electronic health record (EHR) system (Centricity, GE) at Boston Medical Center pediatric clinic. The clinic’s pediatricians reviewed the lists and eliminated any family they deemed inappropriate for the study. Informed written consent from parents and assent from children was obtained.

Randomization

Fifty parent-child dyads were randomized in blocks of six to either the intervention condition (HEAT) or WLC condition. The blocks were generated by an investigator who did not have contact with the participants. Assignments to condition were placed in sealed envelopes and opened after all baseline measures were completed.

Intervention

Both parents and children received a 12-week telephone counseling intervention delivered by an automated IVR system. The intervention also included an EHR behavioral counseling tool used by the PC clinician during well-child follow-up visits. Similar but separate interventions were developed for parents and children.

The IVR was designed to monitor, educate, and counsel parents and children on healthy weight management and television time through weekly IVR telephone conversations. During these conversations, the system spoke to participants using computerized voice by means of text-to-speech technology (TTS). Participants communicated by speaking into the telephone receiver or by pressing keys on the telephone keypad. The conversation is tailored to the individual user of the IVR such that the IVR asked questions and provides tailored feedback based on the user’s response. Questions are asked to monitor the user’s behavior and provided education and theory-based behavior change strategies for the targeted behaviors as well as generate a conversation that is more human-like. The HEAT system stores responses that are used to tailor the questions asked during the same conversation or inform subsequent calls. The conversations incorporated principles of Social Cognitive Theory (18,19) and were guided by two evidenced-based programs, the Traffic Light Diet (TLD) (20) and the Student Media Awareness to Reduce Television (SMART) program (21). Separate but parallel interventions were developed for the children and the parents.

Child intervention. Figure 1 outlines the content of the behavior and intervention calls for the children. The core concepts from the TLD (20) and SMART (21) media program guided the development of the HEAT child conversations, which aimed to increase consumption of green foods (low calorie, nutrient dense) and decrease red foods (high fat and/or high calorie) to four per day and to reduce TV time to less than two hours per day. HEAT objectives included (1) learn the Traffic Light diet; (2) learn about rules; (3) learn how to set up contracts, weight, food, and screen-time; and (4) and set up contracts and rewards.

Parent intervention. Figure 2 outlines the content of the behavior and intervention calls guided by Golan’s approach to parent-based interventions (19), and was structured on four goals: (1) creating a home that supports health, (2) building a respectful relationship with the child, and (4) using praise and encouragement to motivate the child to do healthy things. Creating a healthy home was defined as keeping junk food out, bringing healthy green and yellow foods in, making rules about healthy eating and TV-watching, and asking other people in the home to be supportive of healthy changes. The content of the parent conversations ran in parallel with the child’s conversation to promote support and teamwork in the effort to eat healthier and watch less TV. An additional aim was for parents to follow the TLD along with their child to support their efforts.

Both parent and child conversations taught and emphasized goal setting, contracting, parent-child meetings, problem-solving, regular self-weighing, self-monitoring diet, and TV time, and included standard weight management topics such as snacking, substituting low-fat for high fat foods, and finding alternatives to sedentary behaviors. The calls were designed to be interactive and conversational and typically included quizzes or questions that helped direct the conversation and content received. Vignettes and testimonials were used to exemplify education topics or testify about the helpfulness of a behavior change strategy. Pre-recorded human voice files (clips) from age and gender appropriate voice actors were used for these components only.

Both HEAT parents and children used the HEAT-IVR via weekly “inbound” telephone calls for 12 weeks. Participants who were not making calls received a reminder call from a research assistant. The IVR system consisted of two calls per week. The first call focused on education and behavior change content (behavior call), and followed the basic structure of (1) greetings; (2) review of the goal set the previous week and feedback on self-reported progress, (3) education, (4) goal setting, and (5) closing summary of call (see
Figures 1 and 2). The second call each week was a brief monitoring call (tracking call) that asked users to self-report weight, green and red foods consumed, and hours of TV watched. Participants were given the option to complete both the behavior and tracking call back-to-back if they chose, that is, at the end of the behavior call, the IVR asked the callers if they would like to complete the tracking call now or at another time. Each participant was also given either a child or parent guidebook designed to support the calls. The book outlined call topics, bulleted main points, provided a place to write down weekly goals, track weight and foods consumed, and included a list of red, yellow, and green foods from the TLD, a list of community resources for physical activity and recreation, and alternatives to television viewing. The parent’s guidebook included shopping tips, instructions on reading nutrition labels, and examples of healthy meal plans.

**PC-HEAT.** The PC component of HEAT was an EHR template designed to provide data to the child’s pediatrician to support the patient’s behavior change efforts and document the clinical encounter. Data captured in the child IVR system were sent to the child’s EHR to assist the clinician with providing counseling and clinical decision support at the point of care. The EHR template was designed by the research team with input from the pediatric clinic’s providers (22). The template included body weight currently and at the start of the intervention, self-reported levels of diet and television behaviors, comparison to the recommended levels, readiness to work toward recommended levels, and goals set and met. Additionally, bulleted suggestions on how to comment, praise, encourage, and problem solve about these behaviors were based on the patient’s progress and highlighted in the template for the pediatrician. This template was automatically inserted into the annual well-child visit, which occurred approximately within 1 month of the end of the intervention period. Attending physicians, nurses, and clinical staff at the pediatric clinic were given a demonstration on how to use EHR template.

Dyads in the WLC condition received the same assessments as the HEAT group, were reminded to attend their well-child visit, and were offered the HEAT intervention post study.

**Outcomes**

The primary aim of this study was to test the initial efficacy, acceptability, and feasibility of the intervention. Outcomes were for both child and parent and included BMI, intakes of calories, fat, and fruits and vegetables, and television-viewing time. Outcome measures were assessed at baseline and 3 months later (follow-up) by trained research assistants between October 2008 and March 2010. All measures were interviewer administered except for the

| Topic | Week |
|-------|------|
| Follow-up on weekly challenge | X X X X X X X X X X |
| Education | |
| Obesity – what, why, how, weight gain | X |
| Reducing calories, calorie balance | X |
| Stoplight Diet basics | X |
| Stoplight Diet servings needed | X |
| Substitution strategies / healthy snacking | X X |
| Pre-planning, cooking & shopping tips | X |
| Diet tips, tips for eating out & parties | X |
| Meetings, privileges, & contracts | X |
| Point system (reinforcers) | X |
| Discuss guidebook & reasons for tracking | X |
| Problem-solving | X |
| Screen-Time | |
| TV education – why kids watch | X |
| TV budget – contract & log | X |
| TV Turn-Off week | X |
| Summarize concepts & check in | X |
| Graduation | X |
| Set a weekly challenge | X X X X X X X X X X |

**FIGURE 1** The content of the IVR education and behavior calls for the child.
satisfaction questions, which were self-administered. Incentives were given for completing assessments ($40 parents; $10 child). Height and weight were measured without shoes using a portable stadiometer (Seca model 214) and scale (Seca model 882). Change in BMI (kg/m²), BMI percentiles, and z-scores were calculated. BMI percentile was determined from CDC growth charts of national norms using age to the nearest month and sex-specific median, standard deviation, and power of the Box-Cox transformation (23). Diet was assessed using Block Dietary Data Systems Kids Food Screener version 2, which assessed the number of days in the last week 39 items were consumed and portion consumed (24,25). Parent diet was assessed using the Block 2007 Fat, Sugar, Fruit, and Vegetable Screener (25). Validated measures were used to assess television and recreational activities. Children were asked to recall the amount of time they spent yesterday before lunch and after lunch on 11 different recreational activities (26). TV time was also measured with one question from the Youth Risk Behavior Survey (27), and a 12-item proxy measure (26). The proxy measure asked parents to report the time their child spent in leisure time activities (e.g., TV, computer) the previous day. The proxy measure has good test-retest reliability (r = 0.94) (26). Parent TV time was assessed with one item from the CARDIA study (28).

Acceptability and feasibility of HEAT was assessed at follow-up. Parents and children completed a paper survey about their experience with various aspects of HEAT, for example, use, credibility, satisfaction. Participants rated their agreement to statements on a scale (1 = strongly disagree to 5 being strongly agree). Feasibility was assessed using data extracted from the IVR system and interviews with providers at the end of the study period.

**Statistical analysis**

Given that the primary aim of this study was to examine the acceptability, feasibility, and preliminary efficacy of the intervention, the analyses presented compared only those who had data at baseline and follow-up (i.e., per-protocol analyses). However, intention-to-treat analyses with baseline values carried forward for those missing at follow-up were also conducted. Independent, paired t-tests, and analysis of covariance (using baseline value as the covariate) were used to examine change from baseline to follow-up for the primary outcomes. A post hoc comparison was performed to examine whether use of HEAT improved weight and weight management behaviors. The HEAT group was split into two groups based on a clinical decision of what might be considered meaningful use. High users were those who completed four or more calls, which represented 57% of the HEAT group. All analyses were performed separately for parents and children. Analyses were performed using PASW Statistics 18 (SPSS, Chicago, IL, USA; http://

| Topic                                      | Week |
|--------------------------------------------|------|
| Follow-up on weekly challenge             | X    |
| Education                                  | X    |
| Obesity – what, why, how, weight gain      | X    |
| Reducing calories, calorie balance        | X    |
| Stoplight Diet basics                      | X    |
| Stoplight Diet servings needed             | X    |
| Substitution strategies / healthy snacking | X    |
| Pre-planning, cooking & shopping tips      | X    |
| Diet tips, tips for eating out & parties   | X    |
| Meetings, privileges, & contracts          | X    |
| Point system (reinforcers)                 | X    |
| Discuss guidebook & reasons for tracking   | X    |
| Problem-solving                            | X    |
| Screen-Time                                | X    |
| TV education – why kids watch              | X    |
| TV budget – contract & log                 | X    |
| TV Turn-Off week                           | X    |
| Summarize concepts & check in              | X    |
| Graduation                                 | X    |
| Set a weekly challenge                     | X    |

**FIGURE 2** The content of the IVR education and behavior calls for the parent
All statistical tests were two-tailed with $P < 0.05$ considered statistically significant.

**Results**

There were 241 potentially eligible pediatric patients at the time of the study (Figure 3). Of the sample pool, 140 were mailed a letter inviting the patient and a parent to participate. Of those, 14% were not eligible, 22% refused to participate, and 28% could not be reached by phone. Of the 81 eligible dyads, 62% agreed to participate. Fifty dyads were randomized into HEAT ($n = 24$) or WLC ($n = 26$). The randomized sample was primarily African-American (72%), lower income (73.5% reported an income of less than $40,000/year), and high-school educated (52.5%). Additionally, 98% of the adults were overweight or obese. Seven dyads did not complete the follow-up assessments (see Figure 3); however, there were no significant differences on demographic variables between those who dropped out and those who completed the study. Two mothers in the WLC were excluded from the weight analyses. One mother was in a wheelchair and the other reported that she was pregnant. The pregnant mother was also excluded from the diet analyses. For
TABLE 1 Characteristics of the randomized sample at baseline by group

| Variable          | Total N = 50 | HEAT N = 24 | WLC N = 26 | P    |
|-------------------|--------------|-------------|------------|------|
| Child             |              |             |            |      |
| Female (%)        | 42%          | 37.5%       | 46.2%      | 0.54 |
| Age, y(SD)        | 10.3 (1.1)   | 10.9 (1.3)  | 10.5 (1.2) | 0.36 |
| Height (cm), y(SD)| 147.4 (8.8)  | 150.3 (7.7) | 144.8 (9.1)| 0.03 |
| Weight (kg), y(SD)| 56.3 (9.7)   | 59.2 (9.6)  | 53.6 (9.1) | 0.04 |
| BMI, y(SD)        | 25.7 (2.1)   | 26.0 (2.2)  | 25.4 (2.1) | 0.27 |
| BMI percentile, y(SD) | 96.5 (1.6)  | 96.6 (1.5)  | 96.4 (1.7) | 0.60 |
| BMI z-score, y(SD)| 1.9 (0.27)   | 1.9 (0.3)   | 2.0 (0.3)  | 0.60 |
| Parent            |              |             |            |      |
| Female (%)        | 96%          | 96%         | 96%        | 0.95 |
| Age, y(SD)        | 40.0 (9.1)   | 40.3 (7.6)  | 40.4 (10.7)| 0.98 |
| Weight (kg), y(SD) | 88.5 (19.0) | 83.4 (14.2) | 93.5 (22.0)| 0.07 |
| BMI, y(SD)        | 34.0 (6.7)   | 31.8 (4.8)  | 36.3 (7.0) | 0.02 |
| Race (%)          |              |             |            |      |
| African-American  | 72%          | 70.8%       | 73.1%      | 0.21 |
| White             | 6%           | 0%          | 15.4%      |      |
| Other             | 22%          | 29.2%       | 11.5%      |      |
| Married (%)       | 46%          | 50.0%       | 42.3%      | 0.60 |
| Employment (%)    |              |             |            |      |
| Full or part-time | 68%          | 62.5%       | 46.2%      | 0.54 |
| Not employed      | 32%          | 25%         | 38.5%      |      |
| Income (%)        |              |             |            |      |
| <$40,000          | 72%          | 60.9%       | 84.6%      | 0.10 |
| >$40,000          | 26%          | 39.1%       | 15.4%      |      |
| Education level (%)|             |             |            |      |
| <High school      | 8%           | 8.3%        | 7.7%       | 0.13 |
| High school/GED   | 44%          | 29.2%       | 57.7%      |      |
| Any college       | 48%          | 62.5%       | 34.6%      |      |

Both children and parents, the per-protocol analyses resulted in the same statistical findings as the intention-to-treat analyses.

Children

Baseline characteristics for the randomized groups are presented in Table 1. There were group differences in weight and height but not BMI scores at baseline. Table 2 displays both the within and between-group differences from baseline to follow-up for those who completed both assessments. There were no statistically significant between group differences at P < 0.05.

Analyses of high versus low users of the IVR found that higher users had significant improvements on measures of weight, BMI, BMI percentile, and z-score compared to low users (see Table 3). No statistically significant differences between high and low users were found for demographic variables.

Parents

At baseline, WLC parents had a significantly higher weight and BMI. For the baseline to follow-up comparisons, the HEAT parents consumed 1.1 more cups of fruit per day than WLC (F (1,40) = 4.22, P = 0.046); however, the HEAT parents consumed fewer servings of vegetables than the WLC (F (1,40) = 6.88, P = 0.012). Analyses of high versus low users of IVR found that the high users consumed significantly fewer calories compared to the low users (see Table 3).

Acceptability of the HEAT-IVR. The majority of the parents gave highly favorable responses on questions regarding the intervention’s content. Of those who made at least one call, 75% or more agreed that HEAT was useful, easy to use, made for people like them, credible, and helped them eat healthy foods, and watch less TV. The majority of children agreed that HEAT was easy to talk to, made for people like them, credible, and helped them eat healthy foods, but only 35% agreed that HEAT helped them watch less TV. All of the parents and 83% of the children agreed that they would recommend HEAT to a friend. Questions about how and where HEAT was delivered were favorable: 100% of the parents and 82% of the children agreeing that they liked using HEAT because they could use it at home. The parents and children agreed that they liked HEAT because they could use it over the phone (88% and 59%, respectively). Half of parents and 47% of the children agreed with the statement, “I would rather do HEAT on a website.”

Feasibility of the HEAT-IVR. HEAT-IVR was designed as an “inbound” system that relies on participants calling in each week for 12 weeks. The IVR was called at least once by 17 of the 21 children (81%) and 16 of the 21 parents (76%). Of the parents who called HEAT more than once, the mean number of total calls was 9.1 (5.2). The parents made an average of 5.2 (2.8) education and behavior calls and 3.9 (2.6) tracking calls. Of the children who called HEAT more than once, the mean number of total calls was 9.0 (SD 5.7). The children made an average of 6.2 (3.6) education and behavior calls and 2.8 (2.8) tracking calls.

Feasibility of PC-HEAT. All study outcomes were assessed before any PC visits; however, families were told that their data would be available for viewing by their PCP at a follow-up visit after the study. The primary goal of this component of the study was to test the feasibility of PC-HEAT. Families were initially recruited 4 months prior to the child’s expected yearly well-child visit in order to allow time for enough IVR data to be collected and delivered to the EHR so that the acceptability and feasibility could be assessed. Data for families were transferred to the EHR in a semiautomated process. Data transfer was only performed if children had made at least two calls so that meaningful data would be available to the clinician at the time of the visit. Transfer required (1) recognition of a pending visit and (2) a single manual copy and paste of compiled data from HEAT into a specialized EHR form that would save the data for automatic extraction once the patient arrived for the scheduled visit. Because of technical challenges with the EHR, data for the first five families meeting these criteria could not be transferred to the EHR. For the remaining 10 families, 5 (50%) of the patients successfully kept their first follow-up appointment after completion of the study (1 arrived before completion and 4 either cancelled or did not keep their initial follow-up visit). Thus, 5
|                  | HEAT n = 21 |          | Within group Δ |          | Within group Δ | Between group Δ | Between group P for Δ |
|------------------|-------------|----------|----------------|----------|----------------|-------------------|----------------------|
|                  | Baseline    | Follow-up|                |          |                |                   |                      |
| **Children**     |             |          | **Mean (SD)**  |          | **Mean (SD)**  |                   |                      |
| Height (cm)      | 150.9 (7.8) | 153.0 (7.8) | 2.1 (1.2)      |          |                |                   |                      |
| Weight (kg)      | 59.5 (10.0) | 61.2 (10.9) | 1.7 (3.0)*     |          |                |                   |                      |
| BMI (Kg/m²)      | 26.0 (2.3)  | 26.0 (2.6)  | −0.01 (1.1)    |          |                |                   |                      |
| BMI percentile   | 96.4 (1.5)  | 95.8 (1.9)  | −0.7 (0.9)*    |          |                |                   |                      |
| BMI z-score      | 1.9 (0.24)  | 1.9 (0.28)  | −0.06 (0.1)*   |          |                |                   |                      |
| Total kcal/d⁴    | 946.0 (461.0)| 744.0 (385.0)| −202 (397.0)*  |          |                |                   |                      |
| Fruits (cups/d)  | 1.5 (1.2)   | 1.1 (0.7)   | −0.4 (1.3)     |          |                |                   |                      |
| Vegetables (cups/d)| 0.7 (0.5) | 0.6 (0.6)   | −0.02 (0.7)    |          |                |                   |                      |
| Saturated fat (gm/d)| 12.4 (8.1)| 7.9 (5.6)   | −4.5 (7.2)*    |          |                |                   |                      |
| Total fat (gm/d) | 35.0 (21.2) | 27.0 (14.6) | −8.0 (20.8)    |          |                |                   |                      |
| School day TV (hr/d) | 2.0 (1.5) | 1.4 (1.4)   | −0.6 (2.3)     |          |                |                   |                      |
| TV time (hr/d)   | 1.6 (1.7)   | 1.0 (1.5)   | −0.7 (2.2)     |          |                |                   |                      |
| PR TV (hr/d)     | 2.4 (1.4)   | 1.8 (1.1)   | −0.6 (1.3)     |          |                |                   |                      |
| Screen time (hr/d)| 2.8 (2.1)  | 1.7 (2.3)   | −1.0 (2.9)     |          |                |                   |                      |
| PR screen time (hr/d)| 4.5 (2.5) | 4.6 (3.3)   | −0.12 (3.6)    |          |                |                   |                      |
| **Parent**       |             |          | **Mean (SD)**  |          | **Mean (SD)**  |                   |                      |
| Weight (kg)a,**  | 83.6 (15.2) | 83.2 (15.6) | −0.4 (2.9)     |          |                |                   | −1.7                 | 0.57                 |
| BMI (Kg/m²)a,**  | 31.9 (5.1)  | 31.7 (5.3)  | −0.2 (1.1)     |          |                |                   |                      |                      |
| Total kcal/d     | 1107 (607.0)| 1044 (561.0)| −62 (430.0)    |          |                |                   | 1015                 | 0.55                 |
| Fruits (cups/d)  | 1.2 (1.0)   | 2.0 (1.6)   | 0.9 (1.6)*     |          |                |                   |                      |
| Vegetables (cups/d)| 1.1 (0.7) | 0.7 (0.5)   | −0.4 (0.7)*    |          |                |                   |                      |
| Saturated fat (gm/d)| 12.4 (8.3)| 11.5 (7.6)  | −0.8 (6.4)     |          |                |                   | −0.5                 | 0.01*                |
| Total fat (gm/d) | 39.1 (21.8) | 35.3 (18.2) | −3.8 (16.0)    |          |                |                   | −1.5                 | 0.52                 |
| TV (hr/d)        | 1.9 (1.6)   | 2.1 (1.3)   | 0.3 (1.1)      |          |                |                   | −0.5                 | 0.08                 |

PR, Parent-reported; *P < 0.05; **BMI and weight: WLC N = 20, wheelchair-bound parent removed from WLC analysis and pregnant woman removed from all WLC personal analysis.  
⁴Three participants with values more than two standard deviations from the mean were capped at 1880 kilocalories.
(33%) of the 15 families who made at least two calls actually completed a well-child visit on schedule. For the five families completing visits on schedule, one family did not have any IVR data in the system because of technical difficulties, four families had IVR data in the EHR note. Of the four families with IVR data in the note, only one had documentation of PCP counseling during the visit.

Acceptability of PC-HEAT. To better understand the potential acceptability of the PC-HEAT forms, we completed qualitative interviews with pediatricians to obtain acceptability of the form’s potential. Comments were similar to those obtained during the design phase (22). Pediatricians commented that it was clear, concise, and important to pursue but recommended functionality that included a reminder system.

Discussion
The HEAT study demonstrated that it is possible to translate programs with known effectiveness into a fully automated treatment program using IVR technology. Although the intensity and effectiveness of the HEAT intervention did not have outcomes at the magnitude of the parent programs (20,21), they were found to be acceptable to children and their parents from an underserved population.

This study was limited with regard to statistical power (i.e., small sample size) and nonequivalent study arms following randomization. However, a number of important findings were found. Although the intervention was associated with statistically significant improvements in television time for children and fruit intake for parents, a larger sample size may have detected more between-group differences. Comparison of high versus low users of the intervention suggests that children who completed more calls gained less weight. It also suggests that parents who made more calls showed more improvements in dietary fat and calorie intake.

Although the primary outcome was to reduce child BMI, parents were a major component of the intervention given that the most effective

### TABLE 3 Comparisons of high versus low users of the HEAT-IVR on the change in outcome variables from baseline to the end of the intervention within and between groups

|                   | High Users  | Low Users  |
|-------------------|-------------|------------|
|                   | (n = 22)    | (n = 22)   |
|                   | Baseline    | Follow-up  | Δ          | Baseline    | Follow-up  | Δ          | Between group | P for Δ  |
| **Children**      |             |            |            |             |            |            |              |         |
| Weight (kg)       | 57.6 (8.8)  | 57.5 (7.4) | −0.1 (2.0) | 62.2 (11.5) | 66.2 (13.3) | 4.0 (2.4)* | −4.0         | 0.001*   |
| BMI (Kg/m²)       | 25.5 (2.0)  | 24.9 (1.6) | −0.5 (0.9) | 26.7 (2.5)  | 27.3 (3.2)  | 0.7 (0.9)  | −1.2         | 0.01*    |
| BMI percentile     | 96.2 (1.7)  | 95.2 (1.8) | −1.0 (0.9)*| 96.9 (1.3)  | 96.7 (1.9)  | −0.2 (0.8) | −0.8         | 0.05     |
| BM z-score         | 1.9 (0.2)   | 1.8 (0.2)  | −0.1 (0.1) | 2.0 (0.2)   | 2.0 (0.3)   | 0.0 (0.1)  | −0.1         | 0.04*    |
| Total kcal/d       | 989.0 (597.0)| 830.0 (419.0)| −159.0 (538)| 967.0 (486.0)| 629.0 (320.0)| −338.0 (326.0)*| 179.0 | 0.19 |
| Fruits (cups/d)    | 1.2 (0.9)   | 1.3 (0.7)  | 0.1 (1.1)  | 1.9 (1.9)   | 0.9 (0.7)   | −1.1 (1.3)* | 1.2          | 0.08     |
| Vegetables (cups/d)| 0.7 (0.6)   | 0.8 (0.7)  | 0.1 (0.8)  | 0.6 (0.4)   | 0.4 (0.3)   | −0.2 (0.5) | 0.4          | 0.15     |
| Saturated Fat (gm/d)| 12.8 (9.5)| 8.3 (6.7)  | −4.5 (8.7) | 11.8 (6.3)  | 7.2 (4.0)   | −4.5 (5.1)* | 0.1          | 0.75     |
| Total Fat (gm/d)   | 36.0 (24.5) | 29.6 (16.6)| −6.3 (24.8)| 33.7 (17.2) | 23.4 (11.4) | −10.2 (15.0)| 3.9          | 0.38     |
| School day TV (hr/d)| 2.2 (1.5)  | 1.2 (1.1)  | −1.0 (2.0) | 1.7 (1.5)   | 1.6 (1.8)   | −0.1 (2.6) | −0.9         | 0.36     |
| Screen time (hr/d) | 2.9 (2.4)   | 1.9 (2.7)  | −1.0 (3.2) | 2.6 (1.8)   | 1.6 (1.7)   | −1.1 (2.7) | 0.1          | 0.78     |
| TV (hr/d)          | 1.8 (1.7)   | 1.0 (1.5)  | −0.8 (1.9) | 1.3 (1.7)   | 0.9 (1.6)   | −0.4 (2.7) | −0.2         | 0.85     |
| PR TV (hr/d)       | 2.1 (1.3)   | 1.6 (0.8)  | −0.5 (1.1) | 2.76 (1.6)  | 2.1 (1.4)   | −0.7 (1.7) | 0.7          | 0.64     |
| PR screen time (hr/d)| 4.0 (2.3)| 4.8 (3.6)  | 0.8 (4.2)  | 5.09 (2.7)  | 4.3 (3.1)   | −0.8 (2.7) | 0.3          | 0.57     |
| **Parent**         |             |            |            |             |            |            |              |         |
| Weight (kg)        | 85.0 (16.9) | 84.4 (16.2)| −0.6 (2.8) | 81.7 (13.2) | 81.4 (15.6) | −0.2 (3.2) | −0.3         | 0.80     |
| BMI (Kg/m²)        | 31.9 (5.4)  | 31.7 (5.2) | −0.2 (1.0) | 31.8 (5.0)  | 31.6 (5.8)  | −0.2 (1.2) | 0.4          | 0.95     |
| Total calories (kcal/d)| 1176.0 (427.0)| 920.0 (386.0)| −257.0 (302)*| 1014.0 (808.0)| 1211.0 (726.0)| 197.0 (453.0)| −454.0 | 0.02* |
| Fruits (cups/day)  | 1.2 (1.0)   | 1.8 (1.6)  | 0.6 (1.4)  | 1.1 (1.1)   | 2.3 (1.7)   | 1.2 (1.9)  | −0.6         | 0.40     |
| Vegetables (cups/d)| 1.0 (0.7)   | 0.6 (0.5)  | −0.4 (0.5)*| 1.2 (0.8)   | 0.9 (0.6)   | −0.3 (0.9) | −0.01        | 0.23     |
| Saturated fat (gm/d)| 14.2 (7.2)| 11.1 (5.7) | −3.1 (5.2) | 10.0 (9.5)  | 12.1 (10.0) | 2.2 (6.8)  | −5.2         | 0.14     |
| Total fat (gm/d)   | 44.3 (19.4) | 34.7 (13.9)| −9.5 (14.0)*| 32.3 (24.0) | 36.1 (23.7) | 3.8 (16.0) | −13.4        | 0.15     |
| TV time (hr/d)     | 1.6 (1.4)   | 1.8 (1.2)  | 0.3 (1.4)  | 2.2 (1.7)   | 2.6 (1.3)   | 0.3 (0.7)  | −0.1         | 0.39     |

*P < 0.05. PR, parent reported.
obesity treatment programs have been family- (parent-child) (6,29) and parent-based (7). The parent-focused components of HEAT were based on the concepts and content of evidenced-based obesity treatment programs (7); however, there were only modest treatment effects on the parent’s dietary behaviors and no effects on parent weight status or television viewing behaviors. The lack of changes in parent BMI is similar to findings in Project Story (16), which used a more intensive weight management intervention delivered in a group setting. Future modifications could include emphasizing the content of the tracking call which included self-weighing, a known, effective weight loss strategy (30), by integrating them with the behavior call. The intervention did not explicitly direct parents to lose weight nor did it include a caloric intake recommendation but encouraged participation in the same weight management behaviors as their child (e.g., self-monitoring weight, diet, TV, increasing green foods, reducing red foods). Parents were provided with a list of three possible goals to choose from each week. These goals were either about supporting the child’s efforts or about engaging in the behavior itself. More direct messages and goals regarding parent weight loss may be needed to see significant weight loss in parents.

A recent review suggests that high-intensity interventions (35-97.5 hrs) typically result in more weight loss, yet low-intensity interventions (less than 10 hrs) can also result in a clinically meaningful benefit (31). Traditional IVR systems are known to have limitations in the depth and breadth of a counseling conversation, which means it is important to select the most important variables to effect change. This study was successful at translating key components of evidence-based programs into a system that many families were able to use effectively. Children who used the system more frequently had greater improvements in weight status and self-management behaviors consistent with previous computer-based diet and exercise interventions for child and adult PC populations (15,32,33). Even interventions with modest effects may have a meaningful impact if they can reach large numbers of families. The findings of this study as well as a recent study by Pinard et al. (17) suggest that IVR interventions are not only acceptable but are well positioned to reach underserved populations. IVR interventions could overcome some of the barriers families encounter with clinic-based programs such as time and schedule (11), which could also have the added benefit of reducing costs to the health care system (i.e., fewer resources required and greater reach) (14).

Those who used the IVR more than once reported favorable ratings suggesting it is acceptable to parents and children as an obesity treatment. Yet, the more cogent finding of acceptability is that parents and children made calls to a “totally” automated IVR. Although testing automated systems for disease prevention and treatment is not novel, no IVR intervention has ever been truly, fully automated or devoid of human-like elements. Unlike previous IVR systems, which have used pre-recorded human voice files, the HEAT system used TTS with synthetic speech technology. This approach allows for easier, faster, and less costly modifications to the conversational content, for example, text edits do not require a professional voice actor to re-record the file. Although it can be argued that human-to-human interaction is preferable in theory, findings from other studies suggest that synthetic speech is an acceptable alternative (34). Although the majority of families liked HEAT because it was on the telephone (59% of the children and 88% of the parents), reflecting that a phone-based platform is an acceptable alternative to the Web, about half of the HEAT families reported that they would rather use a program like this on a website. These findings suggest that technology preferences may influence the effectiveness of a given obesity treatment.

A novel feature of the HEAT system was the automated presentation of IVR data in the EHR used by pediatricians at the point of care. Although it was feasible to extract data from the IVR and populate the EHR with the patient’s data, the use of PC-HEAT was not adequately tested. First, many participants were not able to complete a scheduled routine health care maintenance visit on schedule and for those who did, post-study interviews revealed that most clinicians did not remember using PC-HEAT during the visit. Nonetheless, they gave favorable ratings to the concept and encouraged future work in this area. Physician recall, insufficient prompting, and the relatively small number of individual subjects that needed to be identified within a large PC practice were likely responsible for this outcome. The findings from this study are important in light of the HITECH Act (Health Information Technology for Economic & Clinical Health Act) and the Patient Protection and Affordable Care Act, which places new emphasis on the widespread and meaningful use of electronic health records (EHRs). Previous studies have found that data delivered at the point of care are valuable but physicians need prompts to make changes (35).

Although few studies have evaluated a computer-based obesity treatment program linked with PC, HEAT results compare favorably to other technology-based (15) and nontechnology-based interventions delivered in PC, notably the Live, Eat and Play (LEAP) (36) and Obeldicks (37) studies. A recent review of low-intensity interventions suggest a standardized mean differences for weight compared to controls was $-0.39$ kg (95% CI $-0.66$ to $-0.11$) (31). HEAT resulted in a $-0.9$ kg (95% CI $-2.45$ to $0.63$) between group differences at 3 months. Although a longer term follow-up is needed to adequately test the effectiveness, the Obeldicks (37) study found that weight loss at 3 months was predictive of outcomes at 3-year follow-up. HEAT also had comparable retention rates (87.5% and 84.6% treatment vs. control) to other family- or parent-based studies delivered in PC, which range from 60% to 93% (15,16,31,32).

**Conclusion**

This study is the first to evaluate a fully automated behavioral weight management program for children and parents that links the family in the home directly with their PC clinicians through a fully automated system that is driven by spoken language over a ubiquitous technology—the telephone. The findings of this study suggest that for many users this approach has the potential to improve health behaviors and outcomes related to obesity. Further research in larger samples with longer follow-up is needed to examine its effectiveness as an intervention in the treatment of childhood obesity.

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