Rationale and design of the STAR randomized controlled trial to accelerate adoption of childhood obesity comparative effectiveness research ☆,☆☆,★,★★

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ABSTRACT

Background: Comparative effectiveness research (CER) evidence on childhood obesity provides the basis for effective screening and management strategies in pediatric primary care. The uses of health information technology including decision support tools in the electronic health records (EHRs), as well as remote and mobile support to families, offer the potential to accelerate the adoption of childhood obesity CER evidence.

Methods/design: The Study of Technology to Accelerate Research (STAR) is a three-arm, cluster-randomized controlled trial being conducted in 14 pediatric offices in Massachusetts designed to enroll 800, 6 to 12 year old children with a body mass index (BMI) ≥ 95th percentile seen in primary care at those practices. We will examine the extent to which computerized decision support tools in the EHR delivered to primary care providers at the point of care, with or without direct-to-parent support and coaching, will increase adoption of CER evidence for management of obese children. Direct-to-parent intervention components include telephone coaching and twice-weekly text messages. Point-of-care outcomes include obesity diagnosis, nutrition and physical activity counseling, and referral to weight management. One-year child-level outcomes include changes in BMI and improvements in diet, physical activity, screen time, and sleep behaviors, as well as cost and cost-effectiveness.

Conclusions: STAR will determine the extent to which decision support tools in EHRs with or without direct-to-parent support will increase adoption of evidence-based obesity management strategies in pediatric practice and improve childhood obesity-related outcomes.

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1. Introduction

In 2012, the Institute of Medicine report on Accelerating Progress in Obesity Prevention [1] called on health care professionals to increase their support structure for achieving better population health and obesity prevention. For children, the primary care setting provides the structure and opportunities to alter the subsequent course of health and disease for children at risk for obesity and its complications. Regular primary care visits during childhood allow detection of elevated body mass index (BMI) levels and offer opportunities for prevention, screening, and treatment of obesity. The continuity of the pediatrician/family relationship, as well as new models of care that promote family-centered care for children with chronic illnesses [2,3], are further examples of how primary care-based interventions to manage childhood obesity are particularly likely to be of benefit.

Despite their advantages, primary care settings have not realized their full potential in obesity management. Since 1998, when the first Expert Recommendations on the evaluation and treatment of childhood obesity were released, pediatric providers have often failed to diagnose childhood obesity and only inconsistently use BMI [4] and/or provide nutrition and physical activity counseling [5–9]. Although more parents of overweight and obese children reported that their doctors told them of this condition in 2007 through 2008 versus 1999 through 2000, the proportion still amounts to fewer than one-quarter [10]. As screening for and recognition of obesity is the first step towards appropriate management, system-wide changes to encourage adoption of standardized practice approaches to obesity management in primary care can address these gaps [11,12].

We designed the Study of Technology to Accelerate Research (STAR) randomized controlled trial to test strategies for accelerating the adoption of childhood obesity comparative effectiveness research (CER) evidence by pediatric clinicians and families. This study is funded by the Office of the Secretary for Planning and Evaluation in the Department of Health and Human Services in response to a call for proposals to accelerate adoption of comparative effectiveness research results by providers and patients (RFA-AE-10-001). In this article we describe the rationale and design of the STAR study, which is due to complete data collection in September, 2013.

2. Study rationale

2.1. Childhood obesity comparative effectiveness research

The Federal Coordinating Council for Comparative Effectiveness Research and the Institute of Medicine have highlighted accelerating the adoption of CER evidence as a national research priority [13,14]. Childhood obesity is a high priority CER topic, in part because of the high prevalence, its associated co-morbidities, and the need for testing of available prevention and treatment strategies. Recent CER evidence on childhood obesity provides the basis for effective screening and management strategies [15,16].

Included in the available CER evidence is the United States Preventive Services Task Force (USPSTF) report released in February 2010 which provided evidence-based recommendations on screening and management of obesity in children [17]. The USPSTF recommendations, based on over 15 good-quality weight management interventions among children 4 to 18 years of age [16], determined there was sufficient evidence to recommend that clinicians screen children ≥6 years of age for obesity using BMI and offer them comprehensive, intensive behavioral interventions to promote improvement in weight status [17]. The USPSTF review offers strong CER evidence that 1) screening and evaluation of children for obesity is an important prelude to effective treatment, 2) comprehensive treatment including counseling for weight loss, and healthful nutrition and physical activity is effective, and 3) behavioral management techniques to make and sustain lifestyle changes are important intervention components [18].

2.2. Strategies to accelerate the adoption of CER evidence among pediatric clinicians and families

2.2.1. Decision support delivered using health information technology

The use of health information technology, such as electronic health records (EHRs), offers potential to accelerate the adoption of childhood obesity CER evidence [19,20]. EHRs enable delivery of decision support tools for clinicians at the point-of-care that can be linked to CER-based management algorithms and that meet national benchmarks of pediatric obesity quality of care. In pediatric outpatient settings, electronic decision support has already been shown to improve prescribing patterns [21], increase immunization rates [22], and improve delivery of preventive asthma care [23]. We have previously shown that commonly used functions in the EHR that could facilitate pediatric obesity management include viewing growth charts and trajectories, accessing previous laboratory test results, using structured templates to facilitate documentation and referrals, and the ability to print tailored after-visit summaries with parent educational materials [24]. In in-depth interviews we conducted with pediatric clinicians as part of the formative work for the STAR study, clinicians also suggested combining structured templates already commonly used for well child care visits with content that would meet obesity-related quality benchmarks and that would assist clinicians in incorporating behavioral modification tools in their visits [25].

2.2.2. Direct-to-parent support using remote and mobile technologies

Health information technology strategies may be especially effective if augmented by outreach and support directly to patients and families. In a school-based setting, direct outreach to parents about children's BMI screening was an informative, motivational tool for parents and resulted in improvement in family diet and activity [26,27]. Additionally, telephone support has been employed to deliver motivational interviewing and brief focused negotiation to effect behavior change. Recently, mobile technology strategies such as text messaging have been used to provide outreach and support for behavior change to patients. One study showed parents preferred text messages to phone calls when used for immunization reminders [28]. Few studies, however, have assessed text messages as a self monitoring tool and to communicate educational messages for management of childhood obesity [29].

3. Conceptual framework

Studies based on a sound conceptual framework, with adequate attention to the various levels within health care systems that need to be targeted for effective implementation of any intervention can substantially increase the likelihood that an intervention will be effective. The overarching model for the STAR intervention is the Chronic Care Model developed by Wagner et al. [30]. The Chronic Care Model identifies the essential elements of a health care system that encourage high-quality care of chronic conditions. Evidence-based change concepts under each element including changes to clinical information systems, decision support tools, self-management support, and delivery system design, foster productive interactions between informed, "activated" parents who collaborate with providers who have resources and expertise. While the model's originators have applied it to the care of adult chronic disease, we and others recently adapted it to primary care management of obesity in children [31].

4. Methods

4.1. Overview of study design

STAR is a cluster-randomized controlled trial being conducted within 14 pediatric offices of Harvard Vanguard Medical Associates (HVMA), a multi-specialty group practice in eastern Massachusetts. We randomly assigned each practice to one of 3 intervention arms (Fig. 1): 1) computerized point-of-care decision support (alerts) to pediatric primary care providers; 2) computerized alerts *plus* direct-to-parent outreach and support relating to their child's BMI, recommended screening, and management; and 3) usual care (control). The target population is children ages 6 to12 years with a BMI ≥ 95th percentile. The primary, intention-to-treat, analysis will examine whether there is a difference between the extent to which each intervention arm improves adoption of CER evidence on point-of-care obesity screening and management, and improves children's BMI and obesity-related behaviors over a 1-year intervention period. We will also assess

the cost and cost-effectiveness of the intervention. All study activities were approved by the Institutional Review Board at Harvard Pilgrim Health Care.

4.2. Randomization

We used a stratified block randomization scheme to assign practices to one of the 3 study arms. Strata were based on the volume of children aged 6.0 to 12.9 with a BMI ≥ 95th percentile seen for well-child visits at each site from April 2010 through March 2011. A biostatistician (KPK) blinded to the names of the practices ordered them on this characteristic, then introduced a false practice at a random spot within the order to make the number of "practices" evenly divisible by 3. Strata consisted of consecutive groups of three practices from this ordered list. He then used a pseudo-random number generator in SAS 9.2 (SAS Institute, Cary NC) to assign one practice from each strata to each of the arms, with the exception that the false practice was deterministically assigned to the usual care arm. This resulted in 5 practices in each of the intervention arms and 4 in the usual care arm.

4.3. Blinding

Research staff performing all assessments is blinded to specific study hypotheses and to intervention assignment. Study participants and the pediatricians in each practice are blinded to specific study hypotheses but not to intervention assignment.

4.4. Eligibility and recruitment

Eligibility for STAR includes: 1) child is 6.0–12.9 years old at baseline, 2) child's BMI ≥ 90th percentile for age and sex at the baseline well child visit, 3) child has received well child care at HVMA within the past 15 months, and 4) at least one parent can communicate in English. Children were excluded if: 1) their sibling had already been enrolled in the study, 2) their family was planning to leave HVMA within the study
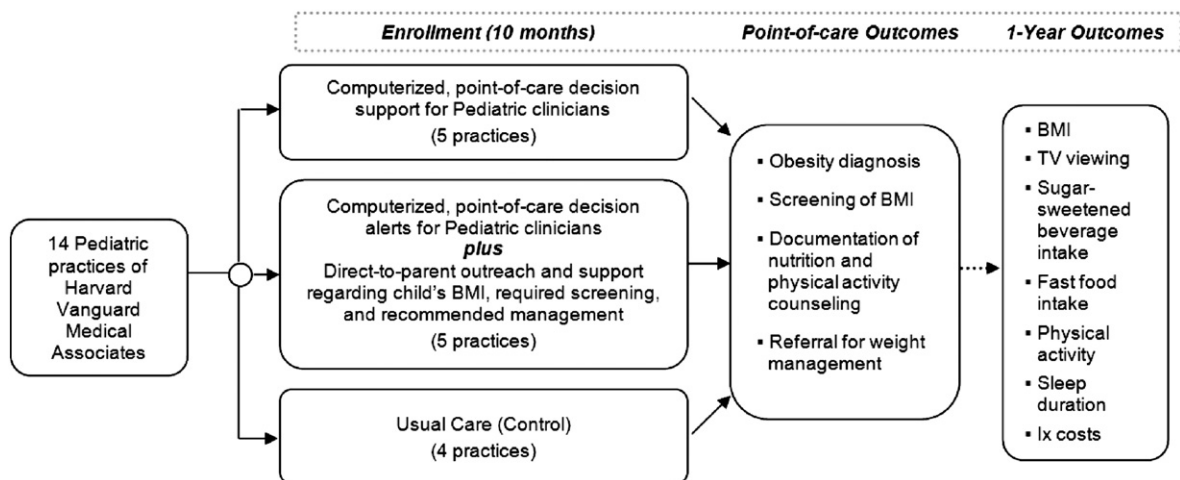

Fig. 1. Study design, randomization, and outcomes of the *Study of Technology to Accelerate Research (STAR)* Intervention, a cluster randomized controlled trial in pediatric practices in eastern Massachusetts, 2011–2013.

time frame, 3) their clinician did not feel the study was appropriate for them or their families, or 4) they had a chronic medical condition that impacted their diet or physical activity.

Recruitment began in October, 2011 and will end in August 2012. After receiving permission from primary care providers to contact eligible patients, study staff sends each family a letter approximately one month prior to the child's scheduled well child visit introducing the study and inviting the family to participate. The letter includes an opt-out phone number to call if parents do not want to be contacted. Parents are also encouraged to call this number if they are interested in participating. We call parents who do not refuse additional contact beginning 7 days after mailing the letter. Research assistants who were blinded to intervention groups establish eligibility, explain the study, answer questions, obtain verbal consent, and complete the baseline survey over the phone. Research assistants verify contact information and mail parents a $20 gift card for completing the baseline survey. They also mailed a written informed consent form required for participation in the remainder of the study's activities. After receiving their signed consent form, we inform participants of their assigned intervention group. The participant flow to date for STAR is shown in Fig. 2.

4.5. Sample size estimations

STAR is recruiting a total of 800 children and their parents across the 14 practices of HVMA within a 10-month period. Based on previous studies within these practices, we anticipate 680 (~85%) children will complete the study. Data collected as part of High Five for Kids, a moderate intensity obesity intervention in HVMA, revealed standard deviations of approximately 1.35 kg/m^2 for the difference between BMI measurements 1 year apart [31]. Based on these estimates, with 80% power and a sample size of 680, we will be able to detect differences of about 1.1 kg/m^2. The USPSTF found the amount of absolute or relative weight change associated with moderate intensity obesity interventions, such as the STAR study, was 0.85–3.3 kg/m^2 difference in mean BMI 6–12 months after starting treatment, compared with controls [16]. Thus, our sample size will allow for ample power to examine 1-year change in BMI.

4.6. Intervention arms

4.6.1. Usual care

Participants randomized to the control group receive the current standard of care offered by their pediatric office. This includes well child visits and follow-up appointments for weight checks with their primary care provider, subspecialist, or a nutritionist. They also receive generic health-related materials in the mail from STAR. Clinicians in the usual care arm do not have access to the computerized point-of-care alerts for the duration of the intervention.
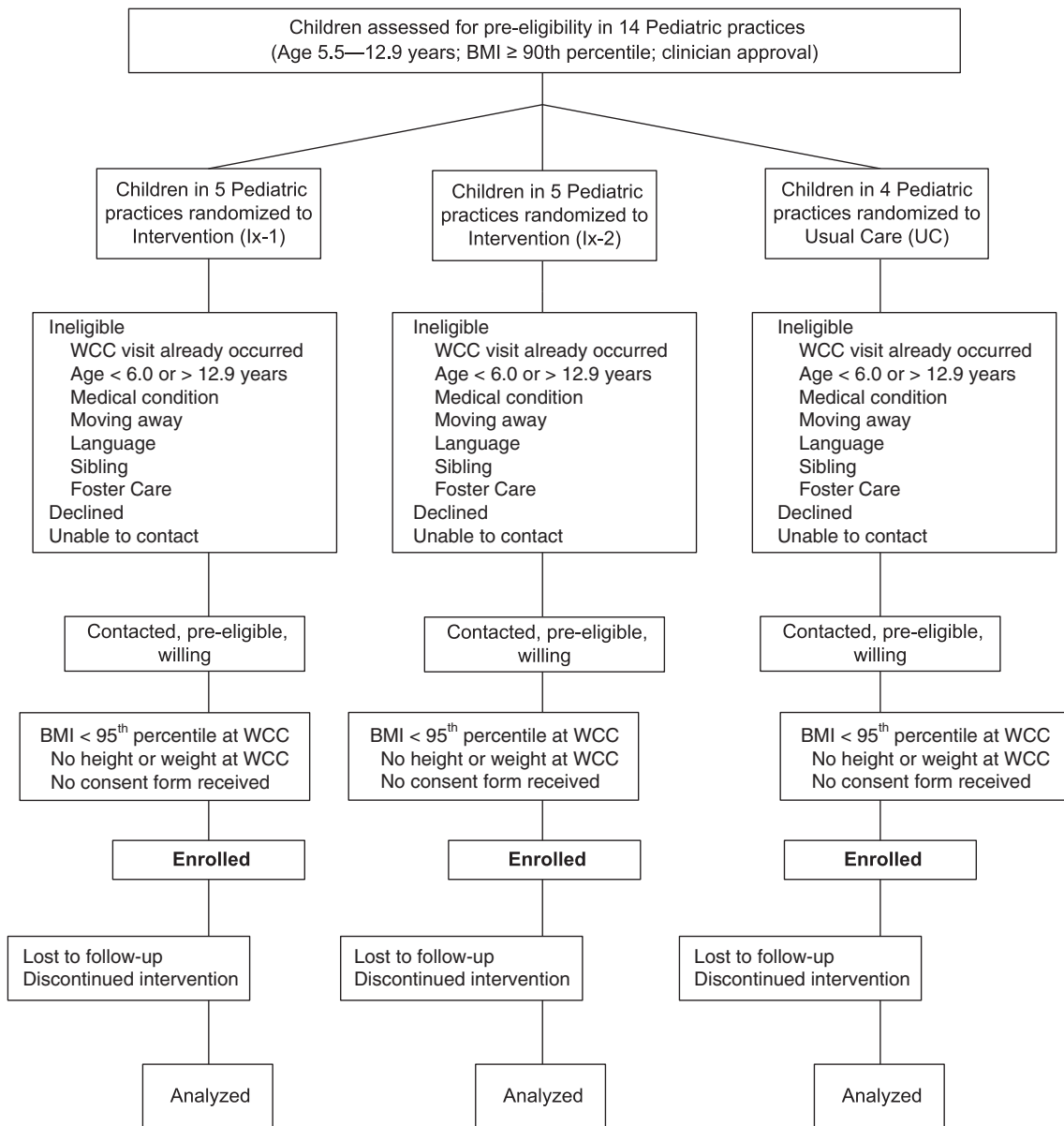
4.6.2. Intervention

4.6.2.1. Computerized point-of-care alerts. In the 10 practices randomized to the intervention, we modified the existing EPIC EHR to deploy a BestPractice® alert to pediatricians at the time of a well child care visit with a child between the

ages of 6–12 years with a BMI≥95th percentile (Fig. 3 and Appendix). Medical assistants measure height and weight and enter the values into the EHR which automatically calculates BMI. The alert was designed to trigger as a new window "in front of" the screen on which the clinician was working to identify children with a BMI≥95th percentile. The alert contains links to the CDC growth charts, links to existing childhood obesity CER evidence, and a link to a pre-populated, SmartSet® standardized well child visit template specific for obesity that includes: 1) place and instructions for documentation and coding of BMI percentile and diagnosis of obesity (ICD-9 Diagnosis Code V85.54), 2) documentation of nutrition (ICD-9 V65.3) and physical activity (ICD-9 V65.41) counseling, 3) placing referrals for internal to HVMA or outside weight management programs, 4) placing orders for obesity-related laboratory studies if appropriate (e.g. fasting lipid profile and glucose), and 5) links to printable patient education information and to a study website with additional obesity-related educational materials only for intervention participants.

We provided clinicians with a list of local weight management programs that deliver moderate (26–75 h) or high (>75 h) intensity behavioral treatment based on the recommendations by the USPSTF. We made this list available to clinicians via a study-specific website which serves as a repository of materials for obesity management. The study website also features resources to aid clinicians during follow up obesity visits, including an outline of how to structure the visits, printable patient handouts on each of the STAR target behaviors, a searchable database of local physical activity programs, and tools for improving obesity-related communication with parents through a motivational interviewing style of counseling. Additionally, the website has many links to outside resources for clinicians to access more information on obesity, parenting, media and child health, sleep, and sugary drinks. We also gave each intervention site posters to hang in the waiting and exam rooms (Fig. 4). The poster outlines each of the study behavioral goals and is intended to help cue parents to talk about these goals with their children and their clinician.

We conducted on-site visits at each of the 10 intervention sites, as well as a webinar to introduce the study and explain the EHR components. After the alert was launched, we conducted a second round of on-site visits to provide technical assistance to clinicians using these new EHR tools at the intervention practices. We also offered clinicians 1-on-1 support and training by a study staff member. In addition, all health professionals in the Harvard Vanguard Medical Associates health care system have access to cultural competency trainings as part of their continuing education credits. During the on-site visits, we provided clinicians suggestions on appropriate language for discussing body mass index with parents and children.

4.6.2.2. Direct to parent outreach and support. In one of the intervention arms (5 practices), we provided direct to parent outreach and support to their enrolled families in addition to the computerized decision support tools available for their clinicians. Prior to the well child visit, study staff mail a letter to parents in this arm that provides an explanation of their child's most recent BMI from their previous well child care visit and shows their child's BMI and weight category on the CDC BMI charts. The letter encourages parents to discuss BMI

Fig. 2. Flow of clusters and individuals, based on CONSORT guidelines, for the *Study of Technology to Accelerate Research (STAR)* Intervention, a cluster randomized controlled trial in pediatric practices in eastern Massachusetts, 2011–2013.

with their doctor at their child's upcoming visit. Following the well child care visit, parents receive a mailed letter from their clinician endorsing obesity-related behavior change and offering support for the child's involvement in the study. The letter also includes a welcome message from the participant's assigned STAR study health coach. The clinician endorsement mailing is followed by a mailed brochure that outlines the STAR behavior goals and the schedule of study contacts with their assigned health coach. The schedule includes a phone call from a study health coach at 1, 3, 6 and 9 months after the well child visit. Study health coaches use a motivational counseling style to identify what health behavior goal(s) parents are interested in working on with their children, how

they think they can make that change, and what might get in the way of meeting that goal. Between the telephone calls, health coaches mail educational handouts to participants that address the targeted health behaviors. An incentive for the child is included in two of these mailings. The children are also sent 4 issues of a healthy cooking magazine for kids during the intervention year.

Study health coaches also use text messages to provide behavior change support. In most weeks parents receive 2 text messages. The first is an educational message about one of the recommended behaviors, and the second is a self-monitoring message that asks how the child did with a certain target behavior the day before. The outgoing text asks
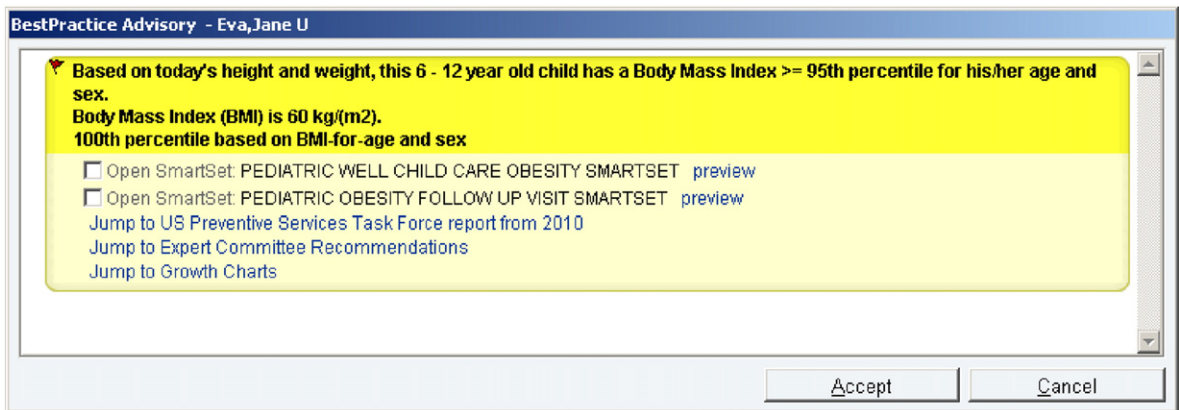
Fig. 3. Screen shot of electronic health record BestPractice® alert developed for the *Study of Technology to Accelerate Research (STAR)* Intervention, to alert pediatric clinicians at the time of a well child care visit of a child between the ages of 6–12 years with a BMI ≥ 95th percentile.

parents to reply to these messages, and in turn they receive an automated feedback response message tailored to how they indicated they are doing meeting that behavior goal. For example, it might say "Great job!" "That's close to the goal. Keep at it!" or "Change is hard. Keep trying! See the STAR tip sheet for ways to tackle the challenge." For parents who

Fig. 4. Waiting room poster developed for the *Study of Technology to Accelerate Research (STAR)* Intervention, highlighting several behavioral outcomes of the study.

Table 1

Behavioral targets and measures used in the *Study of Technology to Accelerate Research (STAR)* Intervention, a cluster randomized controlled trial in pediatric practices in eastern Massachusetts, 2011–2013.

Behavior	Intervention goals	Measures and validity relationships
Diet and diet quality		
Sugar-sweetened beverages	• Lower daily intake of beverages with sugar added	Parent report using questions from a validated semi-quantitative child food frequency questionnaire.[35] Associated with BMI.[36]
Family meals	• Increase frequency of meals eaten together as a family	Parent report of times/week child ate dinner or supper together with at least some of the family;[37] associated with dietary intake and with child BMI.[38,39]
Fast food	• Lower weekly intake of fast food meals	Modified question adapted from the Growing Up Today Study [40]; associated with BMI.
Television and screen time		
Screen time exposure viewing	• Limiting screen-viewing time to<2 h/day	Parent report of average daily hours spent watching TV or videos; playing video games; and using the computer;[41] associated with child BMI.[42]
TV in room where child sleeps	• No TV in room where child sleeps	Presence of TV in bedroom; related to BMI [43,44] in children.
Sleep duration and routines		
Sleep duration	• Increase sleep duration to 10 h/day	Parent report of average amount of daily sleep their children obtained; associated with childhood BMI. [45–47]
Regular bedtime	• Regular bedtime on most days	Parent report of typical bedtime on weekday and weekend days. [48]
Physical activity	• At least 1 h of moderate to vigorous physical activity/day.	Parent report of child's average weekly hours spent in three classes of recreational activity: walking, light-to-moderate activities, and vigorous physical activities.[49]

decline the text messaging component, an email option is available that mimics the text messaging system.

4.6.2.3. Outcome measures. Our main outcomes are at both the system and the individual level. System level outcomes include point-of-care and 1-year measures of obesity-related quality of care; child-level outcomes include 1-year changes in child BMI and obesity-related behaviors. We are also measuring the cost of the intervention. We collect outcomes measures using the child's electronic health record from the baseline and 1-year well child care visit and using researcher-administered surveys of parents. To measure obesity-related quality of care at each well child care visit, we conduct a data pull of the EHR to look for pediatric obesity Healthcare Effectiveness Data and Information Set (HEDIS) measures which include 1) documentation and diagnostic coding of a BMI percentile and 2) documentation of counseling or referral for nutrition and physical activity counseling [32]. An additional quality of care outcome we measure is the number of obese children who left their well child care visits with a referral or follow-up plan for weight management.

One year child outcomes include changes from baseline in BMI, obtained from the EHR from each well child care visit, as well as changes in behaviors. HVMA medical assistants measure height and weight according to the written standardized protocol of the health centers and all undergo bi-annual trainings and quality assurance of their height and weight measurements using standard training materials [33]. Research assistants administer a telephone survey to parents at baseline and at one year to assess behavioral outcomes. These are summarized in Table 1.

We will assess the cost of the intervention with two goals: (a) to inform clinicians and health care systems about what investment would be required to adopt this intervention in other settings, and (b) to generate key assumptions for analysis of the cost-effectiveness of the intervention. To assess fixed direct costs e.g. those required to develop and implement the intervention, we collect information on the cost of developing all aspects of the intervention (e.g., the EHR decision support tools, the telephone and text messaging capabilities) as well as the up-front cost of all training required for the clinicians on the use of the decision support tools and the health coaches for delivering the direct-to-parent outreach and support. To measure marginal direct costs, e.g. those associated with all types of intervention contacts between the health coach and parents such as telephone calls and text messages, we use health coach process logs to calculate these costs and vendor contracts supporting our intervention's technology (e.g., text messaging service).

4.6.2.4. Data analysis. We will examine baseline distributions of participant characteristics by intervention status. In intent-to-treat analyses, we will correct for clustering by practice, and examine differences from baseline to 1 year between the 2 intervention and usual care groups.

5. Discussion

STAR will determine whether there are differences in the extent to which decision support tools in EHRs along with direct-to-parent support via text and telephone will increase adoption of comparative effectiveness research evidence on childhood obesity among primary care clinicians and parents and ultimately improve childhood obesity-related outcomes.

As in any study, this one is subject to several potential limitations. One is generalizability. Much pediatric primary care is currently provided in settings unlike HVMA, i.e. small practices without electronic health records. However, as a relatively large medical group, HVMA is a typical health care setting for many children and their families, and EHRs are increasingly penetrating even small practices. Thus the intervention we propose is likely to generalize to more and more pediatric settings in the future. Furthermore, with so few effective strategies to accelerate adoption of childhood obesity CER evidence, it is important to show effectiveness in some model settings that can later be adapted to the range of

settings in which children receive care. Second, parents could exaggerate improvements in behaviors (social desirability bias). This is a limitation of all behavioral interventions, and is another reason to have child BMI as one of the outcomes. Third, the 3-year timeline of this study does not allow measurement of outcomes beyond 1 year.

If successful, this project will provide new and sustainable approaches for accelerating adoption of comparative effectiveness research evidence for childhood obesity, for improving quality of care for childhood obesity in pediatric primary care, and for effectively supporting patients and families in improving obesity-related behaviors outside of the clinical setting.

Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.cct.2012.10.005.

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