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CHECK: A randomized trial evaluating the efficacy and cost-effectiveness of home visitation in pediatric weight loss treatment

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Abstract

Background: Socioeconomically-disadvantaged households have a high prevalence of pediatric overweight/obesity, and also face barriers to accessing weight loss treatment in healthcare settings. Delivering family-based pediatric weight loss treatment in the home setting may enhance its efficacy by facilitating treatment attendance, enabling more tailored treatment recommendations informed by observations of the home environment, and increasing accountability. This paper describes the design of the Creating Health Environments for Chicago Kids (CHECK) Trial, which evaluates the efficacy, cost-effectiveness, and mechanisms of home visitation in family-based pediatric weight loss treatment for children in low-income households.

Design: CHECK is a two-arm, parallel group, randomized controlled trial that is enrolling N=266 children, ages 6–12 y, who have overweight/obesity (BMI percentile ≥85) and live in a low-income household. Participants are randomized in a 1:1 ratio to either standard of care family-based weight loss treatment delivered in the home, or the identical intervention delivered in an academic medical center. The primary outcome is change in child BMI z-score from baseline to 12 months. Program delivery costs are rigorously documented to enable cost-effectiveness analyses from the societal and payer perspectives. Objectively-documented changes to the home environment and aspects of intervention delivery (e.g., hours of in-person contact received, quantity of behavioral goals set per session) will be tested as hypothesized treatment mechanisms.

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Competing interests. The authors have no competing interests to disclose.

Implications: Findings will inform the design of future interventions, and treatment dissemination decisions by public health agencies and third-party payers.

Trial Registration: [ClinicalTrials.gov](https://clinicaltrials.gov) identifier:

Keywords

Pediatric obesity; Weight loss; Cost effectiveness; Socioeconomic status

1. Introduction

Children from low-income households are roughly twice as likely to have obesity as those from higher-income households¹. As pediatric obesity is highly predictive of future chronic disease risk²⁻⁴, disseminating effective pediatric obesity treatments in disadvantaged populations is essential for reducing health disparities.

The current standard of care treatment for pediatric overweight/obesity consists of family-based interventions that target children's eating patterns, physical and sedentary activity, and sleep^{5,6}. Several meta-analyses support the efficacy of family-based interventions⁷⁻⁹. These interventions have traditionally been delivered in healthcare settings, such as academic medical centers, which may present obstacles to participation among low-income families who often have difficulty accessing the healthcare system^{10,11}. School schedules, lack of transportation, and the challenge of arranging affordable childcare represent additional barriers. Delivering pediatric obesity treatment in the home setting may increase completion of intervention visits, which would result families receiving a higher overall intervention dosage¹². Home visitation also provides interventionists with regular opportunities to directly observe and address risk factors in the home environment, which may enable them to provide more specific and relevant guidance to caregivers regarding healthy changes to household routines and aspects of the physical home environment. Conducting sessions in the home also allows caregivers to learn and rehearse new behaviors in the context in which they are to be implemented, and may instill a sense of accountability insofar as they expect intervention staff will be visiting their home on a regular basis. Thus, home visitation may improve weight loss outcomes in children from low-income households via three mechanisms: 1) increasing intervention dosage, 2) enabling tailored feedback, and 3) increasing accountability.

Despite its potential advantages, there is a lack of empirical data to support home visitation in pediatric obesity interventions^{13,14}. A recent systematic review indicated that the vast majority of trials that evaluated an intervention with home visitation were pragmatic in nature^{15,16}, and compared an intensive intervention with home visitation to far less intensive comparators. As a result, it is unclear whether home visitation is truly an important component of pediatric obesity interventions for low-income families, or if it is simply characteristic of more intensive interventions.

Home visitation likely has a higher operational cost (from the healthcare system perspective) due to the need for interventionist travel. There are a number of real-world examples of behavioral and public health interventions that incorporate home visits for prenatal, infant

and child health^{17–19}. However, data on their operational cost and cost-effectiveness are extremely limited, and it is unclear whether any added weight loss benefit of home visitation is justified economically.

This paper describes the design of the Creating Healthy Environments for Chicago Kids (CHECK) Trial, which is designed to determine whether home visitation enhances the efficacy of family-based pediatric weight loss treatment for children in low-income households. Secondary aims of the trial are to quantify the cost-effectiveness of home visitation from the societal and payer perspectives, and to test several hypothesized mechanisms through which home visitation may improve pediatric weight loss outcomes.

2. Methods

2.1. Study design overview

The CHECK trial is a two-arm, parallel group randomized controlled trial designed to test whether home visitation improves weight loss outcomes in family-based pediatric obesity treatment. The trial will randomize 266 children and their caregivers to 12 months of treatment delivered in the home (Home Visit Arm) or an academic medical center (Medical Center Arm). Both arms receive the same standard-of-care intervention targeting family routines and aspects of the home environment that influence children's dietary intake, physical activity, sedentary time, and sleep. The primary outcome is change in child BMI z-score (zBMI). Recruitment began in August 2017, and is expected to conclude in July 2020. The trial is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (). Study procedures were approved by the Institutional Review Boards of Rush University Medical Center and University of Illinois at Chicago.

2.2. Participants

This trial enrolls 6–12 year old children who have overweight/obesity and live in a low-income household. At least one primary caregiver is also enrolled. Potential participants are screened for eligibility during a run-in period that includes assessment activities both in their home and at the study site. This run-in period is designed to ensure adequate motivation to complete assessments on the part of participants, and demonstrate that participants have the ability and willingness to attend clinic visits and meet with researchers in their homes. The run-in period is intended to last one week, but can be extended for one additional week (up to 14 days total) in the event that the index child does not achieve the minimum wear time requirement for the accelerometry protocol within the first week. Eligibility criteria are as follows:

2.2.1. Inclusion criteria

1. Child is 6 to 12 years old at baseline.
2. Child has a BMI $\geq$ 85th percentile for age and sex.
3. Child's household has an income-to-poverty ratio $\geq$ 2.0 (e.g., \$51,500/year for a 4-member household in 2019).

2.2.2. Exclusion criteria

1. Child or caregiver(s) are not fluent in English or Spanish.
2. Unwilling to attend and complete either home-based or clinic-based treatment, or to complete any aspect of the study assessment battery.
3. Failure to successfully complete the run-in protocol.
4. Medical contraindication or barrier to weight loss treatment (e.g., chromosomal abnormality, phenylketonuria, paraplegia, syndromal cause of obesity, need for oral steroid medication, type 1 diabetes) as determined by the child's pediatrician at the recruitment site.
5. Caregiver has a major medical or psychiatric condition likely to interfere with treatment (e.g., schizophrenia, dementia, terminal illness with life expectancy <12 months).
6. Plans to relocate outside the Chicago area in the next 12 months, or living in temporary or group housing with other families (the intervention assumes that children's caregivers have sole control over their home environment).
7. Resides more than 15 miles from the study site.
8. Conditions in or around the home that jeopardize staff/interventionist safety (extreme unsanitary conditions, gang presence, illegal activity in the immediate vicinity of the home).

In the event that more than one child in a household meets eligibility criteria, one child is randomly selected as the "index child" for assessment purposes. Only the index child will complete the accelerometry/sleep actigraphy protocol and is referenced in child-specific surveys. Interventionists are blinded to which child has been selected as the index case, and the intervention targets all overweight/obese children in the household.

2.3. Recruitment

Participants are primarily recruited from pediatric primary care centers at two large Chicago academic medical centers. Healthcare providers identify children who are potentially eligible for the trial, and are encouraged to provide caregivers with a basic description of the study and the contact information for the research team. Providers also seek caregivers' permission to pass their names and contact information to the research team. Additionally, potential participants are identified by screening the electronic health record system of the pediatrics practices at each recruitment site for patients who meet the age and BMI percentile inclusion criteria. Caregivers of identified children receive a letter from their child's pediatrics practice notifying them to expect a phone call from research staff about the study. Caregivers have 7 days to opt out of being contacted.

Caregivers who express interest in participating are asked to provide verbal consent for an initial telephone screening to assess eligibility. Individuals who are not excluded during the telephone screening are invited to an in-person screening, where written informed consent and child assent are obtained. Individuals who remain eligible at the in-person screening

visit progress to the run-in period. Participants are not randomized unless they complete the entire baseline assessment, which includes the baseline assessment battery and accelerometry protocol. At the end of the run-in period, researchers visit the child's primary residence to retrieve the accelerometer and issue participant compensation for completing the baseline assessment.

2.4. Randomization

Participants are randomized to the Home Visit Arm or the Medical Center Arm in a 1:1 ratio using permuted randomized blocks of size 4 and 6. Randomization is stratified by obesity status (BMI 85.0–94.9 vs. ≥95.0 percentile) and recruitment site to prevent disproportionate allocation based on these factors. The study biostatistician is responsible for generating the randomization schedules and assigning participants to an intervention group. After being allocated to an intervention group, participants are randomized to an interventionist who will conduct all intervention activities throughout its duration. Thus, each interventionist delivers treatment to families in both arms. Randomly assigning participants in both groups to an interventionist (rather than having interventionists deliver treatment in only one arm) eliminates any potential influence of interventionist characteristics on treatment effects. The main concerns about having interventionists deliver treatment in both arms are contamination (elements of an intervention being delivered to participants in the other group) and potential bias (i.e., an interventionist's performance varies by condition based on their expectations or other factors). In this trial, both arms receive the identical intervention, and only differ in *where* the intervention is delivered. Thus, contamination risk is inherently low. Robust fidelity tracking procedures, described below, further reduce contamination risk and the potential for bias.

2.5. The CHECK Intervention

2.5.1. Intervention format and intensity.—Given the aims of the trial, CHECK was designed to be representative of contemporary interventions in terms of intensity²⁰ and content^{5,21}. CHECK is a 12-month intervention that includes 18 in-person visits and 12 telephone coaching calls that taper in frequency (Figure 1). Planned contact duration is 30–60 minutes for in-person visits, and about 15 minutes for phone calls (~23 hours total contact time). CHECK is caregiver-focused²², with parents viewed as the primary or sole agents of change, as this approach is efficient and as effective as intervening with the entire family²³.

2.5.2. Theoretical foundation.—CHECK is grounded in a socioecological model that emphasizes the roles of both physical and social/family aspects of children's home environments in the development and maintenance of obesity²⁴. For example, family routines (e.g., bedtime routines, family meals) and aspects of the physical home environment (e.g., availability of energy-dense foods and beverages) are considered important, modifiable, proximal influences on children's weight management behaviors^{25–27}.

2.5.3. Intervention components.—CHECK includes three main intervention components: 1) Self-monitoring of household routines and the home environment; 2) caregiver skills training and education; and 3) telephone coaching. The most foundational

component is weekly self-monitoring and guided modification of the home environment. Each week, caregivers are asked to complete a single-page Home Monitoring Checklist that assesses the presence of risk and protective factors for pediatric overweight/obesity in the home environment (Supplemental material). In addition to aspects of the physical home environment (e.g., food availability, access to media equipment), key parent behaviors that constitute the child's social home environment (e.g., bed time routines, rewarding children for healthy choices) are also included on the Home Monitoring Checklist. Interventionists and caregivers jointly review the Home Monitoring Checklist together in each session (either at home or in the medical center, depending on group assignment), and consider its implications when collaboratively selecting educational materials and setting behavioral goals.

The second intervention component is caregiver skills training and education. Interventionists verbally present a 10-module curriculum that was previously developed and pilot tested by our team (Table 1). The curriculum provides caregivers with the basic knowledge and skills needed to shape their home environments and household routines to promote child weight loss. Each module emphasizes one or two action items for caregivers to implement during the next one to two weeks (e.g., establish a bedtime routine, purchase low-calorie beverages). Modules and their associated handouts are written for use with a low-literacy population. With the exception of the first module, which provides an overview of the program, caregivers and interventionists collaboratively select the order in which modules are covered based on the present needs of the family. All modules are presented at least once, and can be reviewed when interventionists or caregivers believe that a review would be helpful and timely.

Telephone coaching is the third major intervention component of CHECK. One purpose of telephone coaching is to provide ongoing social support to caregivers as they implement the program. Telephone coaching also provides an opportunity for interventionists and caregivers to jointly review progress with goals set in prior sessions, and address motivational or logistical barriers through coaching techniques described below.

2.5.4. Coaching techniques.—CHECK includes three coaching techniques that interventionists can use to help participants implement elements of the program. These three techniques are 1) goal setting, 2) structured problem-solving techniques, and 3) simplified motivational interviewing. Goal setting is a cornerstone of behavioral interventions, including those for pediatric obesity^{28,29}. Interventionists work collaboratively with parents to identify concrete goals to complete in between sessions. Goals specifically address modifiable aspects of the home environment, as identified during the review of the Home Monitoring Checklist. Structured goal setting is implemented at the end of each session to facilitate the translation of material/skills reviewed in the session to everyday life. Progress towards goals are reviewed by the interventionists during each phone contact and at the beginning of the subsequent in-person visit. When participants do not reach a behavioral goal, the interventionist works with the parent to identify barriers to change. Barriers are then classified by interventionists as either a *logistic* or *motivation* barrier. For logistic barriers, the interventionist implements a structured problem-solving approach. Specifically, the barrier is framed as a solvable problem, a variety of solutions to the problem is

generated, potential solutions are compared, and one solution is chosen to implement and evaluate. These problem-solving strategies are a key component of effective behavioral interventions for pediatric obesity³⁰. For motivation barriers, a simplified motivational interviewing approach is used. The benefits and drawbacks (“pros and cons”) of making a behavior change are elicited from parents to help resolve ambivalence towards making this change. Interventionists take a non-judgmental stance to elicit and strengthen parents’ own motivation to change. Motivational interviewing techniques have been found effective in other parent-based pediatric obesity interventions³¹.

2.5.5. Differences between conditions.—By design, the Home Visit and Medical Center arms differ only in the location in which the intervention is delivered. Participants in the Home Visit Arm complete all in-person intervention sessions in the child’s primary residence, whereas those in the Medical Center Arm complete all in-person intervention sessions in clinic space at Rush University Medical Center. It is important to note that the vast majority of pediatric obesity and prevention interventions consider the home environment to be a primary treatment target, including interventions that take place exclusively in academic or healthcare settings^{14,23,32–36}. Thus, the CHECK program’s *content* is relevant to and compatible with both arms of the trial.

Participants randomized to the Medical Center Arm are reimbursed for parking or the cost of public transportation to the medical center, as this is common in trials of clinic-based interventions and represents an added financial barrier that could selectively impact attendance between the two arms.

2.5.6. Interventionist characteristics and training.—Based on data that suggest higher efficacy in pediatric weight loss interventions delivered by higher-level interventionists³⁷, CHECK is delivered by registered dietitians, nurses, and those with similar professional credentials (e.g., exercise physiology, social work). Each interventionist completes an initial 12-hour training curriculum that covers delivery of all intervention components, the application of structured goal-setting, motivational interviewing, and problem-solving techniques, and safety and mandated reporting protocols. Training is led by the trial’s intervention supervisor, a health psychologist with expertise in weight management. Training incorporates role plays in which interventionists apply coaching techniques, and subsequently receive constructive feedback from the intervention supervisor.

2.5.7. Intervention fidelity monitoring.—Interventionists receive supervision from the intervention supervisor during biweekly in-person meetings. The intervention supervisor reviews a randomly selected subset (~10%, from each of the two intervention groups) of audiotaped intervention sessions and provides interventionists with timely feedback on their delivery of the intervention. Following each in-person session with participants, interventionists document the start and end times of the visit, the number of adult and child family members present, the intervention modules presented, the use of different coaching techniques, data from home monitoring checklist, and goals set with the caregiver (recorded verbatim) in a database. This tracking information is reviewed by the intervention supervisor, in conjunction with the select audiotaped intervention sessions, to provide

comprehensive feedback to the interventionist. In this way, fidelity of intervention delivery is encouraged and the likelihood of associated bias diminished.

2.6 Outcomes assessment and data collection staff blinding

All outcomes assessments are conducted by trained data collection staff who are blinded to group allocation and have no contact with the intervention team about individual participants. Data collection staff are also blinded to study hypotheses. Though it is not possible to blind participants to the nature of the intervention they are receiving, both arms are described to participants as active treatments and have identical content and contact time. Therefore, expectancy effects among participants should be minimal.

2.7. Assessment protocol

The trial includes assessments at baseline and months 3, 6, 9, and 12. The baseline, 6-, and 12-month assessments collect all outcomes and measures, as well as adverse events. The 3- and 9-month assessments collect only anthropometric measurements and adverse events. The first baseline assessment visit occurs at the study site, and all subsequent assessments take place in children's homes. Collecting data via home visits is advantageous for increasing retention and minimizing data missingness. All data collection staff receive training in anthropometric assessment and must demonstrate convergence with the trainer's measurements to within 0.25 cm for height and 0.1 kg for weight.

2.8 Primary outcome

12-month change in child BMI z-score (zBMI) will be derived from height and weight measurements taken in light clothing using research grade scales and stadiometers (SECA models 876 and 213, respectively, Hamburg Germany).

2.9. Hypothesized mechanisms of group differences

The trial includes measurements of the three sets of putative mechanisms through which home visitation is hypothesized to improve weight loss outcomes in children from low-income households: 1) increasing the dosage of intervention received, 2) enabling interventionists to provide more tailored feedback in the form of goals, and 3) increasing accountability, reflected in greater changes to the home environment.

2.9.1. Intervention dosage.—The dosage of intervention received in each arm will be calculated in units of hours of contact time. Contact time for in-person visits and telephone calls will be separately calculated, and total contact time for in-person visits will be considered the primary candidate mediator in analyses.

2.9.2. Tailored feedback.—The average number of goals set in each intervention visit will be calculated for each condition based on the documentation entered by interventionists following each contact with participants.

2.9.3. Change in the home food environment.—Change from baseline to 12 months in the number of obesity-promoting foods and beverages in the home environment are assessed with a home food inventory³⁸ completed by research staff during in-home

assessment visits. Analyses will focus on changes in the availability of fruits and vegetables and sugar sweetened beverages, and in the inventory's "obesogenic food availability score," which captures the presence of 71 energy-dense indicator foods.

2.9.4. Change in the home physical activity and media environment.—The presence of sports equipment and media devices in the home are measured using a structured, room-by-room staff audit of the home³⁹. Of particular interest for analysis is the availability of total media equipment in the household and in the index child's bedroom.

2.9.5. Change in family routines.—Change in family routines associated with pediatric obesity risk from baseline to 12 months will be quantified using the 20-item Family Nutrition and Physical Activity Screening Tool⁴⁰. Analysis will focus on the total score to assess global change in obesity-related family routines.

2.10 Other measures

2.10.1. Costs.—The cost-effectiveness aim of the trial requires an estimate of program delivery and participant costs. Program delivery costs include interventionist time, transportation costs, training materials, intervention materials, and telephone service. These variables are documented by interventionists for each intervention contact using electronic data capture forms. Participant costs are primarily driven by transportation and opportunity costs, the value of their time spent engaged in the intervention rather than other activities (e.g., working).

2.10.2. Demographic information and household characteristics.—Child and caregiver sex, age, and race/ethnicity will be documented. Caregivers will report on their marital status, educational attainment, employment status, and income. Household size and composition are recorded. Household income is expressed as a multiple of the current federal poverty threshold at the time of enrollment. Caregiver work schedules and ability to find and pay for childcare are assessed, as these may impact intervention attendance.

2.10.3. Pubertal stage.—The index child's pubertal development is assessed by self-report (age 10+) or proxy report (age <10) with the Pubertal Development Scale⁴¹.

2.10.4. Treatment perceptions and acceptability.—Prior to randomization, participants complete a 2-item measure (one discrete choice, one visual analogue scale) regarding their preference for being randomized to either condition. Participants also complete an adapted version of the 6-item Treatment Credibility/Expectancy Questionnaire⁴² to gauge their expectations regarding the degree to which their child may benefit from CHECK. A 10-item program acceptability survey is administered at the conclusion of the month 12 assessment visit.

2.10.5. Physical activity, sedentary time, and sleep.—Daily minutes of moderate-vigorous physical activity and sedentary time are objectively measured for the index child with a 7-day accelerometer protocol (Actigraph GT3x+ accelerometers, ActiGraph, LLC, Pensacola, FL). The device is worn over the right hip using an elastic waist band during the

day, and transferred to the non-dominant wrist on a hook-and-loop strap at night to collect sleep actigraphy data.

2.10.6. Food security.—The 2013 update of the U.S. Department of Agriculture’s food insecurity module⁴³ captures household and child food insecurity.

2.10.7. Depression and anxiety.—Caregiver symptoms of anxiety and depression are measured with the 4-item short forms of both the PROMIS Anxiety and Depression instruments⁴⁴. Caregivers also complete the parent proxy short forms of the PROMIS Anxiety (8 items) and Depression (6 items) instruments with respect to the index child.

2.10.8. Physical function.—The timed floor to stand – natural task⁴⁵ is a performance-based measure of physical function that involves a child rising from a cross-legged, seated position, walking 6 m around a marker at a natural pace, and returning to a cross-legged, seated position. Completion time is recorded to the nearest .01 s.

2.10.9. Weight-related problem behaviors.—Caregivers complete the 24-item Lifestyle Behavior Checklist⁴⁶, which assesses the degree to which misbehavior with food, overeating, obesity stigma, and physical inactivity have been problematic in the past month.

2.10.10. Dietary intake fast food, beverages, and fruits and vegetables.—Index child consumption of fast food and various beverages is assessed with a screener developed for adolescents by Nelson and Lytle⁴⁷. The NCI fruit and vegetable screener – all day version⁴⁸, which has been previously used in adolescents⁴⁹, estimates usual intakes of fruits and vegetables in the past month in units of cups per day.

2.10.11. Screen time.—Total time spent by the index child viewing television/videos, playing video games, using social media, or using computers or mobile devices for recreational purposes is measured using 4 items adapted from the Center for Disease Control and Prevention’s 2013 State and Local Youth Risk Behavior Survey⁵⁰. Screen time is assessed separately for weekdays and weekends.

2.10.12. Sleep.—Typical bed time, wake time, and sleep duration on weekdays and weekends during the past 2 weeks is assessed with the Sleep Habits Survey for Adolescents⁵¹, which has been validated against sleep actigraphy and sleep diaries in children. The 7-item “I’M SLEEPY” pediatric obstructive sleep apnea screener⁵² is also completed by parents.

2.10.13. Disorganization in the home environment.—The Confusion, Hubbub, and Order Scale⁵³ has 15 true/false items that sum to a total score reflecting the degree of chaos in the home environment as perceived by the caregiver.

2.11. Analysis plan

2.11.1. Primary analysis.—The primary objective of the trial is to test whether children randomized to the Home Visit Arm demonstrate greater decreases in zBMI from baseline to 12 months than children randomized to the Medical Center Arm. This analysis will follow

the intention-to-treat principle; the nature of data missingness will be assessed⁵⁴ and an appropriate data imputation or modeling method will be used⁵⁵. A two-sample t-test (or the Mann-Whitney test if the primary outcome is not normally distributed) will compare the two arms on mean zBMI. As a secondary analysis, the proportions of children in each arm that achieve a decrease in zBMI of at least 0.25, which is considered to be a threshold for clinically significant weight loss [albeit based on limited data;^{56–59}], will be compared. Linear mixed models will be used to investigate the pattern of change in zBMI over time. In these models, zBMI at 3, 6, 9, and 12 months will be regressed on time, and the interaction between time and intervention group will be tested. Baseline zBMI, and potential confounding variables (e.g., race, family composition, household size) that differ ($p < .20$) between intervention groups at baseline, will be considered for inclusion using the least absolute shrinkage and selection operator (LASSO) method.⁶⁰

2.11.2. Cost-effectiveness analysis.—Cost-effectiveness will be calculated from the societal and payer perspectives. The incremental cost effectiveness ratio (ICER) for achieving a -0.25 zBMI reduction with home-based versus medical center-based intervention will be calculated, such that $ICER = (C1 - C0)/(E1 - E0)$, where C is cost, E is effectiveness, subscript 1 denotes the Home Visit Arm, and subscript 0 denotes the Medical Center Arm. The ICER yields the added cost required to obtain the incremental benefit of an intervention (i.e., home visitation) over and above a comparison. 95% confidence intervals for the ICERs will be calculated⁶¹ to evaluate uncertainty in the estimates, and one-way and multi-way sensitivity analyses will test whether estimates are sensitive to plausible changes in key parameters.

2.11.3. Testing mechanisms of home visitation.—Mediation analyses will test three distinct mechanisms that could partially or fully account for the hypothesized beneficial effect of home visitation on zBMI. Bootstrap estimates of the mediated effect and its confidence interval will be calculated, which are then used to compute a test statistic (t -test) for the mediated effect that can be evaluated for significance^{62,63}. Three sets of mediators will be tested: 1) intervention dosage (hours of total contact time), 2) tailored feedback (average number of goals set in each intervention visit), and 3) accountability (change in the home availability of fruits and vegetables and obesity promoting foods, home availability of media devices, obesity-related family routines). The lack of an observed group difference in zBMI would preclude the mediation tests described above. In this case, analyses will instead examine whether intervention dosage, number of goals set per session, and changes in the home environment are differentially associated with zBMI within the two arms reflected in an interaction term between each hypothesized mechanism and treatment condition. In the absence of such interactions, main effects of the hypothesized mechanisms will be examined to determine their importance in treating pediatric overweight/obesity in low-income populations.

Secondary analyses will evaluate potential behavioral mediators of weight loss effects, including changes in moderate-vigorous physical activity, sedentary time, sleep duration, and intake of fast food consumption and sugar-sweetened beverages. As a first step, analyses will test whether 12-month changes in these behaviors are 1) associated with zBMI, and 2)

differ between the Home Visit and Medical Center Arms. If both of these conditions are met for a given target behavior, it will be subjected to a formal test of mediation to see if it accounts for group differences in weight loss outcomes.

2.12.2. Sample size and power.—The primary analysis tests group differences in zBMI from baseline to 12 months. Sample size calculations required assumptions about the magnitude of the expected between-group difference in zBMI and its standard deviation (SD). The trial was powered to detect a mean difference in zBMI of -0.10 units or larger. The standard deviation of 12-month zBMI was calculated using the formula $(SD^2_{\text{change}} = SD^2_{T1} + SD^2_{T2} - 2\rho(SD_{T1})(SD_{T2}))$, where the subscripts T1 and T2 indicate the time point of each zBMI observation, and ρ is the correlation between the two measurements. Values for SD_{T1} and SD_{T2} were based on 13 published values from 6 family-based pediatric obesity trials^{64–69} involving participants in the same age and BMI ranges. The 25th %ile (.35), median (.39), and 75th (.43) percentile SDs of zBMI from these studies were modeled in our sample size calculations. A value of $\rho=.82$ was assumed for the correlation between repeated zBMI measures over 12 months, which is more conservative than estimates from published studies [$\rho=.90$;⁷⁰], and those derived from the electronic health records of 6–11 year-old overweight children at our study site ($\rho=.86$). Sample size calculations using PASS 12 (Kaysville, UT) indicated that a sample size of $n=106$ per arm will provide power of 0.80 at $\alpha=0.05$ (two-tailed) to detect a mean difference in mean zBMI of -0.10 or greater across a range of assumptions. Additionally assuming a 20% attrition rate, our total recruitment target is $N=266$.

The exploratory mediation analyses described for Aim 3 will have power of 0.80 or higher when at least small to moderate magnitude associations (Cohen's $d>.26$) are observed between the predictors and mediators, and between the mediators and zBMI.⁷¹ The cost-effectiveness analysis does not involve statistical hypothesis testing, but sample size will affect the width of the 95% confidence intervals for the ICER estimates.

3. Discussion

The CHECK Trial is designed to directly test whether home visitation enhances the efficacy of family-based pediatric weight loss treatment for children in low-income households. Though a number of pediatric weight loss interventions have incorporated home visitation, the limitations of prior studies preclude conclusions as to whether it truly improves pediatric weight loss outcomes. The CHECK trial is unique in that it aims to evaluate an intervention *format* rather than test a qualitatively different intervention approach. To isolate the effect of intervention format, the content and intensity of treatment are constant across both conditions in the CHECK Trial.

Beyond testing efficacy, the CHECK trial will capture additional data relevant to the selection of home visitation vs. traditional clinic-based format in future interventions. The trial includes a cost-effectiveness analysis to estimate the added cost associated with any additional improvement in weight loss outcomes achieved through home visitation. The cost-effectiveness analysis necessitates rigorous documentation of program delivery costs in both arms, including interventionist time, travel expenses, and resource use. The trial also

includes a post-treatment satisfaction survey that will gauge the acceptability of receiving intervention visits in the home versus a healthcare setting among diverse, low-income families in the community. These assessments are important because interventions with high costs or low acceptability are unlikely to be implemented in the real world, even if efficacious.

The CHECK Trial will test three mechanisms through which home visitation is hypothesized to enhance intervention efficacy: increasing the dosage of intervention received, enabling tailored feedback, and increasing accountability. Understanding these mechanisms would provide an empirically-supported theoretical rationale for home visitation, and offer insights into how to best tailor future pediatric weight loss interventions. For example, support for the hypothesized role of increased intervention dosage as a mediator of weight loss outcomes would suggest value in testing alternative treatment formats that further increase intervention dosage (e.g., telehealth e-visits), or that home visitation could be included as part of an adaptive intervention that conserves resources by offering home visitation only to families with poor intervention attendance.

Some aspects of the trial's design will bear on the interpretation of results. The trial is enrolling only low-income households, and findings may not generalize to higher-income households for whom accessing treatment at a medical center may be less difficult. Family-based pediatric weight loss interventions are sometimes delivered in a group format, which is potentially more cost-effective than delivering treatment to individual families. However, it is not possible to hold group sessions in participants' homes. To avoid confounding treatment location (home vs. medical center) with group vs. individual formats, both arms of the CHECK trial are delivered to individual families. Future studies examining the efficacy and cost-effectiveness of individual home-based treatment relative to group-based treatment could be valuable.

Pediatric obesity is a significant public health issue that disproportionately affects socioeconomically disadvantaged groups, and designing effective pediatric weight loss interventions for this population is a top priority. The CHECK Trial may show that home visitation does *not* improve weight loss outcomes or is *not* cost-effective than clinic-based treatment. Such findings would indicate that the public health and behavioral medicine communities have gravitated towards home visitation prematurely, which is crucial to know so that we can reprioritize our efforts. Conversely, if home visitation does improve weight loss outcomes in low-income children, the trial will provide a compelling justification for this approach that is based on a rigorous scientific comparison, a detailed cost-effectiveness analysis, and a mechanistic understanding of *how* home visitation is beneficial.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Schedule of intervention contacts and assessments in both arms of the CHECK trial

Table 1.

The CHECK caregiver skills training and education curriculum includes 10 modules covering key concepts

Module title	Content
The CHECK Intervention	Overview of treatment rationale, intervention targets, and expectations
Catch ‘em being good!	Effective parenting practices; positive reinforcement for healthy choices
Setting up a sleep plan	Education about child sleep needs and hygiene; developing bed time routines
Don’t drink your calories!	Visual aids depicting sugar in sweetened beverages, strategies to reduce intake
Healthy eating on a budget	Navigating “food deserts”; compare costs of healthy foods vs. fast food and less healthy foods on sale
Rolling with resistance	Strategies to cope with children’s resistance to changes in their diet and activity
Reading food labels	Interpreting nutrition facts labels; review key dietary guidelines for children
Screen-free challenge	Identify acceptable, feasible, inherently rewarding alternatives to screen time
Proper portions	Portion size; promote family meals at home; limiting meals out
Keeping it going	Relapse prevention strategies