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A Digital Health Behavior Intervention to Prevent Childhood Obesity
The Greenlight Plus Randomized Clinical Trial

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Visual Abstract

Multimedia

Supplemental content

IMPORTANCE Infant growth predicts long-term obesity and cardiovascular disease. Previous interventions designed to prevent obesity in the first 2 years of life have been largely unsuccessful. Obesity prevalence is high among traditional racial and ethnic minority groups.

OBJECTIVE To compare the effectiveness of adding a digital childhood obesity prevention intervention to health behavior counseling delivered by pediatric primary care clinicians.

DESIGN, SETTING, AND PARTICIPANTS Individually randomized, parallel-group trial conducted at 6 US medical centers and enrolling patients shortly after birth. To be eligible, parents spoke English or Spanish, and children were born after 34 weeks' gestational age. Study enrollment occurred between October 2019 and January 2022, with follow-up through January 2024.

INTERVENTIONS In the clinic-based health behavior counseling (clinic-only) group, pediatric clinicians used health literacy–informed booklets at well-child visits to promote healthy behaviors (n = 451). In the clinic + digital intervention group, families also received health literacy–informed, individually tailored, responsive text messages to support health behavior goals and a web-based dashboard (n = 449).

MAIN OUTCOMES AND MEASURES The primary outcome was child weight-for-length trajectory over 24 months. Secondary outcomes included weight-for-length *z* score, body mass index (BMI) *z* score, and the percentage of children with overweight or obesity.

RESULTS Of 900 randomized children, 86.3% had primary outcome data at the 24-month follow-up time point; 143 (15.9%) were Black, non-Hispanic; 405 (45.0%) were Hispanic; 185 (20.6%) were White, non-Hispanic; and 165 (18.3%) identified as other or multiple races and ethnicities. Children in the clinic + digital intervention group had a lower mean weight-for-length trajectory, with an estimated reduction of 0.33 kg/m (95% CI, 0.09 to 0.57) at 24 months. There was also an adjusted mean difference of −0.19 (95% CI, −0.37 to −0.02) for weight-for-length *z* score and −0.19 (95% CI, −0.36 to −0.01) for BMI *z* score. At age 24 months, 23.2% of the clinic + digital intervention group compared with 24.5% of the clinic-only group had overweight or obesity (adjusted risk ratio, 0.91 [95% CI, 0.70 to 1.17]) based on the Centers for Disease Control and Prevention criteria of BMI 85th percentile or greater. At that age, 7.4% of the clinic + digital intervention group compared with 12.7% of the clinic-only group had obesity (adjusted risk ratio, 0.56 [95% CI, 0.36 to 0.88]).

CONCLUSIONS AND RELEVANCE A health literacy–informed digital intervention improved child weight-for-length trajectory across the first 24 months of life and reduced childhood obesity at 24 months. The intervention was effective in a racially and ethnically diverse population that included groups at elevated risk for childhood obesity.

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Childhood obesity is highly prevalent in the United States, with well-described health disparities by race, ethnicity, and socioeconomic status.[1] Disparities in obesity prevalence emerge in early childhood, suggesting the need for early intervention strategies, which have the potential to prevent the development of childhood overweight and obesity and their long-term implications for cardiometabolic health and health equity.[2-4] Despite this well-established prevention paradigm, childhood obesity has been recalcitrant to many interventions, including those aimed at prevention.[5] In a prior study, a health literacy-informed, primary care–based intervention, called Greenlight, resulted in improved infant weight-for-length trajectories through age 18 months, but these improvements were not sustained through age 24 months.[6]

Digital interventions allow for frequent and asynchronous contact as well as the ability to incorporate personalized health information that can be readily updated in real time.[7-14] In addition, the nearly ubiquitous access to mobile phone technology in the United States enables digital interventions to reach most of the country's population.[15] These factors suggest that digital obesity interventions are well suited for reducing health disparities in childhood obesity, with an approach that could be readily scalable.

The purpose of this study was to test the effect of adding a digital obesity prevention intervention that consisted of health literacy–sensitive, responsive text messages and a web-based dashboard to health behavior counseling delivered by pediatric primary care clinicians. The primary hypotheses were that children randomized to receive the digital intervention plus health behavior counseling would have healthier weight-for-length trajectories over the first 24 months of life and lower incidence of overweight and/or obesity at age 24 months compared with children randomized to receive health behavior counseling alone.

Key Points

Question Can adding a health literacy–informed responsive text messaging and web-based dashboard intervention to health behavior counseling delivered by pediatric primary care clinicians support healthy growth over the first 2 years of life?

Findings A 2-group randomized trial was conducted with 900 parent-infant pairs (86.3% retention). The intervention led to lower weight-for-length trajectories over the first 24 months of life (estimated reduction at 24 months, 0.33 kg/m).

Meaning Adding a digital intervention to health behavior counseling improved growth trajectories over the first 24 months among a racially and ethnically diverse population compared with health behavior counseling alone.

Methods

Trial Design and Oversight

The Greenlight Plus Trial was a multicenter, individually randomized, parallel-group trial. Six medical centers enrolled patients: Duke University, University of Miami, New York University Grossman School of Medicine/Bellevue Hospital Center, University of North Carolina at Chapel Hill, Stanford University, and Vanderbilt University Medical Center. Study implementation occurred at clinics affiliated with each medical center, including those staffed by pediatricians and advanced practice health professionals (n = 3 clinics) and medical residents (n = 7 clinics). The methods of the Greenlight Plus Trial have been published,[16] and the study protocol and statistical analysis plan are available in Supplement 1. This report follows the CONSORT reporting guidelines for randomized clinical trials. Institutions participating in the study are part of PCORnet, the national patient-centered clinical research network funded by the Patient-Centered Outcomes Research Institute, and this study received PCORnet study designation.[17]

The institutional review board (IRB) at Vanderbilt University Medical Center approved this study and served as the single IRB, with additional review conducted by the IRB at each of the participating centers. Parents of eligible children signed informed consent prior to participating. The study was monitored by an independent data and safety monitoring board. The study was registered at ClinicalTrials.gov prior to beginning enrollment (NCT04042467).

Study Participants

Parents were recruited from newborn nurseries or pediatric primary care clinics. Child eligibility criteria included (1) age 0 to 21 days of life and attendance at a newborn clinic visit by day of life 21, (2) born after 34 weeks' gestation, (3) birth weight greater than 1500 g, (4) weight greater than third percentile at enrollment based on World Health Organization (WHO) growth curves, and (5) no chronic medical conditions known to alter weight gain (eg, metabolic disease, uncorrected congenital heart disease). Parents were eligible if they (1) were 18 years or older, (2) had English or Spanish as their preferred language, (3) owned a smartphone with access to data services, (4) had no plans to leave the pediatric primary care clinic within 2 years, (5) had no impairment of corrected vision or neurologic condition that would preclude participation, and (6) completed baseline data collection.

Randomization

Randomization was stratified by medical center, parent language (English or Spanish), and baseline health literacy level (Newest Vital Sign score).[18] Assignments were concealed prior to randomization and could not be changed. Principal investigators, study directors, and outcome assessors were blinded to randomization assignment.

Intervention Groups

The clinic-only group received health behavior counseling delivered by pediatric primary care clinicians. It was a health communication intervention designed to support pediatric primary care clinicians in delivering anticipatory guidance around health behaviors to parents of children from birth to age 2 years, with the goal of obesity prevention. The materials for the clinic-only group included 8 core booklets (eFigure 1 in Supplement 2). These booklets were developed with parent input and delivered in conjunction with typical health preventive services visits in the United States (newborn and at ages 1, 2, 4, 6, 9, 12, 15, and 18 months).[16,19] Each booklet was designed to deliver developmentally appropriate guidance and goal setting around feeding, satiety, physical activity, sleep, and media use. Tangible tools (eg, sippy cup, portion size snack cups) were also provided (eFigure 2 in Supplement 2). All content was translated into Spanish and assessed for cultural appropriateness.

The clinic + digital intervention group included the health behavior counseling plus 2 digital intervention strategies: an interactive, responsive text messaging intervention and a web-based dashboard. As such, this study design was classified as an additive design, whereby the randomized clinical trial was focused on analyzing the effect of adding the text messages and web-based dashboard to the health behavior counseling.[20]

The text messaging portion of the intervention used behavior change techniques such as facilitated goal-setting, self-monitoring, and tailored feedback around developmentally appropriate health behaviors known to support healthy child growth.[21] Goals were organized into 2-week cycles in which a goal was set on the first day of the cycle, followed by 5 automated check-in messages over 2 weeks. Parents were asked to self-rate their goal progress. A fully automated system then provided immediate adaptive feedback, tips, and encouragement based on goal progress. After the first 6 months, the content of goal cycles was tailored based on a parent's response to a survey every 3 months that assessed readiness to change and self-efficacy for specific health behaviors.[16]

The web-based dashboard provided parents the opportunity to track goal progress, monitor their child's weight and length in a color-coded growth chart, and access intervention content. Intervention content was based on social cognitive theory, emphasizing effective communication strategies for parents with low health literacy.[22,23] eFigures 1, 2, and 3 in Supplement 2 show examples of intervention materials.

Study design, content, and implementation were informed by a national stakeholder advisory board, comprised of parents, medical professionals, and clinic staff from each of the participating sites.

Outcomes

The primary outcome was child weight-for-length (kg/m) trajectory over 2 years.[24] Child weight and length (anthropometric) measurements were obtained during routine pediatric primary care preventive services visits (see study protocol for exceptions) and abstracted from the medical record. The clinic staff at each participating clinic were trained by the study team annually in growth measurement best practices. Anthropometric data underwent a blinded cleaning process prior to analysis, which included cross-sectional checks for outliers, use of the *growthcleanr* algorithm, visual growth curve inspection, and contextual chart reviews.[25] Cleaning led to exclusion of approximately 0.01% of weight measures and 3% of length measures (eTable 1 in Supplement 2). Consistent with the paradigm for child obesity trials, 6 additional related secondary anthropometric outcomes are reported: weight-for-length *z* score trajectory, body mass index (BMI) *z* score trajectory, and the percentage of children at the 24-month follow-up with a BMI 85th percentile or greater and 95th percentile or greater using the US Centers for Disease Control and Prevention (CDC), and a BMI *z* score greater than 2 and greater than 3 using WHO growth curves.[26,27]

Study Measures

Parents completed baseline surveys; items related to the current analyses included sociodemographic measures, parent health literacy (Newest Vital Sign),[18] preferred language (English or Spanish), education level, annual household income, and household food insecurity (6-item US Department of Agriculture measure).[28] Child birth weight was abstracted from the medical record. Both parent and child race and ethnicity were reported by parents and were measured because there are well-described disparities in obesity prevalence among racial and ethnic groups in the United States.[1]

Study Power

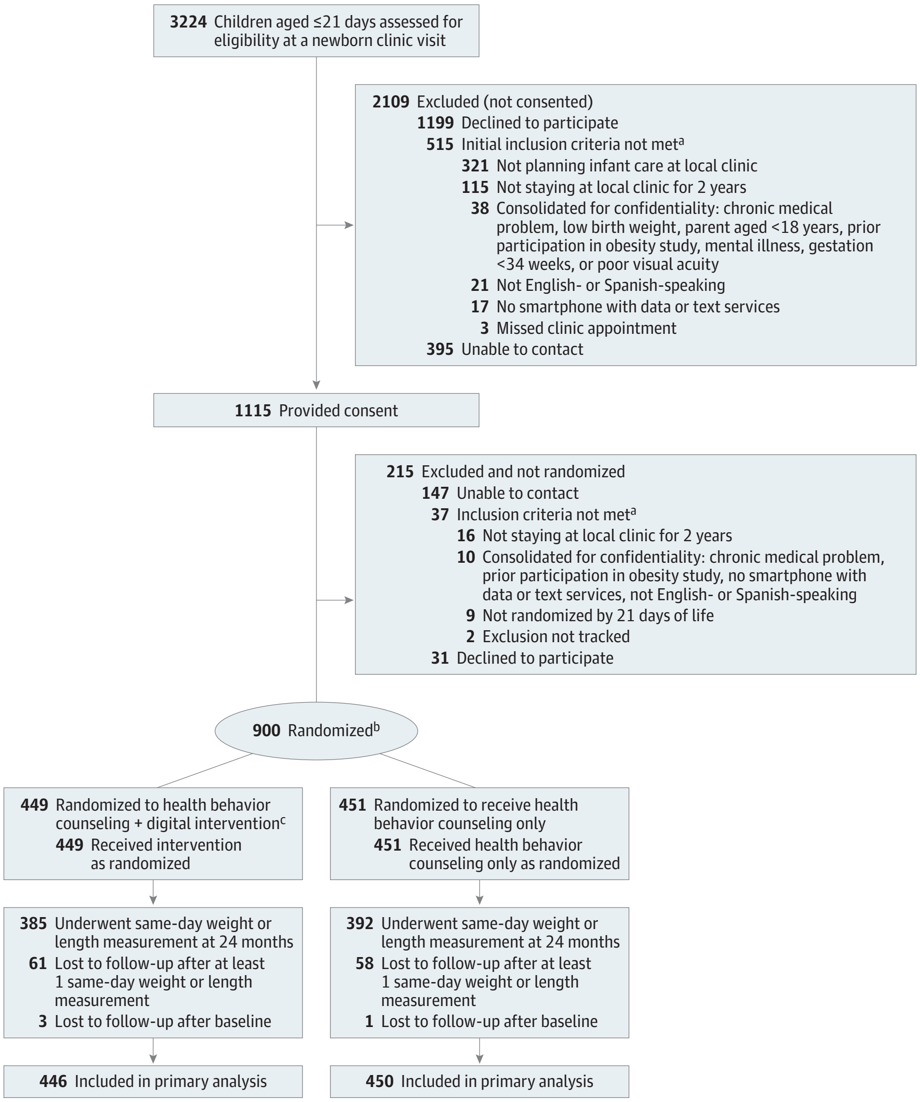
A target sample size of 900 parent-child pairs was obtained from simulation-based power calculations. Prior to enrollment, power calculations indicated that the study had 91% power to detect a difference in growth trajectories that yielded a 0.2-standard deviation change in child weight-for-length trajectory at 24 months. After completing baseline enrollment, the power calculation was updated with baseline data and indicated that the study had 83% power to detect the same effect size.

Statistical Analyses

The primary analysis classified each child in the group to which they were originally randomized. The primary analysis compared child weight-for-length trajectory between the clinic + digital intervention group and the clinic-only group across 2 years. The primary outcome and continuous secondary outcomes were analyzed using nested linear mixed-effects models (random intercepts and slopes for clinics and participants within clinics).[29] Binary secondary outcomes were analyzed using a longitudinal logistic regression model, specifically the marginalized transition and latent variable model.[30] Models adjusted for prespecified baseline variables to enhance precision: child birth weight and biological sex, parent-reported race and ethnicity, health literacy, preferred language, education level, annual household income, and household food insecurity. Cross-sectional intervention effects on secondary outcomes of child overweight and obesity at the 24-month time point were estimated with log-linear regression models with robust "sandwich" standard errors. These models controlled for clinic, child birth weight, parent health literacy, and parent preferred language. Tests for intervention effects were based on Wald tests with a 2-sided, .05 significance level. Because each of the 6 secondary outcomes were alternate ways of indexing height and weight, and therefore highly correlated, no adjustment for multiple comparisons was made.[31]

Based on results of the original Greenlight trial, parent race and ethnicity, parent preferred language, parent health

Figure 1. Flow of Participants Through a Trial of a Digital Health Behavior Intervention to Prevent Childhood Obesity



The clinic + digital intervention group received health behavior counseling delivered by pediatric primary care clinicians plus the digital intervention (ie, text messages and web dashboard); the clinic-only group received health behavior counseling only. Additional information about the 6-, 12-, and 18-month time points, and text message discontinuation within the clinic + digital intervention group, is shown in eFigure 4 in Supplement 2; the number of measures across the trial for each child is shown in eFigures 5 and 6 in Supplement 2.

[a] Could be more than 1 criterion not met.

[b] Randomization was stratified by medical center, parent preferred language, and baseline health literacy level.

[c] All intervention participants received at least 1 text message. There was no crossover between groups, meaning no participants in the clinic-only group received text messages intended for the clinic + digital intervention group.

literacy, and household food insecurity were selected for prespecified analyses of heterogeneity of intervention effect.[32] The intervention effect within subgroups defined by these variables was estimated and tested for heterogeneity by adding subgroup × treatment and subgroup × treatment × age functional interactions to the primary weight-for-length analysis model.

Missing baseline variables were imputed 100 times with chained equations and a predictive mean matching algorithm.[33] Analyses were conducted on all datasets and the results were combined using the Rubin Rule.[34] Missing outcome data were handled using the multiple-imputation-then-deletion method.[35]

All intervention effect estimates are presented with point estimates, 95% confidence intervals, and *P* values. Analyses were conducted using R version 4.3.3 (R Foundation). Full details of the statistical analyses, missing data, and imputation procedures are provided in Supplement 2, with details related to missing data provided in eFigures 5 and 6 and eTable 2 in Supplement 2 and details about each statistical model in eTable 6 in Supplement 2.

Results

Participant Characteristics

Of the 3224 parent-child pairs assessed for eligibility, 900 were randomized (clinic + digital intervention group, n = 449; clinic-only group, n = 451). At the 24-month time point, same-day weight and length measures were available for 385 of 449 children (85.7%) in the clinic + digital intervention group and 392 of 451 children (86.9%) in the clinic-only group (**Figure 1**; eFigure 4 in Supplement 2). Baseline characteristics of the parent-infant pairs are reported in **Table 1**,

Table 1. Comparison of Baseline Characteristics by Study Group

Characteristic	Clinic + digital intervention (n = 449)[a]	Clinic only (n = 451)[a]
Child characteristics		
Sex, No. (%)		
Male	206 (45.9)	218 (48.3)
Female	243 (54.1)	233 (51.7)
Gestational age	n = 448	n = 451
Median (IQR), wk	39.3 (38.6-40.0)	39.1 (38.4-40.0)
Race and ethnicity, No. (%)[b]	n = 447	n = 451
Black, non-Hispanic	62 (13.9)	81 (18.0)
Hispanic	204 (45.6)	201 (44.6)
White, non-Hispanic	95 (21.3)	90 (20.0)
Other or multiple	86 (19.2)	79 (17.5)
Born via cesarean delivery, No. (%)	122 (27.2)	125 (27.7)
Currently receiving breast milk, No. (%)	398 (88.6)	399 (88.5)
Parent and household characteristics[c]		
Parent's first child, No. (%)	183 (40.8)	181 (40.1)
Parent sex, No. (%)		
Male	15 (3.3)	10 (2.2)
Female	433 (96.4)	441 (97.8)
Other	1 (0.2)	0
Maternal prepregnancy BMI	n = 408	n = 413
Median (IQR)	25.7 (22.3-31.2)	26.4 (22.6-32.0)
Preferred language, No. (%)		
Spanish	155 (34.5)	158 (35.0)
English	294 (65.5)	293 (65.0)
Parent race and ethnicity, No. (%)[b]		
Black, non-Hispanic	68 (15.1)	85 (18.8)
Hispanic	230 (51.2)	215 (47.7)
White, non-Hispanic	104 (23.2)	100 (22.2)
Other or multiple	47 (10.5)	51 (11.3)
Parent born in the United States, No. (%)	231 (51.4)	231 (51.2)
Parent insurance type (for child), No. (%)		
Medicaid	297 (66.1)	289 (64.1)
Private insurance	119 (26.5)	125 (27.7)
None	33 (7.3)	37 (8.2)
Parent annual household income, No. (%), $		
<20 000	114 (25.4)	103 (22.8)
20 000 to 49 999	115 (25.6)	108 (23.9)
50 000 to 99 999	42 (9.4)	58 (12.9)
≥100 000	64 (14.3)	60 (13.3)
Do not know/not sure	91 (20.2)	96 (21.3)
Prefer not to answer	23 (5.1)	26 (5.8)
Parent household difficulty paying monthly bills, No. (%)	n = 446	n = 450
Not at all difficult	183 (41.0)	184 (40.9)
Not very difficult	100 (22.4)	94 (20.9)
Somewhat difficult	146 (32.7)	153 (34.0)
Very difficult	17 (3.8)	19 (4.2)
Parent marital status, No. (%)	n = 449	n = 450
Married	200 (44.5)	196 (43.6)
Single, never married	128 (28.5)	120 (26.7)
Member of unmarried couple living together	111V(24.7)	122 (27.1)
Divorced, separated, or widowed	10 (2.2)	12 (2.7)
No. of other children in household (excluding the index child), median (IQR)	1.0 (0.0-2.0)	1.0 (0.0-2.0)
No. of adults in household (including parent), median (IQR)	2.0 (2.0-2.0)	2.0 (2.0-3.0)
Parent health literacy, No. (%)[d]	n = 436	n = 435
Adequate	186 (42.7)	185 (42.5)
Limited	250 (57.3)	250 (57.5)
Food insecurity, No. (%)[e]	n = 446	n = 448
Food insecure	67 (15.0)	74 (16.5)
Food secure	379 (85.0)	374 (83.5)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by square of height in meters).

[a] The clinic + digital intervention group received health behavior counseling delivered by pediatric primary care clinicians plus the digital intervention (ie, text messages and web dashboard); the clinic-only group received health behavior counseling only.

[b] See Supplement 2 for a full description of how race and ethnicity were included in the survey.

[c] Parental characteristics are listed for the index parent enrolled in the study. This was the parent selected by the participants as most frequently accompanying the child to clinic visits and the contact for surveys.

[d] Parent health literacy was assessed by the Newest Vital Sign 6-item literacy screening tool. A score greater than or equal to 4 was categorized as adequate.

[e] Food insecurity was assessed by the 6-item US Department of Agriculture measure. A score greater than or equal to 2 was categorized as food insecure.

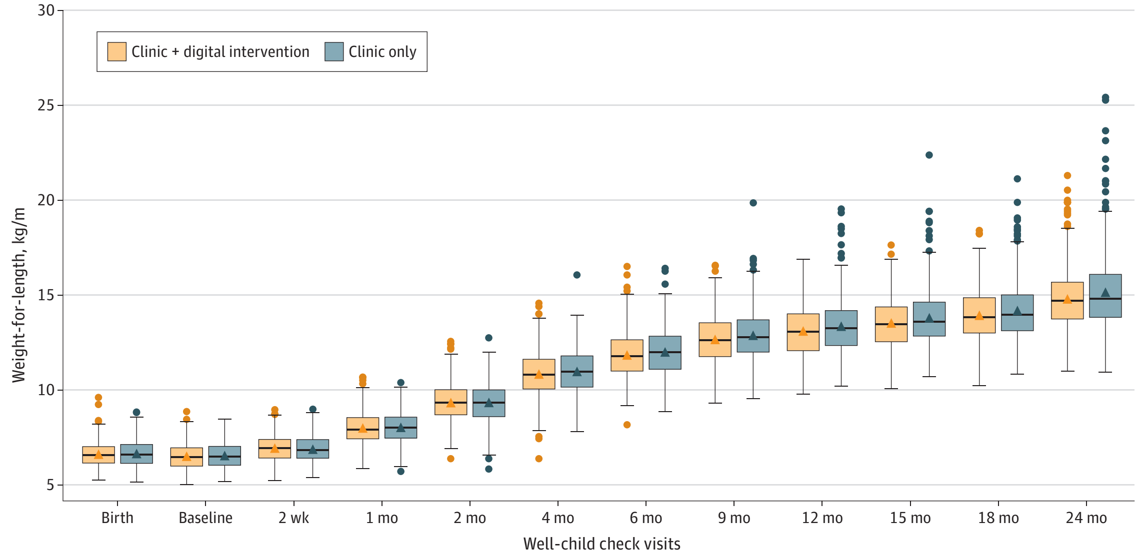
with no meaningful differences between study groups. Among children, 143 (15.9%) were Black, non-Hispanic; 405 (45.0%) were Hispanic; 185 (20.6%) were White, non-Hispanic; and 165 (18.3%) identified as other or multiple races and ethnicities. Among parents, 587 (65.2%) opted to receive the intervention in English, 313 (34.8%) opted for Spanish, 500 (55.6%) had limited health literacy, and 141 (15.6%) reported household food insecurity. A comparison of baseline characteristics for participants with and without valid anthropometric data at the 24-month time point is shown in eTable 2 in Supplement 2.

Primary Outcome

The distribution of observed child weight-for-length values at each point is shown by group in **Figure 2.** At the 24-month time point, the mean weight-for-length was 14.8 kg/m (SD, 1.6) in the clinic + digital intervention group and 15.1 kg/m (SD, 1.9) in the clinic-only group. The primary outcome model showed that children in the clinic + digital intervention group had significantly lower weight-for-length trajectories across the 24 months of follow-up than children in the clinic-only group (*P* < .001 for the trajectory difference), with the estimated differences between the groups (effect sizes) over time shown in

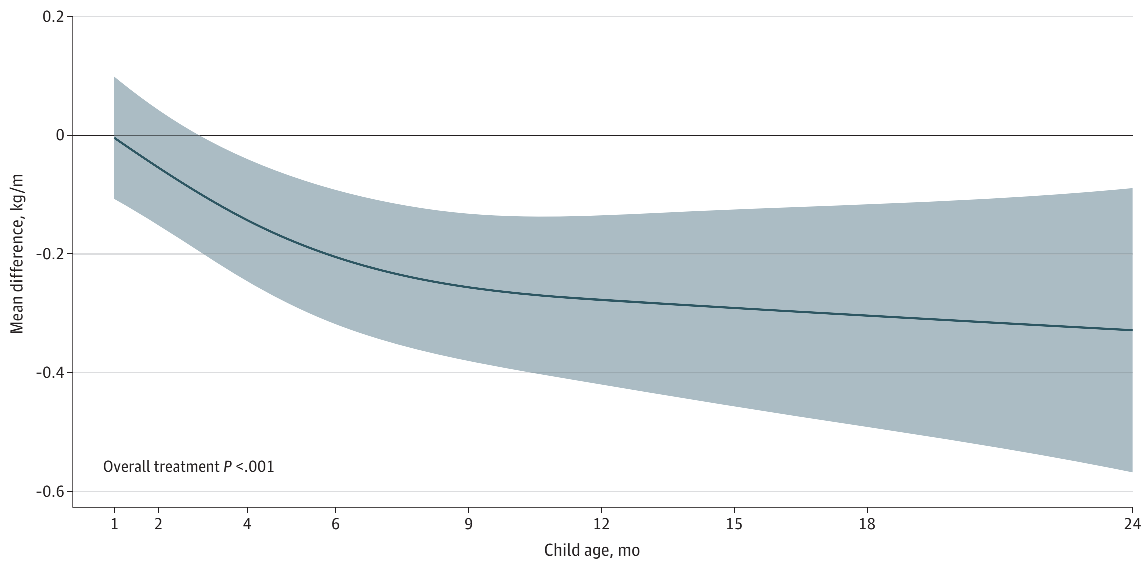
Figure 2. Intervention Effect on Child Weight-for-Length Trajectory (Primary Outcome)

A Observed weight-for-length data



No. of children												
Clinic + digital intervention	357	328	304	259	410	380	372	355	346	294	323	380
Clinic only	368	342	294	271	405	375	378	364	337	319	349	387

B Estimated mean difference in weight-for-length



No. of children									
Clinic + digital intervention	259	410	380	372	355	346	294	323	380
Clinic only	271	405	375	378	364	337	319	349	387

A, Box plots show the observed weight-for-length data for children who received only health behavior counseling delivered by pediatric primary care clinicians (clinic only) and those who received the combined health behavior counseling + digital intervention (clinic + digital intervention), after data cleaning. The number of weight-for-length measures that were marked invalid based on data cleaning is detailed in eTable 1 in Supplement 2. The middle line of the box represents the median; boxes represent the interquartile range; whiskers extend to 1.5 times the interquartile range; and dots represent observed values outside that range. Triangles represent the mean weight-for-length. B, The adjusted intervention effect over time is also shown, comparing the clinic + digital intervention group with the clinic-only group. The heavy curve line represents the mean weight-for-length difference (clinic + digital intervention minus clinic only), and the shaded gray area corresponds to the point-wise 95% confidence interval across follow-up. The *P* value shown is from a test of the null hypothesis that the growth trajectories across 24 months were equal in the clinic + digital intervention and clinic-only groups against the alternative that they differed.

Table 2. Intervention Effect on Overweight and Obesity at 24 Months

	Observed rate, No./total (%)		Marginalized risk difference, % (95% CI)[b]	Adjusted risk ratio (95% CI)
	Clinic + digital intervention[a]	Clinic only[a]		
WHO BMI *z* score				
>2[c]	47/380 (12.4)	−4.9 (−9.4 to −0.7)	62/387 (16.0)	0.68 (0.48 to 0.93)[d]
>3[c,e]	10/380 (2.6)	−3.4 (−6.5 to −0.6)	22/387 (5.7)	0.46 (0.24 to 0.89)[d]
CDC BMI percentile				
≥85th[f]	78/336 (23.2)	−2.4 (−8.6 to 4.1)	85/347 (24.5)	0.91 (0.70 to 1.17)
≥95th[f]	25/336 (7.4)	−6.3 (−11.3 to −1.4)	44/347 (12.7)	0.56 (0.36 to 0.88)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); CDC, Centers for Disease Control and Prevention; WHO, World Health Organization.

[a] The clinic + digital intervention group received health behavior counseling delivered by pediatric primary care clinicians plus the digital intervention (ie, text messages and web dashboard); the clinic-only group received health behavior counseling only.

[b] Marginalized risk difference and 95% CIs were calculated using the parameter estimates and uncertainty estimates from the fitted regression model. Full details are provided in Supplement 2.

[c] While the recommended clinical approach in the United States is to define overweight and obesity at age 24 months using growth curves published by the CDC, results based on the WHO criteria for overweight (BMI *z* score >2) and obesity (BMI *z* score >3) have also been reported to facilitate comparability with other trials.

[d] Calculated from the parameters generated by the longitudinal logistic regression model, with the intervention effect summarized at age 24 months. Specifically, odds ratio estimates, confidence limits, and the observed prevalence of overweight or obesity in the clinic-only group were used to calculate the adjusted risk ratios.

[e] For the WHO BMI *z* score greater than 3 model, the relatively low prevalence of the outcome limited the effective sample size. Therefore, the model adjusted for the following subset of variables from the primary analysis model: clinic, health literacy, parent preferred language, and child birth weight.

[f] Log-linear regression model with robust, sandwich, standard errors. The model adjusted for clinic, health literacy, parent preferred language, and child birth weight. To calculate a BMI percentile using CDC growth curves, a child must be older than 2 years at the time of the measurement. Because the data collection windows allowed for children to be measured prior to their second birthday, it was not always possible to calculate a CDC BMI *z* score. For this analysis, 84 children had the "2-year" weight and length measures recorded prior to their second birthday and could not be included in these models.

Figure 2 and model-estimated growth trajectories shown in eFigure 7 in Supplement 2. The model-estimated child weight-for-length intervention effect at 24 months was −0.33 kg/m (95% CI, −0.57 to −0.09).

Secondary Outcomes

Analyses comparing weight-for-length *z*-score trajectories and BMI *z*-score trajectories demonstrated significant differences between study groups ($P < .001$ for each trajectory difference) (eFigures 8 and 9 in Supplement 2). The estimated intervention effect for weight-for-length *z* score at 24 months was −0.19 (95% CI, −0.37 to −0.02); for BMI *z* score at 24 months, it was −0.19 (95% CI, −0.36 to −0.01). The intervention effect emerged by 4 months for each of the primary and secondary quantitative anthropometric outcomes (eTable 5 in Supplement 2).

Results of analyses of binary secondary anthropometric outcomes at 24 months are reported in **Table 2**. Based on WHO criteria, the clinic + digital intervention group, compared with the clinic-only group, had lower rates of both overweight (WHO BMI *z* score >2) (12.4% vs 16.0%; adjusted risk ratio [aRR], 0.68 [95% CI, 0.48 to 0.93]) and obesity (WHO BMI *z* score >3) (2.6% vs 5.7%; aRR, 0.46 [95% CI, 0.24 to 0.89]). This corresponds to an adjusted relative reduction in obesity based on WHO criteria of 54% (95% CI, 11% to 76%). Based on the CDC BMI criteria, the incidence of child overweight or obesity (CDC BMI ≥85th percentile) at 24 months was not statistically different between the clinic + digital intervention (23.2%) and clinic-only (24.5%) groups (aRR, 0.91 [95% CI, 0.70 to 1.17]). The incidence of child obesity (CDC BMI ≥95th percentile) at 24 months was significantly lower in the clinic + digital intervention group (7.4%) compared with the clinic-only group (12.7%) (aRR, 0.56 [95% CI, 0.36 to 0.88]). This corresponds to an adjusted relative reduction in obesity based on CDC criteria of 44% (95% CI, 12% to 64%).

Heterogeneity of Intervention Effect

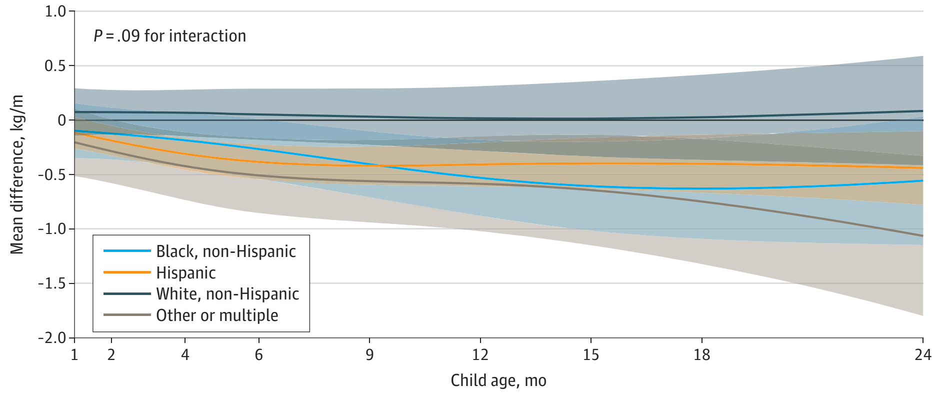
Figure 3 and **Figure 4** show results of the prespecified heterogeneity of intervention effect analyses. The intervention effect across ages differed for children with food insecurity compared with those without food insecurity ($P = .02$), and at 24 months the mean difference in weight-for-length (clinic + digital intervention group minus clinic-only group) for households with food insecurity was −0.77 kg/m (95% CI, −1.39 to −0.14), compared with a mean difference of −0.25 kg/m (95% CI, −0.51 to 0.01) for households that were food secure. The test for heterogeneous intervention effects according to race and ethnicity groups was not statistically significant ($P = .09$). Tests for heterogeneity of intervention effects were not significant for parent preferred language or parent health literacy. However, the intervention did reduce average weight-for-length in groups traditionally at elevated risk for obesity (ie, non-Hispanic Black children, Hispanic children, and those whose parents had low health literacy).

Adherence to the Study Protocol

Among parents randomized to the clinic + digital intervention group, 90.0% of the planned 265 messages per participant were confirmed as sent (107 117/118 985 total messages). The median percentage of text messages responded to by the 449 parents in the clinic + digital intervention group was 54.0% (25th-75th, 20.4% to 84.5%).

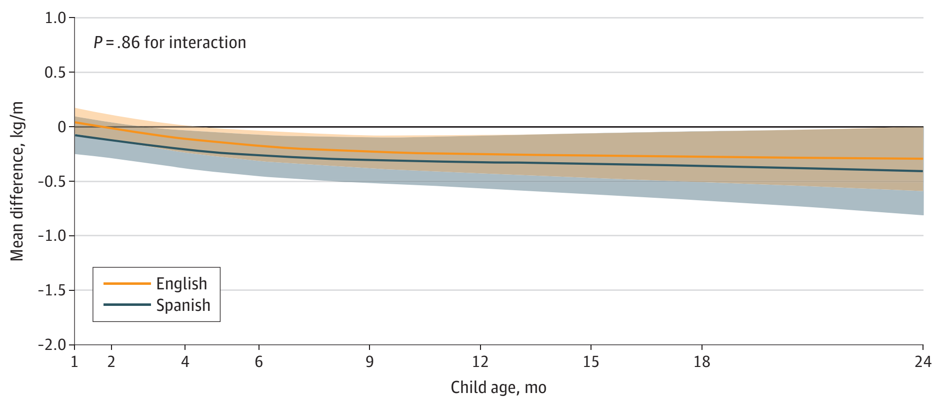
Figure 3. Heterogeneity of Intervention Effect by Parent Race and Ethnicity and Parent Preferred Language

A Parent race and ethnicity



No. of children	1	2	4	6	9	12	15	18	24
Clinic + digital intervention									
Black, non-Hispanic	34	62	58	51	51	54	36	43	55
Hispanic	153	210	189	189	181	168	144	168	194
White, non-Hispanic	41	96	92	95	89	90	84	82	90
Other or multiple	31	42	41	37	34	34	30	30	41
Clinic only									
Black, non-Hispanic	50	81	65	72	63	57	51	67	69
Hispanic	148	185	178	181	174	164	156	164	189
White, non-Hispanic	42	95	91	84	87	78	76	78	86
Other or multiple	31	44	41	41	40	38	36	40	43

B Parent preferred language



No. of children	1	2	4	6	9	12	15	18	24
Clinic + digital intervention									
English	153	266	249	245	231	231	197	214	249
Spanish	106	144	131	127	124	115	97	109	131
Clinic only									
English	164	268	250	248	238	218	202	231	250
Spanish	107	137	125	130	126	119	117	118	137

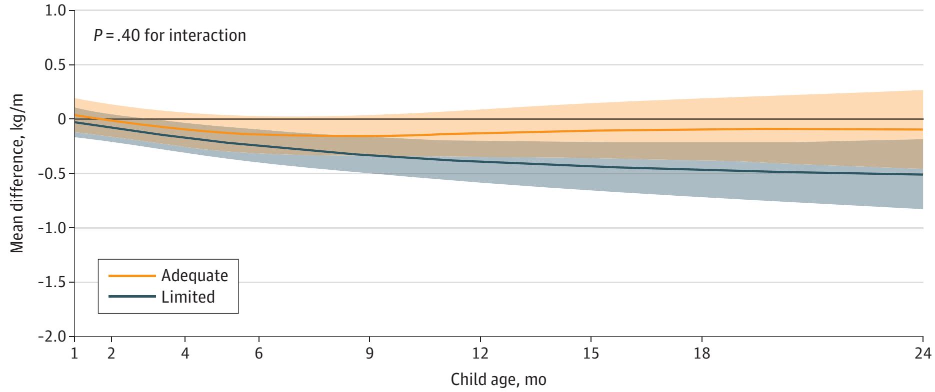
Each panel shows the model-estimated difference in the weight-for-length trajectory comparing children who received health behavior counseling delivered by pediatric primary care clinicians (clinic only) with those who received the combined health behavior counseling plus digital intervention consisting of text messages and a web dashboard (clinic + digital intervention) for prespecified subgroups. A negative weight-for-length difference represents a desirable intervention effect. Shaded regions indicate 95% confidence intervals. The *P* value corresponds to the test of the null hypothesis that no intervention effect heterogeneity exists against the alternative that intervention effect heterogeneity exists. Additional details regarding interpretation of the heterogeneity of intervention effect analyses are provided in Supplement 2.

Adverse Events

There were no study-related adverse events. Two children died from sudden unexplained infant death syndrome. These deaths were evaluated by the independent data and safety monitoring board and judged to be unrelated to the study. One child was removed from the study for failure to thrive, and this was not believed to be due to the study. Neither of the 2 deaths nor the child removed from the study were randomized to the clinic + digital intervention group. At the 24-month time point, 3 of 387 children in

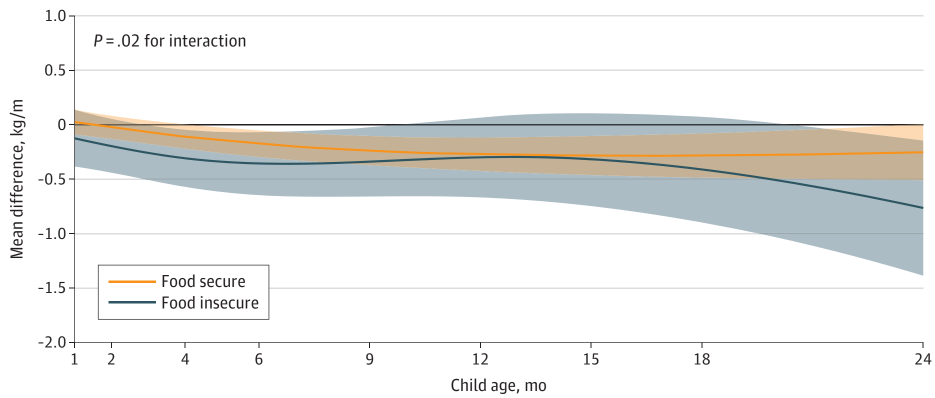
Figure 4. Heterogeneity of Intervention Effect by Parent Health Literacy and Food Insecurity Score

A Parent health literacy



No. of children	1	2	4	6	9	12	15	18	24
Clinic + digital intervention									
Adequate	96	181	171	169	157	156	148	152	170
Limited	163	229	209	203	198	190	146	171	210
Clinic only									
Adequate	103	181	176	168	160	149	151	158	170
Limited	168	224	199	210	204	188	168	191	217

B Food insecurity score



No. of children	1	2	4	6	9	12	15	18	24
Clinic + digital intervention									
Food secure	215	354	325	325	307	300	260	285	331
Food insecure	44	56	55	47	48	46	34	38	49
Clinic only									
Food secure	221	341	319	322	307	284	270	295	323
Food insecure	50	64	56	56	57	53	49	54	64

Each panel shows the model-estimated difference in the weight-for-length trajectory comparing children who received health behavior counseling delivered by pediatric primary care clinicians (clinic only) with those who received the combined health behavior counseling plus digital intervention consisting of text messages and a web dashboard (clinic + digital intervention) for prespecified subgroups. A negative weight-for-length difference represents a desirable intervention effect. Shaded regions indicate 95% confidence intervals. The *P* value corresponds to the test of the null hypothesis that no intervention effect heterogeneity exists against the alternative that intervention effect heterogeneity exists. Additional details regarding interpretation of the heterogeneity of intervention effect analyses are provided in Supplement 2.

the clinic-only group were underweight (<2nd percentile on WHO growth curves), and 1 of 380 children in the clinic + digital intervention group was underweight.

Discussion

In this large, multicenter, randomized trial, the text messaging and web-based intervention improved child weight-for-length trajectory from baseline to age 24 months. The effect of the intervention could be observed as early as 4 months, and model-estimated weight-for-length difference between the clinic health behavior counseling + digital intervention and clinic health behavior counseling-only group at 24 months was 0.33 kg/m. This reduction is comparable to clinically meaningful effect sizes, as defined by the US Preventive Services Task Force.[36,37] Although this average difference may be seen as modest, it translated into an estimated reduction in obesity from 12.7% to 7.4% (a 44% adjusted relative reduction) at 2 years according to the CDC BMI criteria and an estimated reduction in obesity from 5.7% to 2.6% (a 54% adjusted relative reduction) at 2 years according to the WHO BMI criteria. Taken together, these results indicate that the effect of the digital intervention was predominantly among children at the highest ends of the weight-for-length (and BMI) distributions. This is important, because the goal of the intervention was not to change healthy weight trajectories but unhealthy ones. The observed incidence of childhood obesity at 2 years in each group (7.4% in the clinic + digital intervention group and 12.7% in the clinic-only group) would translate to a number needed to treat of only 19 patients to prevent 1 case of obesity and could have an important effect if scaled to the population. By improving early growth trajectories and reducing the incidence of obesity, the digital intervention (text messaging and web dashboard) could help prevent later obesity and cardiometabolic disease.[38]

The intervention had a stronger effect on children from households with food insecurity compared with others. Specifically, beginning at approximately age 15 months, the intervention effects diverged between those with and without food insecurity. The other 3 analyses of heterogeneity of intervention effect did not identify statistically significant effects. Although the study was not powered to detect intervention effects in subgroups, the results showed treatment benefits in groups who have traditionally been at higher risk for obesity (ie, non-Hispanic Black children, Hispanic children, and those whose parents had low health literacy).

The intervention was delivered in pediatric primary care clinics affiliated with academic medical centers and included a variety of clinician types (ie, faculty pediatricians, advance practice health professionals, and resident physicians). Because academic medical centers often serve families who are uninsured or publicly insured, these were ideal settings to support recruitment of a diverse patient population.[39] As a low-cost, automated text-messaging intervention that has already been created, the text messaging and web-based components have the potential to be quickly scaled up and implemented across multiple health care systems. Potential barriers to implementation would include the cost of providing printed materials, the time needed to train physicians, and health systems barriers to implementing text-messaging interventions. Future studies should consider alternatives to paper booklets and assess the impact and cost-effectiveness of a stand-alone text messaging intervention.

In the current study, the intervention effect was noted as early as 4 months and sustained throughout the 2 years of follow-up. These findings are especially relevant given prior studies suggesting that rapid growth in the first 6 months of life is associated with increased risk of later cardiovascular disease.[40] One notable intervention that has been successful at preventing childhood obesity across the first 3 years of life is INSIGHT, a nurse home-visiting intervention focused on responsive parenting, feeding, sleep, interactive play, and emotion regulation.[41] The current study advances the field by using a less resource-intensive, automated text-messaging intervention and by showing the effect with a larger and more diverse population of families.

Digital interventions hold the promise of improving reach to underserved populations for many health behavior–driven chronic diseases.[42] For adults, digital health interventions that use text messaging have been successful at supporting short-term health behavior change in multiple areas, including smoking cessation, diabetes self-care, and weight management (including promotion of healthy diet and physical activity).[43-45] Among children, however, few trials have examined the impact of text-messaging interventions on obesity prevention, and none have been effective at preventing obesity in the first 2 years of life.[46-52] Several potential reasons for the sustained effectiveness of the current intervention, which distinguish it from previous digital interventions, include (1) early intervention beginning in the first weeks of life, which is when many unhealthy behaviors that contribute to childhood obesity begin[53-55]; (2) continued contact via text messaging over 2 years that was asynchronous from pediatric well-visits; and (3) the focus on personally tailored and responsive content. When implementing digital interventions, a variety of factors could lead to the unintentional consequence of worsening health disparities.[56] In this study, however, the opposite was observed: the intervention was potentially more effective among several subgroups that have traditionally experienced the greatest health disparities.

Limitations

This study had several limitations. First, while this was a multicenter study with 6 medical centers across the United States that enrolled a diverse patient population, some population groups were underrepresented or not represented at all (eg, patients who did not prefer to speak English or Spanish). Second, this study was not able to collect reliable data on web-based dashboard use, so it may not be possible to determine the extent to which each of the digital components of the intervention contributed to the overall intervention effectiveness. Third, anthropometric measures were routinely collected during the course of clinical care, which may have led to measurement error; however, specialized annual growth measurement training occurred to minimize these measurement errors.

Conclusions

A health literacy–informed digital intervention led to healthier weight-for-length trajectories and reduced the incidence of obesity at age 2 years when added to health behavior counseling delivered by pediatric primary care clinicians. The intervention was effective in populations who have traditionally experienced the highest risk of obesity. The substantial reduction in risk of childhood obesity observed in this study could have significant population-level impact if implemented at scale, suggesting that broader implementation studies are warranted.

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