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A Randomized Trial of Weight Change in a National Home Visiting Program

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Abstract

Introduction—Clinical trials have demonstrated significant impact in reducing weight and incidence of type 2 diabetes mellitus. However, the intensity of these trials limit their scalability to real world settings. The purpose of this study was to embed a lifestyle intervention for overweight and obese mothers within the routine practice of a parent education, home visiting organization.

Design—Pragmatic trial that used a stratified random design.

Setting/participants—Overweight or obese mothers of preschool children located across St. Louis, Missouri enrolled in Parents As Teachers, a home visiting organization reaching women and children nationwide.

Intervention—A lifestyle intervention derived from the Diabetes Prevention Program was embedded within Parents As Teachers entitled Healthy Eating and Active Living Taught at Home (HEALTH).

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Main outcome measures—Outcomes included the proportion of women that achieved 5% weight loss at 24 months and improvements in clinical and behavioral outcomes at 12 and 24 months. Participants were enrolled from 2012 to 2014 and data analysis began in 2016.

Results—Women in the usual care versus intervention group were significantly less likely to achieve 5% weight loss at 24 months (11% vs 26%, $p=0.01$). At 12 months there was a 2.8 kg difference in weight between groups ($p=0.0006$), and by 24 months a 4.7 kg difference in weight (3.2 [SD=7.6] kg vs −1.5 [SD=8.3] kg, $p=0.002$); group differences in waist circumference were also evident by 12 months (2.1 [SD=8.4] cm vs −0.7 [SD=9.8] cm, $p=0.04$) and 24 months (3.8 [SD=10.6] cm vs −2.5 [SD=9.1] cm, $p=0.005$), as were improvements in behavioral outcomes. There was no difference in blood pressure between groups.

Conclusions—HEALTH achieved modest but clinically significant weight loss outcomes, and reduced weight gain in mothers of young children. The scalability of this embedded intervention offers the potential to reach mothers in Parents As Teachers programs nationally.

INTRODUCTION

Diabetes is a major public health problem of the 21st century.¹ Several successful large scale clinical trials have clearly demonstrated the significant impact of intensive lifestyle interventions in reducing weight and incidence of type 2 diabetes mellitus from 29% to 58%.^{2–4} However, the intensity and expense of these clinical trials limits applicability in real world settings. Lifestyle interventions have been translated across a variety of primary care and community health settings, such as the YMCA,⁵ as well as nonhealth focused settings including churches and worksites.^{6,7} Public health priorities continue to call for transfer and scale up of efficacious lifestyle interventions that are sustainable to reach populations at risk.⁸

Higher rates of obesity are reported for women than men.^{9,10} Maternal weight gain, initiated and repeated across pregnancies and maintained after childbirth, impacts lifelong risk for obesity and development of type 2 diabetes in reproductive age and post-menopausal women.^{11,12} Mothers of young children face multiple competing demands that limit their ability to participate or benefit from lifestyle interventions, further increasing risk for weight-related comorbid conditions. Sleep deprivation and fatigue, lack of child care, and competing roles and responsibilities are major deterrents to women engaging in healthy lifestyle behaviors necessary to achieve ideal body weight.¹³ These same barriers are associated with decreased activity and increased intake of convenience or away foods, resulting in additional caloric intake and weight gain.^{14,15} Women also serve as role models and important influencers on the learned lifestyle behaviors of their children and families.^{16,17}

One approach for addressing barriers to obesity prevention and treatment lies in partnerships with home visiting organizations that already reach women at home as part of their mission. Pragmatic interventions embedded in home visiting organizations can enhance accessibility to lifestyle interventions and allow for ongoing contact and support for behavior change. This also offers the opportunity to scale up effective interventions to maximize public health impact in preventing type 2 diabetes.¹⁸ The translational challenge lies in integrating

lifestyle interventions within the mission, standards, and funding requirements of home visiting organizations that may not prioritize health-related content.

Parents As Teachers (PAT) is a national home visiting organization whose mission is to empower parents as their child's most influential teacher, promoting positive child development and school readiness.¹⁹ PAT offers an evidence-based curriculum delivered by parent educators free of charge to families until the youngest child enters school, allowing for ongoing support and contact.¹⁹ The program is supported through federal and state funds. As of 2016, PAT was located in all 50 states reaching 123,468 parents and 148,659 children nationally.¹⁹ PAT offers an excellent organizational system for delivering, sustaining, and scaling-up interventions derived from the Diabetes Prevention Program (DPP) for obese or overweight mothers of young children.

Prior work with PAT effectively tested dietary interventions targeted to African American parents of infants,²⁰ rural parents of young children,²¹ and teen mothers.²² This study tests the impact of Healthy Eating & Active Living Taught at Home (HEALTH),²³ a lifestyle intervention derived from DPP, embedded within the usual PAT curriculum, and targeting overweight and obese mothers of preschool children at risk for excess weight. It is hypothesized that when compared with usual care, participants in the HEALTH intervention group are significantly more likely to achieve and maintain a 5% weight loss at 24 months and show improvements at 12 and 24 months in waist circumference, blood pressure, and behavioral outcomes defined by eating patterns and physical activity.

METHODS

Study Sample

This pragmatic trial used a stratified random design implemented with PAT affiliated programs located across eight St. Louis, Missouri regions. Inclusion criteria included female participants, aged between 18 and 45 years, overweight or obese (BMI 25–45 kg/m²), having at least one preschool-aged child at risk for overweight (BMI percentile ≥60%)²⁴ living in the home, plans to continue in the PAT program for >2 years, and able to give informed consent. Exclusion criteria included women who were currently pregnant or planned to become pregnant in the next 24 months, unable to speak English, current enrollment in a weight loss program, undergoing treatment for diabetes or eating disorders, or inability to engage in a walking program. PAT rolling recruitment of parents was conducted through informational events, provider referrals, and child care organizations. Participants were enrolled from 2012 to 2014, the intervention concluded in 2016, and data analysis began. Study staff called interested mothers to establish eligibility; baseline assessments were completed in a clinical setting where consent was also obtained. Participants were randomized to treatment condition by study staff using randomization sequences generated a priori by the study statistician using a formal probability model with a 1:1 allocation ratio and random block size. Randomization sequences were stratified by region. Sample size was calculated from pilot data assuming a 5% weight loss from baseline, using a two-sided test ($\alpha=0.05$) with a power of 0.9. Data were collected at baseline, 12 months, and 24 months at the study clinic site. Participants received \$50 gift cards for

completing data collection at each time frame. The IRB of Washington University in St. Louis approved this study.

Participants in usual care received the standard PAT program for parents of preschoolers, who can be eligible for up to 25, hour long visits but receive an average of 10 visits per year.¹⁹ Parent educators provide support for parents while delivering a curriculum designed to assure school readiness through promotion of parent–child communication, child development, and family well-being. The curriculum also includes information on general health principles (e.g., accident prevention) but does not address maternal or family obesity-related lifestyle change.

Intervention participants received HEALTH, which embedded a lifestyle intervention derived from DPP within the standard PAT curriculum. Participants were entitled to receive up to 36 visits over 24 months; however, the actual number of visits was based on need. Formative research with PAT staff assured lifestyle content was consistent with organizational mission, practice, and funding requirements. These factors were important to address to assure the sustainability and scalability of the embedded intervention.²⁵ Intervention content was simplified to address specific lifestyle behaviors most likely to impact calorie intake, including limiting intake of sugar sweetened beverages, substituting fruits and vegetables for high caloric snacks, limiting portion sizes, increasing physical activity by walking 30 minutes per day, and decreasing sedentary activity, such as TV viewing. PAT parent–child activities were incorporated into HEALTH content (Appendix Table 1). Social Cognitive Theory guided the adaptation of behavior change content to address intrapersonal (e.g., self-assessment, reinforcement), interpersonal (e.g., observational learning/parental modeling), and home environments (e.g., number of TVs, food access).^{26,27} This approach assured HEALTH met PAT requirements for reimbursement.

To implement the intervention, parent educators were recruited from target communities (N=9, mean age 44 years [range, 29 to 67], 67% have a college degree) with PAT experience and certified on the usual care curriculum. Parent educators then received additional training on the intervention related to: (1) background and rationale, (2) lifestyle change content for weight loss, (3) the importance of parental lifestyle and modeling on child weight and development, (4) overview of the intervention protocol, (5) role-play practice sessions with other parent educators, (6) and feedback from trainers. Trainings took place in person over 1 day (8 hours), consistent with the usual PAT training protocols.

Consistent with routine PAT practice, parent educators delivered the intervention that was randomly assigned to the participant. To ensure that each protocol was appropriately delivered and that there was no risk of contamination across groups, parent educators completed lesson plan checklists documenting delivery of content and audiotaped home visits. Expert study staff then reviewed the checklists and audiotapes to assure that content was delivered appropriately by the parent educator per group assignment. Study staff also randomly observed two home visits a year for each parent educator, an approach consistent with PAT standards of practice.

Measures

Participants completed questionnaires and anthropometric assessments in a clinical setting. Participants' height, weight (primary outcome), and waist circumference (secondary outcome) measurements were obtained in accordance with procedures used by the National Health and Nutrition Examination Survey.²⁸ Blood pressure (secondary outcomes) was measured in accordance with American Heart Association guidelines.^{29,30}

Behavioral assessment included dietary change as measured by the National Health and Nutrition Examination Survey Dietary Screener Questionnaire (caloric intake was a secondary outcome), which asked parents to recall frequency of intake of foods and drinks over the prior month.²³ To assess physical activity the International Physical Activity Questionnaire (moderate intensity walking was a secondary outcome), a seven-item activity module that measures sedentary behavior and general type, frequency, duration, and intensity of physical activity; category scores (low, moderate, or high intensity) were used.³¹ Sociodemographic measures included variables such as: age, marital status, number of children, and monthly income.

Statistical Analysis

Baseline characteristics were compared for participants that did and did not provide data after baseline by unpaired *t*-test (for normally distributed continuous variables), Wilcoxon's test (for ordinal variables), or chi-square test (for binary variables). For participants included in the primary analysis (i.e., participants that provided data after baseline), these methods were also used to compare treatment groups at baseline.

Chi-square tests were used to compare the proportion of participants in each group that achieved >5% weight loss at 12 and 24 months. For continuous outcomes, repeated measures mixed model ANOVA (RM-ANOVA) with an autoregressive covariance structure was used to test hypotheses regarding the equality of changes between baseline and 24 months in the two treatment groups. The RM-ANOVA included the main effects for, and interaction of treatment group **X** timepoint. Statistical contrasts within the RM-ANOVA were used to test null hypotheses that changes between two specific timepoints in the usual care group were equal to corresponding changes in the intervention group. Because the primary hypothesis concerns group differences in change between baseline and 12 months, the *p*-value for this contrast was not adjusted for multiple comparisons. For outcomes that are not continuous, analogous analyses were performed using generalized estimating equations where ordinal outcomes were modeled with a multinomial probability distribution, cumulative logit link function, and independent correlation structure; and binary outcomes were modeled with a binomial distribution, logit link function, and exchangeable correlation structure.

Ancillary RM-ANOVA analyses were performed to determine if the effect of the intervention on change in weight differs across levels of obesity (overweight versus obese I versus obese II/III), race (white versus other), income (<\$30,000 vs \$30,000–\$74,999 vs \$75,000), or number of personal visit sessions completed (tertiary split of <13 vs 13–20 vs

21). The focus of each of these models was the interaction between treatment group, timepoint, and each potential moderator variable.

In the text, mean changes and SDs are expressed relative to baseline. P -values<0.05 were considered significant. Means at each time point are presented in the table, whereas change scores are presented in the text.

RESULTS

As noted in the consort diagram (Figure 1), of the 230 participants who completed the baseline assessment, 179 (78%) participants completed a post-test or follow-up assessment. At 12 months, 173 (75%) of participants completed a post-test; at 24 months 156 (68%) completed a follow-up. Reasons for noncompletion of participants at 24 months included 9% of women who were withdrawn because of pregnancy, and 23% who moved or could not be located. There was no significant difference in participation between groups by BMI or obesity category. There were significant differences by treatment group ($p=0.03$), income ($p=0.0006$), and race ($p=0.01$).

Mean age of participants was 32 (SD=6) years. The majority of the sample was currently married (61%), ethnically diverse (32% African American or black, 7% other) and economically diverse (51% receiving Women, Infants, and Children Program benefits). The majority of participants (63%) met criteria for class I or class II obesity; the remaining sample was evenly divided between overweight (20%) and class III obesity (18%). As noted in Table 1, the intervention participants were generally less educated than usual care ($p<0.05$). There were no significant differences between usual care and intervention participants regarding baseline weight, waist circumference, blood pressure, diet, activity, or other demographic variables.

Intervention participants completed significantly more home visits than usual care (23 [SD=9] vs 13 [SD=6] visits, $p<0.0001$); the average length of visits did not differ (63 minutes [SD=11] vs 63 minutes [SD=11], $p=0.17$). A parent post survey asked participants to rate home visits from poor to excellent (1 to 5). The majority of participants from both groups rated visits as very good or excellent (intervention=90%, usual care= 84%). Data from lesson plan checklists revealed delivery of 87% of objectives for intervention visits and 97% for usual care visits. Study staff review of taped visits and observation visits verified content completion as reported, and found no contamination in delivery across groups.

Intervention outcomes are presented in Table 2. There was no difference between groups in achieving 5% weight loss at 12 months (usual care=10% vs intervention=18%, $p=0.13$ by chi-square); however at 24 months, the intervention group was significantly more likely to achieve 5% weight loss compared to baseline (usual care=11% vs intervention=26%, $p=0.01$ by chi-square).

At 12 months the intervention participants lost 0.7 (SD=6.2) kg while the usual care participants gained 2.1 (SD=4.8) kg, overall a 2.8 kg difference ($p=0.0006$). By 24 months, there was a 4.7 kg difference between groups, as usual care participants continued to gain weight as compared with baseline while intervention participants sustained their weight loss

(3.2 [SD=7.6] kg vs -1.5 [SD=8.3] kg, $p=0.002$). Compared with baseline, this represents a 2.3% and 3.5% increase in usual care weight at 12 and 24 months, respectively; by contrast the intervention group had a 12 and 24 month weight reduction of -0.8% and -1.5%. Weight differences were also reflected in BMI change from baseline between usual care and intervention groups at both 12 months (0.8 [SD=1.8] vs -0.1 [SD=2.4], $p=0.002$) and 24 months (1.3 [SD=2.9] vs -0.5 [SD=3.1], $p=0.0008$) with the following percent difference from baseline at 12 months (2.3% vs -0.5%), and at 24 months (3.8% vs -1.4%).

Compared with baseline, 81% of usual care participants either maintained or decreased obesity category at 12 months compared with 91% of intervention participants; by 24 months 67% of usual care compared with 87% of intervention participants maintained or decreased obesity category. A review of obesity categories depicted in Figure 2 reveals the majority of weight gain occurred among participants by 24 months in the usual care, obese I category, while 24 month weight loss was most likely to occur among intervention participants in the obese III category.

Differences in waist circumference from baseline in usual care and intervention groups were evident by 12 months (2.1 [SD=8.4] cm vs -0.7 [SD=9.8] cm, $p=0.04$) and more pronounced at 24 months (3.8 [SD=10.6] cm vs -2.5 [SD=9.1] cm, $p=0.005$). There was no significant difference in change in systolic or diastolic blood pressure between groups.

There was a significant reduction in sugar through beverage intake from baseline to 12 months between usual care and intervention groups (-1.1 [SD=13.3] vs -4.2 [SD=10.8] teaspoons of sugar, $p=0.04$), which was maintained at 24 months (-1.9 [SD=10.1] vs -2.7 [SD=17.9] teaspoons of sugar, $p=0.03$). There was also a significant reduction in intake of sugar from food between usual care and intervention groups by 12 months as compared with baseline (-1.6 [SD 8.7] vs -4.4 [SD 9.2] teaspoons of sugar, $p=0.03$), which was maintained at 24 months (-1.9 [SD=8.8] vs -3.7 [SD=13.8] teaspoons of sugar, $p=0.01$). There were no significant differences in change between the treatment groups for the other measured dietary variables.

From baseline to 12 months the intervention group significantly reduced their sedentary activity when compared with usual care (-1.6 [SD=3.2] hours vs 0.9 [SD=3.0] hours, $p=0.0001$), a behavior which was not maintained at 24 months. However, a significantly larger percentage of the intervention group moved from low or moderate to high physical activity from baseline to 24 months ($p=0.0004$), with a majority of the change occurring between 12 and 24 months (usual care 42% to 33% versus intervention 39% to 54% high activity at 12 and 24 months, respectively, $p=0.03$).

Ancillary analyses revealed that obesity category ($p=0.11$), race ($p=0.62$), income category ($p=0.11$), and categorized number of home visits completed ($p=0.12$) did not significantly moderate intervention effects on change in weight.

A sensitivity analysis was performed for the primary outcomes that achieved significance in the initial analysis. This included 51 participants who did not provide data after baseline yielding a total sample of 230 for the sensitivity analysis. Review of the resultant p -values from this analysis found no substantive changes to the conclusions reported.

DISCUSSION

These findings inform several key areas of translational research. First, these results suggest an intervention that is low intensity, because it is embedded within the real world practice of a parent education home visiting organization, can achieve clinically significant weight outcomes among overweight or obese women by 24 months. More than one quarter of intervention participants (26%) successfully achieved 5% weight reduction at 24 months, up from 18% at 12 months, and a 15% improvement over usual care. These results are generally consistent with those reported by other translational studies at 12 months or less.^{6,32} The proportion of successful participants is also consistent with the range of 20%–64% reported in a review of translational studies by Aziz and colleagues.⁶

Other weight change indicators also suggest that the intervention achieved clinically relevant improvements overtime. At 12 and 24 months, intervention participants reduced weight (by 0.7 kg and 1.5 kg), BMI (by 0.5% and 1.4%), and waist circumference (by 0.3 cm and 1.0 cm). These modest results are less than the mean weight reductions of 1.8 kg³³ to 2.3 kg¹⁸ reported at 12 months by translational studies conducted in clinical and related settings. However, according to the U.S. DPP each kilogram of mean weight loss is associated with a 16% reduction in diabetes incidence,² whereas a 1% reduction in BMI is estimated to avoid 2 million cases of diabetes annually in the U.S.³⁴ This suggests the intervention had a clinically meaningful impact on diabetes risk at 24 months. A reduction in waist circumference, such as the one achieved by the HEALTH intervention, is also associated with improvements in cardiovascular outcomes.³⁵

Second and of particular interest, is that the HEALTH intervention prevented weight gain between treatment groups at both 12 and 24 months. In the U.S. population, the average weight gain is 0.5 to 1 kg per year, a rather modest accumulation of weight that can lead to obesity overtime.^{36,37} The U.S. Agency for Health Care Research and Quality reports that a 1 kg increase in weight per year leads to diabetes, heart disease, and other chronic disease.³⁸ In this trial, from baseline usual care participants gained an average of 2.1 kg by 12 months, and 3.2 kg by 24 months. They also showed weight gain across all four obesity categories (overweight to obese III), with the highest gain at both 12 months and 24 months in the obesity I category. This is in contrast to intervention participants who had a consistent, but small, amount of weight loss across all obesity categories. The added value of this intervention may be in the prevention of excess weight gain and delay of comorbid conditions.³⁷

These results indicate this intervention, embedded within a real world organization, had a prolonged action phase for behavior change, requiring a longer assessment period to effectively capture clinically significant impact. This is in contrast to stand alone, time intensive interventions typically delivered over 3 to 6 months and reporting larger magnitudes of behavior change and weight loss,⁶ but often associated with diminished effect and weight regain overtime.³⁷ HEALTH was designed to be a scalable intervention, embedded within an organization whose funding is primarily dependent on parenting and child development content and outcomes, not on obesity- or diabetes-related outcomes. This meant content derived from DPP was not the priority of each visit, but rather integrated

within standard PAT home visiting curricula, reinforced by parent educators through multiple visits delivered overtime. The result of this limited content combined with longterm delivery approach was incremental change in specific eating and physical activity behaviors, yielding weight-related outcomes overtime. For example with regard to physical activity, intervention participants reduced sedentary activity at 12 months (e.g., reduced TV watching), and subsequently increased physical activity between 12 and 24 months. This embedded approach supports a lifestyle intervention that can be sustained programmatically and delivered to women over several years, providing reinforcement for simple, small changes that can be incorporated into a woman's everyday life, impacting weight and preventing weight gain overtime.

Third, embedding the HEALTH intervention within PAT provided a way for women with young children to engage in lifestyle interventions by addressing barriers associated with time and child care, which impact participation and retention. Reviews of translational studies across multiple settings reported that greater weight loss is associated with the number and frequency of sessions attended by participants.³² In this study, the intervention group engaged in more home visits overall than the usual care group, whose participation rates reflected those reported by PAT in general. The integration of HEALTH content may have required parent educators to spend more time across multiple visits to cover all topics.¹⁹ However, the high satisfaction rates for both intervention and usual care conditions suggests that women were willing to participate in the additional home visits needed to deliver HEALTH content, and indicates the value of interventions designed to address barriers to participation. In addition, this study reported 25% attrition at 12 months and 32% attrition at 24 months, rates comparable or better than those reported by diabetes and clinic-based translational studies.³⁹

Limitations

Strengths of this study include the pragmatic trial that used a stratified random design that provides outcome data on a large group of mothers and children. Generalizability may be limited to broader populations because of the geographic focus on St. Louis, Missouri. Other limitations of this study include the use of self-report measures, such as food frequency questionnaires that may yield error in outcome estimates or result in bias. However, appropriate steps were taken to assure the relevance and psychometric quality of the measures. Finally, the outcome analyses excluded participants that did not provide data after baseline, which might introduce bias in the results if the failure to provide post-baseline data was not completely at random. An assessment of potential bias compared participants included versus excluded from the analysis and no difference was found for BMI or obesity category, and the balance in baseline characteristics between treatment groups (as intended by randomization) was preserved for participants that were included in the analysis.

CONCLUSIONS

Clinically significant weight reduction in women with young children can be achieved through interventions embedded within real-world settings that already reach the target population. The HEALTH intervention achieved modest but clinically significant outcomes

in reducing weight, and showed promise in the prevention of weight gain in this high-risk group of women. It showed the value of content derived from DPP delivered incrementally, and reinforced overtime by parent educators in the home, and the need for delayed or longer post-assessments to adequately capture cumulative intervention impact. HEALTH was developed in partnership with PAT leadership and parent educators to be consistent with organizational mission and practice, which assured intervention sustainability as a reimbursable component of usual care delivery. To support population health improvement, scale-up efforts for programs, such as HEALTH, are needed to expand the impact of evidence-based interventions, benefit more people, and foster policy and program change on a lasting basis.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
CONSORT diagram.

Figure 2.

Mean weight change from baseline with SE bars by weight category for each treatment group.

Notes: Black bars = Usual Care; Gray bars = Intervention. www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html.

Table 1

Baseline Characteristics for Enrolled Participants Who Provided Follow-up Data at Any Time Point

Maternal focused variables	Total cohort (N=179)	By treatment group		
		Usual care (N=97)	Intervention (N=82)	p-value
Age (years), mean (SD)	32 (6)	33 (5)	32 (6)	0.91 ^a
Race, N (%)				
Black or African American	57 (32)	30 (31)	27 (33)	n/a
White	105 (59)	59 (61)	46 (56)	
Other	13 (7)	8 (8)	5 (6)	
Unknown, not reporting race	4 (2)	0 (0)	4 (5)	
Highest grade of school completed, N (%)				
Some high school, high school graduate	25 (14)	10 (10)	15 (19)	0.05 ^b
Some college/technical/vocational school	65 (37)	33 (34)	32 (40)	
College or university graduate	56 (31)	34 (35)	22 (27)	
Graduate or professional school	32 (18)	20 (21)	12 (15)	
Presently married, N (%)	109 (61)	59 (61)	50 (61)	0.98 ^c
Annual household income from all sources, N (%)				
<\$30,000	66 (39)	36 (38)	30 (40)	0.65 ^b
\$30,000–\$74,999	62 (36)	34 (36)	28 (37)	
>\$75,000	42 (25)	25 (26)	17 (23)	
WIC or other program assistance, N (%)	89 (51)	43 (46)	46 (58)	0.14 ^c
Weight (kg), mean (SD)	93 (15)	93 (15)	93 (16)	0.84 ^a
BMI (kg/m ²), mean (SD)	34.4 (5.2)	34.5 (5.2)	34.4 (5.3)	0.91 ^a
Obesity category, N (%)				
Overweight	35 (20)	19 (20)	16 (20)	0.97 ^b
Obese I	68 (38)	35 (36)	33 (40)	
Obese II	44 (25)	28 (29)	16 (20)	
Obese III	32 (18)	15 (15)	17 (21)	
Waist circumference (cm), mean (SD)	110.8 (12.5)	111.1 (12.3)	110.5 (12.9)	0.72 ^a
Systolic blood pressure (mmHg), mean (SD)	120 (11)	120 (11)	121 (12)	0.58 ^a
Diastolic blood pressure (mmHg), mean (SD)	77 (8)	77 (8)	76 (9)	0.57 ^a
Dietary Screener Questionnaire, daily intake in past month, median (IQR)				
Added sugars from food (tsp)	12.9 (8.9)	13.0 (9.5)	12.6 (9.1)	0.89 ^d
Added sugars from sugar-sweetened beverages (tsp)	4.1 (9.3)	3.9 (9.2)	4.3 (9.3)	0.97 ^d
Fruit/vegetable/legume (cup equivalent)	2.3 (1.3)	2.3 (1.1)	2.5 (1.4)	0.98 ^d
Fruit/vegetable/legume minus french fries (cup equivalent)	2.3 (1.3)	2.3 (1.2)	2.3 (1.3)	0.89 ^d
IPAQ				
Time spent sitting on a weekday (hour), median (IQR)	5.0 (5.0)	5.0 (5.0)	6.0 (4.3)	0.13 ^b
Physical activity category, N (%)				

Maternal focused variables	Total cohort (N=179)	By treatment group		
		Usual care (N=97)	Intervention (N=82)	p-value
Low	42 (29)	22 (28)	20 (30)	0.21 ^b
Moderate	58 (40)	27 (34)	31 (46)	
High	46 (32)	30 (38)	16 (24)	

^aP-value compares treatment groups by unpaired t-test.

^bP-value compares treatment groups by Wilcoxon's test. Ordinal categorical data (i.e., education, income, obesity category, physical activity category) were assigned numbered values in increasing order of magnitude prior to analysis.

^cP-value compares treatment groups by chi-square test.

^dP-value compares treatment groups by unpaired t-test using transformed data per IQR, defined as the 75th minus the 25th percentile; n/a, not applicable; %, percent of treatment group. Due to missing data, sample sizes may vary across variables. DSQ recommendations: For fruits and vegetables, and added sugars from sugar sweetened beverages use the square-root transformation; for added sugars from food, use the cube-root transformation.

WIC, Women, Infants, and Children Program benefits ; IPAQ, International Physical Activity Questionnaire; DSQ, Dietary Screener Questionnaire; IQR, interquartile range

Table 2

Outcomes at Baseline, 12, and 24 Months

Outcome measures	Baseline (BL)	12 month (12M)	24 month (24M)
Weight (kg), mean (SD)			
Usual care	93.0 (15.3)	95.3 (16.0)	97.2 (16.5)
Intervention	92.6 (15.9)	91.5 (16.9)	91.3 (16.8)
<i>p</i> -value BL-12M ^a		<i>p</i>=0.0006	
<i>p</i> -value BL-24M ^a			<i>p</i>_{Sidak}=0.002
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.35
BMI (kg/m ²), mean (SD)			
Usual care	34.5 (5.3)	35.4 (5.7)	36.0 (5.9)
Intervention	34.4 (5.3)	34.1 (5.9)	33.9 (5.6)
<i>p</i> -value BL-12M ^a		<i>p</i>=0.002	
<i>p</i> -value BL-24M ^a			<i>p</i>_{Sidak}=0.0008
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.12
Waist circumference (cm), mean (SD)			
Usual care	111.1 (12.4)	113.1 (11.9)	115.3 (13.1)
Intervention	110.5 (12.9)	109.6 (13.5)	108.5 (13.9)
<i>p</i> -value BL-12M ^a		<i>p</i>=0.04	
<i>p</i> -value BL-24M ^a			<i>p</i>_{Sidak}=0.005
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.11
Systolic blood pressure (mmHg), mean (SD) ^b			
Usual care	120 (11)	120 (12)	122 (11)
Intervention	121 (12)	119 (10)	120 (12)
<i>p</i> -value BL-12M ^a		<i>p</i> =0.08	
<i>p</i> -value BL-24M ^a			<i>p</i> _{Sidak} =0.31
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.99
Diastolic blood pressure (mmHg), mean (SD) ^b			
Usual care	77 (8)	79 (9)	79 (9)
Intervention	76 (9)	76 (9)	78 (9)
<i>p</i> -value BL-12M ^a		<i>p</i> =0.17	
<i>p</i> -value BL-24M ^a			<i>p</i> _{Sidak} =0.92
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.60
Added sugars from sugar-sweetened beverages (tsp), mean (SD) ^b			
Usual care	8.5 (11.2)	8.1 (12.7)	6.6 (8.3)
Intervention	8.1 (11.0)	3.9 (3.5)	5.1 (14.6)
<i>p</i> -value BL-12M ^a		<i>p</i>=0.04	
<i>p</i> -value BL-24M ^a			<i>p</i>_{Sidak}=0.03

Outcome measures	Baseline (BL)	12 month (12M)	24 month (24M)
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.52
Added sugars from food (tsp), mean (SD) ^b			
Usual care	15.3 (9.6)	14.1 (9.8)	13.0 (7.8)
Intervention	14.9 (9.3)	10.5 (4.7)	10.8 (11.3)
<i>p</i> -value BL-12M ^a		<i>p</i>=0.03	
<i>p</i> -value BL-24M ^a			<i>p</i>_{Sidak}=0.01
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.33
Food/vegetable/legume (cup equivalent), mean (SD) ^c			
Usual care	2.6 (1.2)	2.8 (1.5)	2.6 (1.1)
Intervention	2.6 (1.1)	2.5 (1.1)	2.5 (0.9)
<i>p</i> -value BL-12M ^a		<i>p</i> =0.27	
<i>p</i> -value BL-24M ^a			<i>p</i> _{Sidak} =0.93
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.76
Time spent sitting on a weekday (hour), mean (SD) ^b			
Usual care	5.3 (2.9)	5.9 (3.4)	5.2 (3.0)
Intervention	6.3 (3.3)	4.8 (2.9)	5.1 (3.0)
<i>p</i> -value BL-12M ^a		<i>p</i>=0.0001	
<i>p</i> -value BL-24M ^a			<i>p</i> _{Sidak} =0.09
<i>p</i> -value 12M-24M ^a			<i>p</i> _{Sidak} =0.35
Physical activity category, N (%)			
Low			
Usual care	22 (31)	15 (22)	17 (28)
Intervention	20 (33)	12 (22)	6 (11)
Moderate			
Usual care	22 (31)	25 (36)	24 (39)
Intervention	30 (50)	21 (39)	20 (36)
High			
Usual care	28 (39)	29 (42)	20 (33)
Intervention	10 (17)	21 (39)	30 (54)
<i>p</i> -value BL-12M ^d		<i>p</i> =0.20	
<i>p</i> -value BL-24M ^d			<i>p</i>_{Sidak}=0.0004
<i>p</i> -value 12M-24M ^d			<i>p</i>_{Sidak}=0.03

^aP-value compares treatment groups on change between the specified timepoints using a statistical contrast within RM-ANOVA. P-values labelled *p*_{Sidak} are Sidak-adjusted for multiple comparisons.

^bData are rank-transformed prior to analysis.

^cData are square-root transformed prior to analysis.

^dP-value compares treatment groups on change between the specified timepoints using a statistical contrast within GEE.

%, percent of treatment group; BL, Baseline; RM, Repeated Measures__; GEE, Generalized Estimating Equation

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