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A Randomized Controlled Trial to Prevent Obesity among Latino Pediatric Patients

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Abstract

Background: Obesity disproportionately affects Latino youth. Community clinics are an important resource, yet there is little evidence for the efficacy of clinic-based approaches in this population.

Objective: The purpose of this study was to test the efficacy of a clinic-based intervention to lower body mass index (BMI) and improve body composition among overweight Latino children.

Methods: A randomized trial (2 group $\times$ 3 repeated measures) was conducted among 297 randomly sampled, overweight pediatric patients (5 – 10 years old) and their parents. The 12-month family-based culturally tailored behavioral intervention (*Luces de Cambio*) was based on the “traffic light” concepts to address behavior change and was delivered by clinic health educators and mid-level providers. The primary study outcome was child BMI (kg/m^2) assessed at baseline, 6-months ($n=191$) and 12-months post-baseline ($n=201$). A subsample of the children was examined for overall and site-specific adiposity using *Dual-energy X-ray Absorptiometry* (DXA) ($n=79$).

Results: There were no significant intervention effects on child BMI ($p>0.05$), however, intervention children showed significantly ($p<0.05$) lower total and trunk percent fat compared to the usual care condition.

Conclusions: The *Luces* intervention did not reduce child BMI, yet small but significant reductions were observed for child percent body fat. Further research is needed to identify and reduce barriers to recruitment and participation among Latino families.

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Keywords

Obesity; Latino; Intervention; Body Composition

INTRODUCTION

The obesity epidemic among children¹ corresponds with adverse economic,² psychosocial,³ and medical consequences.³ Latino children, especially those from lower socio-economic backgrounds, experience higher rates of obesity than do children from other racial/ethnic groups.⁴ Research consistently shows a higher prevalence of obesity among children of Mexican heritage and non-Hispanic black children, including severe obesity, at 5.2% compared to 3.1% in white non-Hispanic children.³ Latinos are projected to be the largest racial/ethnic minority group in the United States by 2065;⁵ therefore, it is critical to develop effective prevention and control strategies for Latino children to reduce the risk of chronic disease in adolescence and adulthood.

Obesity in Latino children is influenced by numerous factors including genetics, parent health behaviors, parenting strategies, child dietary behaviors, physical activity, sleep behaviors, socioeconomic status (SES), and access to health care.⁶ Given these multiple factors, it is important to implement multi-level strategies, including provider-parent partnerships.⁶ Community-based (e.g., school-based) childhood obesity prevention interventions show moderate evidence of effectiveness,⁷ while primary-care obesity treatment focused interventions show stronger efficacy due to the coordination of clinical efforts and parental involvement.⁸ However, greater research is needed on designing and evaluating prevention strategies in primary-care settings and especially those that provide services to Latinos and low-income communities. Such research can inform evidence-based strategies to combat childhood obesity among these high-risk groups.

The present study adds to the body of pediatric clinic-based obesity prevention and control studies, which in the past have often included few Latino children. This randomized controlled trial tested the efficacy of a culturally- and linguistically-appropriate, evidence-based intervention (*Luces de Cambio*; Lights of Change [English translation], *herein referred to as *Luces*) to reduce body mass index (BMI) among Latino children with overweight. It was hypothesized that children who participated in the *Luces* intervention would demonstrate a lower mean BMI compared to children in the usual care control group at 1-year post baseline. A secondary (exploratory) objective was to test intervention effects on child body composition.

METHODS

Study Design

Luces was a randomized clinic-based trial with a 2-group $\times$ 3 repeated measures design (baseline, 6-months and 12-months post-baseline) to study obesity prevention and control among low-income Latino children. The trial was conducted from 2012 to 2016 following Institutional Review Board (IRB) approval.

Participants and Recruitment

Primary study participants were pediatric patients from a Federally Qualified Health Center (FQHC) in San Diego, California, which provides services to low- and medium-income families (N = 36,192 total pediatric patients) living in the U.S.-Mexico border region. Clinic staff generated a query of age-eligible patients (5 – 10 year olds) seen within the previous 24 months. Pediatric patients with a BMI of 75th percentile but below the 95th percentile were initially eligible for the study (see CONSORT Figure 1). However, due to difficulties recruiting an adequate number of children within the specified BMI range, inclusion criteria were expanded to include children in the 75th to 98.9th percentiles. A two-stage recruitment process was undertaken, first identifying children from medical charts who had a BMI between the 75th and 98.9th percentile. These children were then invited for further screening to measure BMI and determine final eligibility. Other eligibility criteria for families were: 1) planning on living in the target area for the study duration, 2) ability to understand and read Spanish or English, 3) willing to be randomized into one of the two experimental conditions and 4) willing/able to attend the intervention classes if randomized to that condition. Exclusion criteria included: 1) children on a medically-prescribed restricted diet, 2) children with a condition that limits their ability to be physically active or that would affect growth or participation in the intervention, and 3) children who participated in other clinic-based overweight/obesity programs within the past year. The child's primary caregiver (biological parent or legal guardian) was also recruited for concurrent participation in intervention and measurement activities. Recruitment occurred in waves such that once a cohort of 26 families had been enrolled and randomized to condition, the intervention began for that cohort.

Intervention Description

The *Luces* intervention was structured within the Obesity Care Model and from expert panel recommendations.^{9,10} *Luces* emphasized changes in parenting behaviors and improving parent-provider communication to reduce child BMI and promote weight maintenance. The intervention targeted three child health behaviors (dietary behaviors, physical activity, and sedentary behaviors) and corresponding parenting behaviors (role modeling, parenting strategies, and restructuring the home environment). *Luces* was guided by the Socioecological Model for Latino Health Promotion,¹¹ which represents the role and interaction of various theoretically-driven health behavior change approaches to achieve health and environmental changes in Latino communities. The culturally sensitive *Luces* program included individual, family, and community components in the context of the Mexican-derived culture of Southern California. A traffic light concept was the basis for the *Luces* program, where green activities (e.g., active play & family walks) and green foods and beverages (e.g., vegetables & water) were encouraged, while red activities (e.g., watching television) and red foods (e.g., sodas & chips) were discouraged. The components of the 12-month *Luces* program included: a) seven 1.5 – 2-hour group classes with parents and children led by trained bilingual *Luces* Lay Health Educators, held over 6-months (four classes the first two months and three classes between three to six months); b) two visits at the clinic with a clinic mid-level provider (MLP; physician assistant) once before and once after the seven group classes to reinforce key messages from the program; c) six scripted phone calls (averaging 10 minutes in length) with the Lay Health Educator (LHE) after each

of the first six group classes to reinforce concepts taught in class; and d) six monthly group booster classes. The total contact time totaled 19.75 hours over the 12-month period. Participants attended classes every two weeks initially, and then tapered off to monthly classes over the first six months. Classes were offered after-school and evening hours in a clinic room that was equipped to conduct food preparation demonstrations. A total of four LHE and two MLP were trained to conduct the intervention. They each received a one-hour long training to review materials and protocols with study staff. To promote consistency, MLP's completed a standardized checklist for each session and LHE's used standardized PowerPoint presentations for intervention sessions.

The purpose of the two visits with MLP's were to encourage participants to attend the group classes; review lab results (if applicable) and BMI status of the child; and offer an opportunity to address any concerns the family had regarding weight status or related issues. The purpose of the LHE phone calls were to review major class themes, address barriers identified by the family, review family goals set in class, and encourage continued participation in the program. After the first six months of the intervention, six booster classes were held monthly and provided guided activities for both parents and children to review skills learned during the previous six months.

The usual care condition consisted of standard clinical practices offered by pediatricians to pediatric patients with overweight/obesity (e.g., basic nutrition education, health education handouts, didactic education), including two one-on-one visits with a Health Educator, supplemented by follow-up visits with the patient's primary care physician when deemed clinically-appropriate. The total contact time for participants in the usual care condition ranged from 1.25 to 2.25 hours.

Procedures

The measurement team and investigators were blinded to condition assignment and children were randomly assigned (case-by-case) to a condition immediately after completing all baseline assessments. Randomization was conducted by the study statistician using a random number generator. Baseline assessments consisted in obtaining informed consent from parents, assent from children, completion of anthropometric measures (e.g., height, weight), and an interviewer-administered structured questionnaire with the parent. Child and parent data were collected at baseline (T1), 6-months post-baseline (T2), and 12-months post-baseline (T3). Intervention activities occurred at two clinic locations in South San Diego County and assessment activities occurred at a satellite research clinic.

Measures: primary outcome, secondary outcomes and demographics

Body Mass Index (Primary Outcome)—Trained study staff took anthropometric measurements of children (T1, T2 & T3) according to NHANES III Anthropometric Procedures.¹² Child's weight status was classified using the 2000 Centers for Disease Control and Prevention (CDC) Growth Charts:¹³ normal weight (75th to < 85th), overweight (85th to < 95th), and obese (≥ 95th). BMI (kg/m²), BMI z-scores, and BMI percentiles for age were calculated using the CDC SAS macro.

Body composition (Secondary Outcome)—A convenience sample of children (T1 n=121; T2 n=79) were invited to take part in an additional assessment of body composition using *Dual-energy X-ray Absorptiometry* (DXA). Total percent body fat and trunk percent fat were determined from DXA (G. E. Medical Systems, Madison, WI, USA). Certified and trained staff followed measurement procedures and quality control protocols in accordance to the manufacturer's guidelines.

Self-report measures—Questionnaires were administered on the child's parent in their preferred language (English or Spanish). The parent questionnaire collected information on socio-demographic characteristics of the parent and child (age, education, marital status, income, place of birth), and various child and parent behaviors (not included in this report).

Sample size—Based on a 5% significance level (two-sided) and a standardized effect size of 0.31, the sample size requirement per condition at 85% power was n=150, and 15 intervention group classes. Assuming 20% attrition, the number of participants per class was 13. Therefore, the sample size requirement for one condition was $13 \times 15 = 195$. The total sample size required (equal sample size per condition) was 390 children (i.e., parent/child dyads).

Statistical analysis—Descriptive statistics were used to summarize parent/child characteristics and data were stratified by condition assignment (*Luces* vs. Usual Care). The primary outcome (child BMI) was treated as a continuous measure. For the DXA subsample, child total percent fat and trunk percent fat were also treated as continuous measures. Distributions were examined for all outcomes and found to be approximately normally distributed, therefore no transformations were conducted. Selected analyses were carried out with and without using a robust estimator to the assumption of normality and no differences were found in the results; therefore, the results do not use the robust estimator. Preliminary analyses compared the two conditions (*Luces* vs. Usual Care) at baseline (T1) on selected variables using independent-samples t-tests and chi-square tests. Participants who had a T3 measurement were compared to those who did not on selected variables at baseline to examine the possibility of bias due to missing data.

Analysis of covariance (ANCOVA) was used where the outcome at T3 (primary study endpoint) was the dependent variable. Independent variables consisted of the condition indicator variable, the corresponding outcome measure at T1, child gender, and child age at T1. Follow-up analyses examined interactions between condition and gender and condition and age. Mixed effects models were carried out to examine design features and to incorporate the measure at T2 to examine trends over time. Since the intervention condition received group classes and the UC condition received one-on-one visits, we assessed the impact of clustering by treating classes as a random effect in the mixed effects models and estimated intraclass correlations. Trends over time were examined in two ways. First, we treated T2 and T3 as a vector of repeated measures (while still adjusting for T1) to assess whether a differential change in condition may have occurred from T2 to T3 (a condition-by-time interaction) and to take advantage of the additional measurement at T2 for additional power (condition main effect). Second, we compared the overall trajectories of child BMI between the two conditions by treating T1, T2 and T3 as a vector of responses.

Terms in the model included condition, time, the condition-by-time interaction, child gender, and child age. All comparisons followed the intent-to-treat rule.

RESULTS

Participant demographic characteristics

Of the 10,241 potential patient charts that were screened for eligibility during the recruitment process, 2,624 (25.6%) were eligible for recruitment, 966 (9.4%) were eligible for further BMI screening, and 380 (3.7%) were eligible for enrollment (see CONSORT Figure 1). Initial recruitment plans intended to enroll 26 families per group before beginning intervention activities and recruitment for subsequent groups; however, due to delays in enrollment, we enrolled smaller numbers of families per group (mean = 21.2, range = 8-30) and only 14 of the 15 total groups originally planned. Recruitment ultimately yielded 297 families, (22%) fewer participants than planned.

Participant baseline characteristics (by condition) are presented in Table 1. The majority of parents were female and Spanish-speakers, the majority were born in Mexico and more than half had a monthly household income \$1,999. Child age ranged from 5 to 10 years, half were male and most (87%) were U.S.-born. Children's and parent's descriptive statistics across the two conditions did not differ significantly on any of the variables of interest at baseline. There were no differences for baseline characteristics between those retained and those who dropped out.

Primary outcomes

Table 2 shows the results at T3 for the *a priori* study outcome and time-point (BMI) and secondary outcome (percent body fat). Results show there were no significant group differences in BMI. However, the intervention group had a significantly lower total percent fat ($p=0.02$) and trunk percent fat ($p=0.04$) than the usual care condition at T3. The characteristics of this subsample were not statistically different than those of the overall sample. Follow-up analyses were carried out on child BMI restricted to the DXA subsample to determine if they demonstrated different results from the full sample. Results showed that BMI in the DXA subsample was not significantly different between conditions (e.g., BMI = 21.3kg/m^2 for intervention vs. 21.5kg/m^2 for usual care; $p = 0.57$). ANCOVA models were fitted to examine condition-by-gender and condition-by-age interactions, but none were statistically significant (data not shown). Mixed effects models were fitted to examine clustering by group classes for the intervention condition. The results showed no significant clustering effects of group classes (data not shown).

Mixed effects models were fitted to examine T2 and T3 as repeated measures to determine whether additional power might be gained with another data point and to include the 20 participants who only had data at T2 but not at T3. None of the condition-by-time interactions were statistically significant and no differences were seen between the two conditions when the adjusted means were compared across the two time-points (data not shown). Finally, mixed effects models were also fitted to examine whether treating T1, T2 and T3 as a trajectory of points would provide additional insight into differences between

the conditions. However, none of the condition-by-time interactions were statistically significant (data not shown).

DISCUSSION

The present study tested the efficacy of a culturally tailored obesity prevention and control intervention among randomly sampled pediatric patients with overweight (mostly of Mexican heritage). The results of this study showed that the *Luces* intervention did not reduce mean child BMI compared to a usual care condition. Possible explanations for these findings include low participation in intervention activities (average attendance = 4.0 ± 2.6 sessions out of 7) and loss of statistical power due to a smaller than projected sample size. Our results, however, are consistent with the results of a recent review of interventions conducted within primary-care settings to reduce and/or prevent childhood obesity,⁸ which found that only 26% of interventions (8 of 31 studies) achieved reductions child BMI z-score. This review showed that the average 12-month retention rate was 77% (ranging from 57% to 94.9%) among randomized controlled studies. In comparison, our study achieved a 67.7% 12-month retention rate, which may also explain the non-significant results. Importantly, out of the 31 studies include in the review, only two studies had populations demographically similar to our study (i.e., Latino and 5-10 years old); therefore, it is difficult to make direct comparisons of our study findings with many studies that target reductions in child BMI in a primary-care setting. Our study is unique because it specifically targeted a primary-care clinic whose patients are largely Latino and lower-income. Also, our study targeted children who were considered at-risk for obesity and the goal of the intervention was to prevent children from becoming obese or preventing further increases in BMI. In contrast, most primary care-based childhood obesity interventions have focused on obesity treatment and have had limited enrollment of Latino and low-income patients,⁸ and also target different age groups. Thus, our findings are only generalizable to primary care clinics who serve pediatric patients who are primarily Latino and lower-income.

In contrast to the primary findings, the *Luces* intervention resulted in significant reductions in total and trunk percent fat. It is important to note that it is uncommon for intervention studies to measure both BMI and percent fat via DXA given the added costs. The discrepant findings suggest that BMI may not be as sensitive in capturing intervention-related changes in child body composition compared to a DXA-derived measure. Our findings are supported by the few studies that have also found improvements in child body composition following a lifestyle intervention, with no significant or divergent changes in BMI.¹⁴ It is also important to note that the percent body fat and trunk fat improvements were relatively small (~2% difference between groups) which may not be clinically relevant. Evidence suggests that greater body fat in children is associated with several negative health outcomes such as elevated blood pressure and lipoprotein ratios,¹⁵ and early pubertal development among girls.¹⁶ Thus, reducing body fat (specifically) may be more important than lowering BMI in children. These findings warrant further research.

Limitations

There are several limitations to the present study. Due to difficulties in recruiting children specifically in the overweight BMI category, the inclusion criteria were expanded to include the 75th to 98.9th percentiles. This may have limited our ability to detect BMI changes given the wider BMI range and may have also required additional tailoring of intervention activities according to child's BMI. In addition, we were not able to meet the targeted sample size due to difficulties in recruitment and time constraints. Reliance on paper-based health records resulted in a slow recruitment process and some children aged-out of the eligibility criteria by the time we reviewed their medical record. Future studies would benefit from using electronic medical records to facilitate identifying eligible patients in a timely manner. To overcome enrollment challenges, the study team increased resources devoted to the delivery of the intervention which may have counteracted the loss of statistical power of a smaller sample size. However, a post-hoc power calculation of the achieved sample size (n=297) at a 5% significance level and 85% power, indicates that this study could have detected a standardized effect size of 0.39 or greater. This post-hoc effect size is greater than the *a priori* estimated of 0.31.

Conclusions

The *Luces de Cambio* clinic-based program did not reduce BMI among overweight Latino children. Notable challenges included slow recruitment, difficulty identifying eligible children and low family participation in intervention activities. Future studies should identify and reduce barriers to recruitment and participation in clinic-based obesity prevention programs among low income Latino families.

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Figure 1.

CBC = Child Body Composition; DXA = Dual-energy X-ray Absorptiometry; T1 = Timepoint 1 (baseline); T2 = Timepoint 2 (6 months); T3 = Timepoint 3 (12 months); LTF = Lost to follow-up; MTP = Missing time point

* Did not receive intervention reasons: moved, refused

**Lost to follow-up reasons: moved, never reached (disconnected numbers, no contact)

***Missing timepoint reasons: busy, missed multiple scheduled appointments

Table 1.Participant Demographic Characteristics at Baseline (*N* = 297).

	Intervention N=149	Usual Care N=148	Total N=297
<i>Child characteristics</i>	N (%) or M±SD	N (%) or M±SD	N (%) or M±SD
Age (months)	98.0±17.6	96.3±19.6	91.2±18.0
Gender			
Female	69 (46.3)	79 (53.4)	148 (49.8)
Weight Status (BMI percentile)			
Normal (5.0 – 84.99)	24 (16.1)	26 (17.6)	50 (16.8)
Overweight (85.0 – 94.99)	58 (38.9)	56 (37.8)	114 (38.4)
Obese (95.0 – 100)	67 (45.0)	66 (44.6)	133 (44.8)
BMI (kg/m ²)	20.7±2.9	20.5±2.8	20.6±2.8
BMI percentile	92.4±5.9	91.8±6.6	92.1±6.3
BMI z-score	1.57±0.44	1.54±0.46	1.6±0.5
Subsample	N=31	N=48	N=79
DXA Total % fat	33.9±7.5	31.4±7.8	32.4±7.7
DXA Trunk % fat	34.7±8.7	31.4±9.0	32.7±8.9
<i>Parent characteristics</i>	Intervention N=149	Usual Care N=148	Total N=297
Age (years)	35.1±7.6	36.5±7.5	35.8±7.6
Gender			
Female	145 (97.3)	142 (95.9)	287 (96.6)
Relationship to child			
Biological parent	145 (97.3)	141 (95.3)	286 (96.3)
Legal guardian/caregiver	4 (2.7)	7 (4.7)	11 (3.7)
Language			
Spanish	138 (92.6)	137 (92.6)	275 (92.6)
Country of Birth			
United States	44 (29.5)	45 (30.4)	89 (30.0)
Mexico	103 (69.1)	100 (67.6)	203 (68.4)
Other	2 (1.3)	3 (2.0)	5 (1.7)
Marital Status			
Married	103 (69.1)	115 (77.7)	218 (73.6)
Single	28 (18.8)	20 (13.5)	48 (16.2)
Other (Divorced, widowed, separated)	17 (11.4)	13 (8.8)	30 (10.1)
Employment Status			
Employed (full-time, part-time, seasonal)	60 (40.3)	53 (35.8)	113 (38.2)
Not employed (Out of work, retired, other)	12 (8.1)	18 (12.2)	30 (10.1)
Homemaker	76 (51.0)	77 (52.0)	153 (51.7)
Household Monthly Income			
< \$500 to \$1999	94 (63.1)	93 (62.8)	187 (63.6)
\$2000 to \$3999	46 (30.9)	49 (33.1)	95 (32.3)
\$4000 to 6000	7 (4.7)	5 (3.4)	12 (4.1)

Number of people supported by household income	4.1±1.3	4.3±1.3	4.2±1.3
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Table 2.

Intervention effects at T3 for primary and secondary outcomes.

	Intervention N=149	Usual Care N=148		
Primary Outcomes	Mean±SE	Mean±SE	Difference	p-value
Child BMI (kg/m ²)	21.6±0.2	21.5±0.1	+0.1	0.79
Child BMI percentile	91.0±0.7	89.5± 0.6	+1.5	0.10
Child BMI z-score	1.50±0.03	1.46±0.03	+0.04	0.33
Secondary Outcomes	N=31	N=48		
DXA Child total % fat	34.2±0.6	36.1±0.5	-1.9	0.02
DXA Child trunk % fat	35.6±0.7	37.4±0.6	-1.8	0.04

Analysis of covariance model to assess differences between intervention and usual care at T3 adjusting for the baseline measure of the outcome, child age and child gender.