

A store-based intervention to increase fruit and vegetable consumption: The *El Valor de Nuestra Salud* cluster randomized controlled trial

Guadalupe X. Ayala^{a,b,*}, Barbara Baquero^c, Julie L. Pickrel^b, Joni Mayer^{a,b}, George Belch^a, Cheryl L. Rock^d, Laura Linnan^e, Joel Gittelsohn^f, Jennifer Sanchez-Flack^{b,g}, John P. Elder^{a,b}

^a San Diego State University, 5900 Campanile Drive, San Diego, CA 92182, United States

^b Institute for Behavioral and Community Health, 9245 Sky Park Court, Suite 220, San Diego, CA 92123, United States

^c University of Iowa, College of Public Health, Community & Behavioral Health, N418 CPHB, 105 River Street, Iowa City, IA 52242, United States

^d University of California, San Diego, School of Medicine, Department of Family and Preventive Medicine, 9500 Gilman Drive #0901, La Jolla, CA 92093-0901, United States

^e University of North Carolina at Chapel Hill, Gillings School of Global Public Health, Department of Health Behavior, 359 Rosenau Hall, 135 Dauer Drive, Campus Box 7440, Chapel Hill 27599, United States

^f Center for Human Nutrition and Global Obesity Prevention Center, Department of International Health, Johns Hopkins Bloomberg School of Public Health, 615 North Wolfe St, Baltimore, MD 21205-2179, United States

^g San Diego State University–University of California at San Diego Joint Doctoral Program in Health Behavior, 5900 Campanile Drive, San Diego, CA 92182, United States

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ABSTRACT

Introduction: Most evidence-based interventions to improve fruit and vegetable (FV) consumption target individual behaviors and family systems; however, these changes are difficult to sustain without environmental support. This paper describes an innovative social and structural food store-based intervention to increase availability and accessibility of FVs in *tiendas* (small- to medium-sized Latino food stores) and purchasing and consumption of FVs among *tienda* customers.

Methods: Using a cluster randomized controlled trial with 16 *tiendas* pair-matched and randomized to an intervention or wait-list control condition, this study will evaluate a 2-month intervention directed at *tiendas*, managers, and employees followed by a 4-month customer-directed food marketing campaign. The intervention involves social (e.g., employee trainings) and structural (e.g., infrastructure) environmental changes. Three hundred sixty-nine customers (approximately 23 per *tienda*) serve on an evaluation cohort and complete assessments (interviews and measurements of weight) at 3 time points: baseline, 6-months post-baseline, and 12-months post-baseline. The primary study outcome is customer-reported daily consumption of FVs. Manager interviews and monthly *tienda* audits and collection of sales data will provide evidence of *tienda*-level intervention effects, our secondary outcomes. Process evaluation methods assess dose delivered, dose received, and fidelity.

Results: Recruitment of *tiendas*, managers, employees, and customers is complete. Demographic data shows that 30% of the customers are males, thus providing a unique opportunity to examine the effects of a *tienda*-based intervention on Latino men.

Conclusions: Determining whether a *tienda*-based intervention can improve customers' FV purchasing and consumption will provide key evidence for how to create healthier consumer food environments.

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* Corresponding author at: San Diego State University and the Institute for Behavioral & Community Health, 9245 Sky Park Court, Suite 220, San Diego, CA 92123, United States. Tel.: +1 619 594 6686; fax: +1 619 594 2997.

E-mail addresses: ayala@mail.sdsu.edu (G.X. Ayala), barbara-baquero@uiowa.edu (B. Baquero), jpickrel@mail.sdsu.edu (J.L. Pickrel), jmayer@mail.sdsu.edu (J. Mayer), belch@mail.sdsu.edu (G. Belch), crook@ucsd.edu (C.L. Rock), linnan@email.unc.edu (L. Linnan), jgittel1@jhu.edu (J. Gittelsohn), jesanchez@mail.sdsu.edu (J. Sanchez-Flack), jelder@mail.sdsu.edu (J.P. Elder).

1. Introduction

Few members of the US population meet dietary guidelines for fruits (Fs; 33%) and vegetables (Vs; 26%) [1]. US Latinos are more likely to meet guidelines for F compared with non-Hispanic whites (37% versus 31%, respectively). However, the same is not true for V (20% versus 28%, respectively) [1]. Latino men exhibit even greater disparities in FV consumption with fewer than 20% of Latino men consuming FVs five or more times per day compared with 28% of Latinas [2]. Compounding this risk, research indicates that less acculturated US Latinos (e.g., Spanish- versus English-language use) consume fewer servings of FVs with each additional year in the US [3].

Evidence-based interventions to improve FV consumption have focused on the intrapersonal and interpersonal levels of the Social Ecological framework (SEF) by targeting individual behaviors and family systems [4,5], for example, by improving food preparation skills [6] or developing effective family communication and planning around meals [7]. However, these individual and family changes are hard to sustain without environmental support. As a framework designed to consider multiple sources of influence on health [8–11], the SEF also recognizes the importance of policy-level changes, such as those that improve access to healthy foods [12,13]. Policies that have the potential to create community change are often considered more sustainable approaches for promoting healthy eating [14], but these are often targeted to a subset of the population, for example, those who qualify for the Special Supplemental Nutrition Program for Women, Infants, and Children [15]. Given these limitations, researchers and practitioners have argued for identifying effective strategies for changing the consumer food environment [14,16]. Interventions that target change at the community-level, specifically within the food retail environments frequented by Latinos, are missing from this research [17].

Food store interventions are an innovative approach for improving the consumer food environment, as well as improving health-related attitudes and behaviors [18,19], including grocery purchasing. In addition, store-based interventions can be implemented with fidelity [20]. However, evidence from randomized controlled trials is lacking on feasible and effective methods for changing customers' FV consumption. The *El Valor de Nuestra Salud* (or “*El Valor*”; translated as “The Value of Our Health”) study fills this gap in research; it tests a multi-component intervention in small-to-medium-sized ethnic food stores catering to a Latino clientele (i.e., *tiendas*) to improve *tienda* availability and accessibility of FVs, and purchasing and consumption among *tienda* customers. The primary outcome is customer-reported daily consumption of FVs using the National Cancer Institute FV screener and secondary outcomes including customer-reported purchasing and observed FV availability and accessibility within the *tiendas*. The *El Valor* study builds on a previous study conducted in North Carolina that resulted in increased *tienda* availability of Vs and greater consumption of FVs among *tienda* customers [21]. An innovation of both studies is the social and structural aspects of the intervention (e.g., social aspects including manager and employee trainings; structural aspects including new equipment), as most small store-based interventions are limited to a food marketing component and displays [18]. This paper describes the *El Valor* study and presents baseline demographic characteristics of the *tiendas*, managers, and cohort of *tienda* customers.

2. Materials and methods

2.1. Overview and study design

El Valor is a cluster randomized controlled trial with 16 pair-matched *tiendas* randomized to a six-month social and structural intervention or a wait-list control condition. Evaluation activities are designed to determine whether the intervention improves *tienda* availability and accessibility of FVs, and purchasing and consumption among *tienda* customers. Regarding *tienda* availability and accessibility of FVs, source data are collected during face-to-face interviews with *tienda* managers at three time-points (baseline, and 6- and 12-months post-baseline) and monthly *tienda* audits. Sales data are obtained when available, and managers are prompted for this information on a monthly basis by *El Valor* staff. Employees are recruited to participate in the intervention and data collection is limited to intervention involvement. Regarding customer purchasing and consumption, 369 customers (approximately 23 per *tienda*) were recruited to serve on an evaluation cohort; these are our primary study participants. Customers' self-reported FV purchasing and consumption data were collected at baseline prior to *tienda* randomization, and are being collected again at 6- and 12-months post baseline (see Fig. 1). The primary outcome is customer-reported daily consumption of FVs using the National Cancer Institute FV screener; secondary outcomes are at the customer (e.g., FV purchasing) and *tienda* (e.g., availability and accessibility) levels. An extensive process evaluation protocol examines key dimensions of implementation [20,22], such as dose delivered, dose received, and fidelity for all components of the social and structural change intervention. All study protocols were approved by the Institutional Review Board of San Diego State University.

2.2. Study foundation and advisory committee

El Valor recruitment, intervention, and evaluation protocols were informed by a pilot study in *tiendas* in North Carolina [20,21], a formative research study with the target population and in *tiendas* in San Diego [23], previous research in food retail environments [24,25], previous research in workplace interventions [26,27], previous research with Latinos [9,28], and input from an advisory committee comprised of individuals from the national food retail industry and other agencies charged with promoting healthy eating (see Acknowledgements). The advisory committee convened during the first year of funding and is meeting four times in-person over the course of the study to provide input on study protocols and activities. During the first two years of the study, the committee's input was instrumental in developing recruitment protocols and creating intervention components that were relevant to *tienda* managers and their customers.

2.3. Recruitment and eligibility criteria

2.3.1. Tienda enumeration and recruitment

A systematic enumeration of all food stores in San Diego County was conducted using five sources: county food permits, county health department registry, approved outlets of the Special Supplemental Nutrition Program for Women, Infants,

Study design

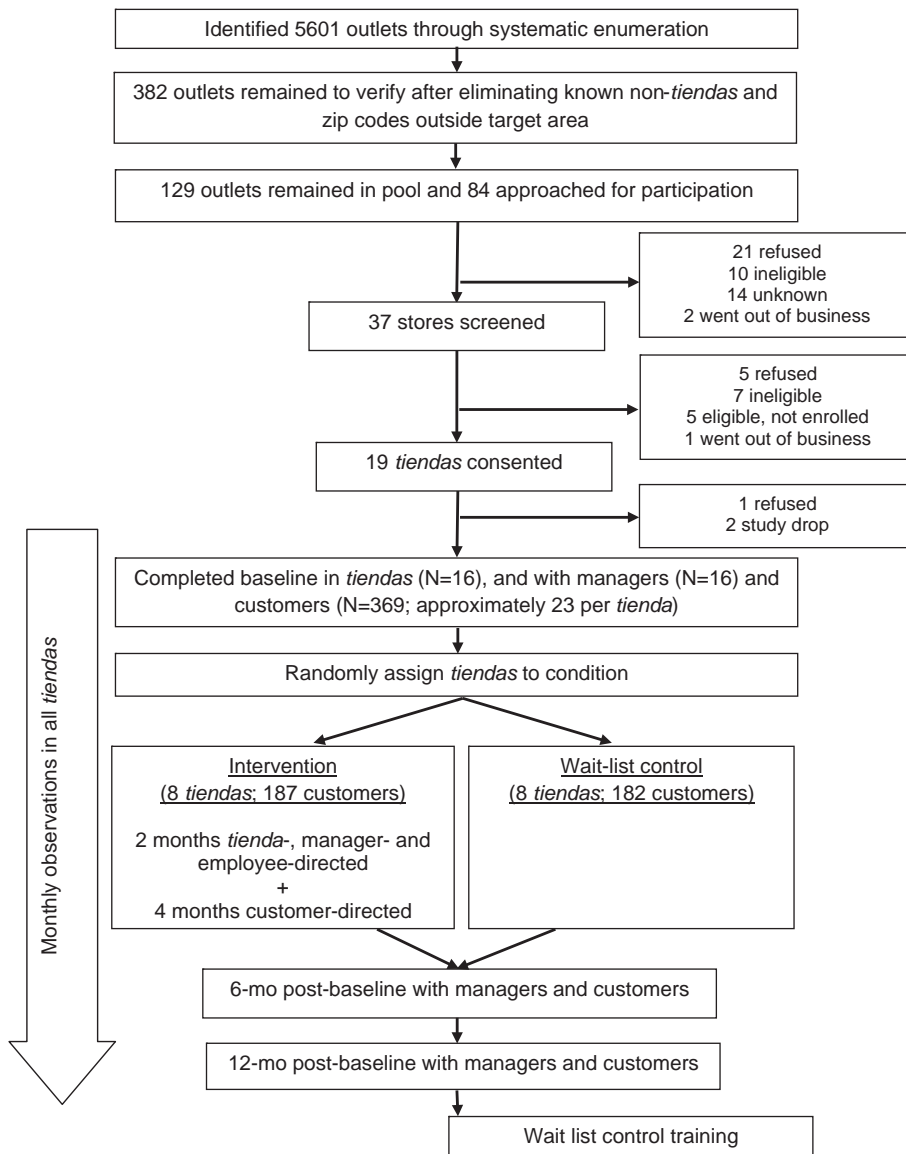


Fig. 1. Study design.

and Children (WIC) program, approved outlets of the Supplemental Nutrition Assistance Program (SNAP), and a previous observational study conducted in the target area [29]. Duplicate entries were removed resulting in a final list of 5601 outlets eligible for the second phase of screening which involved eliminating those clearly identifiable as other than a food store (e.g., car wash, electronics store, non-retail; $n = 1488$). This new list of 4113 outlets was further reduced by excluding zip codes where US 2000 Census data indicated that the proportion of Hispanic/Latino residents was less than 20% (given our focus on Latinos), as well as San Diego's South County given competing intervention activities in stores led primarily by the county health department ($n = 2437$). The remaining 1676 outlets were then filtered to exclude known super centers, supermarkets,

liquor stores, convenience stores, dollar stores, restaurants, etc. and additional duplicates were removed ($n = 1110$). This left 566 that was further reduced to 339 outlets after excluding those ineligible based on internet or phone verification.

Because 2010 Census data were not available when store enumeration was first conducted, 2000 Census data were used to identify zip codes with sufficient Latino representation. Over time demographic shifts occurred that changed the ethnic composition of various neighborhoods. During the final round of *tienda* recruitment, given time and resource constraints for traveling to more distant stores, the team identified four additional zip codes in proximity to the study offices that contained census tracts representing at least 20% Latino population. An additional 365 outlets were identified in those

zip codes (out of the original 5601). Of those, 268 were dropped because they were identified as an outlet other than a grocery store, then another 54 were excluded because they did not fall within census tracts that contained at least 20% Latino population, leaving an additional 43 outlets to be verified. This brought the total available for verification and potential recruitment to 382.

In-person verification involved a store audit to determine whether the outlet was a food store, and if yes, whether it met study inclusion criteria: carried some fresh produce; had a serviced meat department; was considered small or medium-based on the number of cash registers and store aisles (for matching purposes); and catered to a Latino clientele (e.g., had Spanish language signage; some or all employees observed speaking Spanish; some products from Mexico and other Latin-American countries including specific cuts of meat in the serviced meat department, specific dishes in the serviced prepared food department if available). No criteria were used for number of employees given the wide variation observed in previous studies with similar stores [21,24].

Of this 382 outlets, 273 (71%) were not eligible for various reasons from being a convenience store to no longer in business. Six (1.5%) additional duplicates were found and during ground truthing, 26 new stores were found and added, leaving 129 in the recruitment pool. From among these, 84 *tiendas* were approached for participation. To minimize the potential for cross-contamination, the 84 *tiendas* were sorted geographically; once one *tienda* was recruited, possible pair-matched *tiendas* were identified that were located at least one mile away from the recruited *tienda*.

Initial *tienda* recruitment strategies involved mailing an introductory letter followed by an in-store visit or a phone call to schedule a meeting. However, after several attempts, it was determined that many *tienda* managers did not recall receiving the letter. Thus, the approach was modified to include a drop-in visit with a fact sheet and introductory letter in-hand, recruitment on-the-spot, or scheduling a meeting to introduce the study to the *tienda* manager at a later date. The fact sheet included a pilot-study *tienda* manager testimonial and a testimonial by the president of a regional trade association for independent retailers along with answers to frequently asked questions. During the recruitment meeting with the *tienda* manager, the project staff member reviewed study requirements and gave the *tienda* manager a packet to review. If the *tienda* manager was interested, the staff member completed an initial eligibility screener which involved confirming that the *tienda* was eligible. If eligibility was met and the manager agreed, the two parties would review and sign a memorandum of understanding.

2.3.2. Manager and employee recruitment

Tienda manager eligibility criteria included being at least 18 years of age; having worked at least 20 h per week for the participating *tienda* for a minimum of six months; planning to continue as *tienda* manager for the next 12 months; having decision-making authority in the *tienda*; and not being employed at another participating *tienda*. If the *tienda* manager was eligible, the project staff member conducted the baseline assessment with him/her. Recruitment of employees to participate in evaluation activities was dropped due to funding

cuts. As such, employee recruitment was limited to intervention involvement and is described under [Intervention](#).

2.3.3. Primary study participants: *Tienda* customers

To screen for eligibility, customers were approached by trained bilingual (English/Spanish) research assistants as they were entering the *tienda*. As soon as a customer agreed to be screened, recruitment of other customers stopped until all activities were completed with that individual. If the customer expressed initial interest, the research assistant screened him/her for the following eligibility criteria: at least 18 years of age; identified as Latino/Hispanic; primary food shopper for his/her household; shops at the participating *tienda* at least once per week; not presently consuming more than four cups of FV per day; not having dietary restrictions limiting FV consumption; fluency in English and/or Spanish and able to read Spanish; not shopping at another participating *El Valor tienda* once a month or more; having a telephone; planning to remain in San Diego County for the next 12 months; and not participating in another research study. To ensure independent observations, only one individual per household could participate. If the customer was eligible and agreed to participate, the research assistant collected the baseline data immediately or scheduled a future visit to collect these data. If the customer refused at any point during recruitment, the refusal was noted, along with important demographic factors such as gender to characterize those who refused. If the customer was ineligible, he/she was thanked for his/her time and ineligibility criteria were noted along with similar demographic factors as those who refused.

2.4. Intervention

As summarized in [Table 1](#), the intervention involves social and structural changes in the *tiendas*, with activities directed at the *tienda* environment, and the *tienda* managers, employees, and customers. Research-supported intervention activities are designed to occur over a six-month period, with *tienda*-, *tienda* manager- and employee-directed activities occurring over the first two months and customer-directed activities occurring over the subsequent four months; these latter activities occur in the form of biweekly campaigns using a variety of marketing strategies. The ultimate goal of the *El Valor* intervention is to improve the availability and accessibility of FV in the *tiendas*, and promote the purchase and consumption among *tienda* customers.

2.4.1. *Tienda* and *tienda* manager-directed

The *tienda*- and *tienda* manager-directed interventions involve working with the *tienda* manager to implement social and structural changes in the *tiendas*. Social changes are targeted through employee trainings and a food marketing point-of-purchase (POP) campaign. To implement structural changes, *tienda* managers receive \$2000 to purchase equipment to help them promote the sale of fresh FVs. They are encouraged to select from three options: (1) raw produce displays (e.g., bins and racks); (2) prepared produce displays (e.g., cold food bars); and/or (3) hardware to improve current produce displays (e.g., misters). In addition, the *tienda* managers are required to select at least two of the three proposed changes to make in their butcher departments: (1) introduce a new meat-vegetable option (e.g., fajitas), (2) introduce study-created POP materials

Table 1

Intervention components and associated process evaluation measures.

	Planned dose	Process evaluation
Structural changes <i>Tienda</i> -directed	\$2000/ <i>tienda</i> , three options: Raw produce displays Prepared produce displays Produce hardware Serviced meat dept. — minimum of two changes Serviced prepared foods dept. — minimum of one change	Mean (SD) dollars spent on <i>tienda</i> % (n) of <i>tiendas</i> that selected each option and what was implemented % (n) of time each option implemented % (n) of each option implemented
Social changes Employee-directed	25% of employees receive four-part training (four hours total), a minimum of 1 from each department: Butcher Cashier Stocker Prepared foods, if applicable All others 10-min training	Percent of employees fully trained and mean hours of training per employee % (n) employees received 10-min training
Worksite posters Newsletters	Four Nine	Median (range) poster delivered Median (range) of employees the newsletters were delivered to
Customer-directed Initial food marketing POP installation and rotation	60 shelf danglers (rotated with campaign) Four to eight aisle violators (based on <i>tienda</i> size) One poster One banner One produce fact sheet 450 blank EV logo signs (50 per campaign)	% (n) of POP installed and retained at each weekly visit
Biweekly food demonstrations and campaign	Food demonstration announcement flyers 9 unique recipe cards (200 per campaign) 9 unique recipe posters (one per campaign) 225 reusable grocery bags (25 per campaign) 900 magnet calendars (100 per campaign)	# of flyers distributed # of customers visiting food demo # of taste-test samples given out # of recipe cards distributed # of grocery bags distributed Minutes of food demo

promoting meat and FV pairings, and/or (3) cross merchandize fresh FV in the butcher department. For those *tiendas* that have a mailed circular, another option is provided to include promotions of fresh meat and FV pairings in the circular. *Tiendas* with a serviced prepared food department are required to include additional FVs in their menu offerings through implementing one of three proposed changes: (1) offering the *El Valor* biweekly customer-directed campaign recipe (*El Valor* recipe) on their prepared food menu the day of the food demonstration; (2) offering one or more of the *El Valor* recipes on an ongoing basis; and/or (3) modifying existing menu items to incorporate FVs used in the *El Valor* recipes. In this way, *El Valor* targets both the availability and accessibility of FVs in multiple departments and in multiple forms. Decisions on what infrastructure to purchase and what changes to implement in the serviced meat and prepared foods departments are decided collaboratively between the *tienda* manager and intervention staff member to maximize the sales of fresh FVs and reduce spoilage. These decisions are made over the course of three meetings with the *tienda* manager, along with decisions about who to train and logistics of the food marketing POP campaign.

2.4.2. Employee-directed

The employee-directed component involves four trainings delivered to at least 25% of *tienda* employees (minimum of cashier, butcher, stocker and prep food person, the latter if applicable), a 10-minute introductory training for all other employees, materials to support the trainings (e.g., four worksite posters) and nine employee newsletters delivered in conjunction

with the biweekly customer-directed campaigns. An intervention staff member using a study-produced DVD and accompanying materials delivered the four-part training. Training topics include: customer service, product knowledge (focused on FVs), merchandising fresh produce, and how to implement an integrated campaign. Trainings are intended to be delivered optimally in a small group over the course of four 1-hour sessions; however, they can be delivered one-on-one. Trainings include opportunities for role playing and skill practice, with a notable feature of the videos showing 'good' and 'bad' behaviors (e.g., good and bad customer service) and consequences of these behaviors consistent with behavioral modification principles [30]. At the end of each training session, *tienda* employees are given a take home 'skill builder' assignment to practice what they learned. The intervention staff member posts the related worksite poster which summarizes the key points of the training. During the customer-directed intervention described below, all employees receive a biweekly newsletter at the beginning of each new campaign that describes the upcoming food demonstration, including what FVs are being promoted and encourages use of the skills learned during the training.

2.4.3. Customer-directed

The 4-month customer-directed intervention, initiated at the beginning of month 3, involves a food marketing POP campaign, including nine biweekly food demonstrations. The POP materials include shelf-danglers (see Fig. 2a), aisle violators (see Fig. 2b), posters, a banner, a produce fact sheet, and blank signs the *tienda* personnel can use to promote or price



a) Shelf dangler



b) Aisle violator

Fig. 2. a. Shelf dangler. b. Aisle violator.

FVs. Some of the POP materials are static, remaining in place for the entire four-month period. Every two weeks, five to seven days prior to the food demonstration, certain POP materials (e.g., danglers, posters) are refreshed to highlight the recipe and produce items of that two-week period. Food demonstration announcement flyers are distributed to customers. The recipe is prepared for the four-hour food demonstration to allow for taste-testing. During each demo, recipe cards are offered to customers so they can prepare the recipe themselves, and 25 reusable grocery bags carrying the *SABOR* and *Plato Total* messages (details provided below) are distributed to customers. After each food demonstration, remaining recipe cards are made available in the *tienda* until the new campaign begins, and 100 refrigerator magnet calendars bearing the project tagline are distributed to customers by *tienda* employees. In addition to replenishing POP materials and updating them to reflect the new campaign each two weeks, the intervention staff member also monitors the structural and butcher changes such as introducing meat–vegetable pairings, and if applicable, changes in the serviced prepared food department. To maximize implementation fidelity, the intervention staff member addresses concerns with the *tienda* manager either immediately or soon thereafter.

In preparation for the food demonstrations, the intervention staff member encourages the *tienda* manager to ensure that all of the items promoted for the week are available for purchase in the *tienda*. *Tienda* managers are also asked to identify a *tienda* employee to assist with the food demonstrations to maximize the possibilities for sustaining this intervention component

upon study completion. Consistent with the pilot study [20], the food marketing POP campaign was informed by theory and behavior change strategies [31,32]. Two core messages of our campaign are *SABOR* and *Plato Total* (see Fig. 3). Although the former loosely translates to 'taste', *SABOR* is an acronym referring to five behavioral strategies used to promote healthy eating [33,34]: substitute, add, balance, opt for variety, and reform. The goal is to elicit behavior change among customers through the use of POP materials. For example, as depicted in Fig. 2a, each shelf dangler incorporates one of the five behavioral strategies in its message (i.e., English translation: Bored with bland rice? Opt for broccoli, carrots, red bell peppers and peas to make it more colorful). Our "*Plato Total*" (Total Plate) was based on a previous study [7,35] in which the concept was used to promote healthy eating in a family-based intervention; however, it is also similar to the United States Department of Agriculture's "Choose My Plate" dietary guidelines [<http://www.choosemyplate.gov/>] [36]. The *Plato Total* encourages customers to make half their plates FVs, a quarter whole grains, and a quarter lean proteins. The *Plato Total* image and messages are also incorporated into many of the POP materials. The two are combined into the following tagline: *Póngale SABOR a su Plato Total* (Put taste into your total plate).

2.5. Wait-list control condition

Tiendas randomly assigned to the wait-list control condition are offered a three-part employee training following completion of their 12-month assessments, including assessments

Image of Plato Total marketing



Fig. 3. Image of plato total marketing.

with *tienda* customers. The training includes the same components as the intervention training, excluding the fourth training because it is tailored specifically to the *El Valor* food marketing POP campaign that control *tiendas* do not receive.

2.6. Measurement

Impact and outcome data collection is designed to determine whether the intervention successfully improves availability and accessibility of FVs, and purchasing and consumption among *tienda* customers in intervention versus wait-list controls. Our primary outcome is customer-reported daily consumption of FVs; secondary outcomes include customer-reported purchasing of FVs and *tienda* availability and accessibility of FVs. Except where specified, data collection is occurring at three time-points: baseline, 6-months post-baseline and 12-months post-baseline.

2.6.1. Manager interviews

Manager interviews capture information about the *tiendas* and about the *tienda* managers themselves, including their eating habits, consistent with customer data collection described below. *Tienda* information includes *tienda* size and staffing among other variables. At 6- and 12-months, the interview also includes process evaluation questions about intervention implementation.

2.6.2. Tienda audits

Tienda audits are occurring every four weeks in addition to the baseline, 6-month, and 12-month assessments to capture changes in the *tiendas*, specifically availability and price of fresh produce items, the extent to which fresh produce is available in other departments (e.g., butcher, prepared foods), whether the *tienda* is engaging in additional promotions of FVs, and whether more floor space is devoted to fresh produce over the course of the study. Availability of canned and frozen produce is also assessed. Research assistants, blinded to treatment condition at baseline, were trained to conduct these unobtrusive audits. At

baseline, all audits are conducted with a second observer, and at the 6- and 12-month time-points, a 50% random sample of audits are conducted with a second observer present to assess inter-rater reliability. By the nature of the POP campaign, it was impossible to maintain blinding of research assistants after the customer-directed intervention was implemented.

2.6.3. Tienda sales data

Managers are asked to provide weekly or monthly sales data, including overall sales, produce sales, produce purchase figures, and sales of prepared foods, if applicable. The formats in which these data are received varies by each *tienda*'s capacity, and include daily register receipts and produce invoices, hard-copy tables and electronic files.

2.6.4. Primary participants: tienda customers

The primary outcome is daily consumption of FVs. This information is obtained using the National Cancer Institute (NCI) All Day FV Screener [37], which consists of 19 items on how frequently the respondent consumed FVs in various forms and how much was consumed during the past month. Food models and measuring cups are used to improve data collection consistent with recommendations [38]. The secondary outcome is self-reported grocery and produce purchasing at that *tienda* and other food stores. Additional variables include percent energy intake from fat using the NCI Fat Screener [39], behavioral strategies to increase FV intake and reduce fat [33], and the total variety of FVs consumed in the past month. Potential moderators (e.g., eight-item scale measuring the extent to which *tienda* marketing influences grocery purchasing) and mediators (e.g., *tienda* characteristics and *tienda* employee characteristics; barriers to healthy eating) are also being examined.

2.7. Planned analyses

Bivariate analyses will be used to describe the characteristics of the sample by intervention and control group. All analyses will be carried out according to the intention-to-treat rule consistent with standard practice in most trials. The primary aim of this study is to assess the impact of the intervention on customer-reported daily consumption of FVs between baseline and immediately post-intervention (approximately 6 months post baseline). The primary dependent variable is a continuous measure that is normally distributed or may be transformed to approximate normality by natural log or the Box-Cox transformation. Thus, normal-based models will be emphasized, with care taken to assess this assumption and, if necessary, apply appropriate transformations. Based on bivariate analyses (independent sample *t*-test and chi-square test), significant demographic differences between the two conditions will be included in the subsequent multivariate mixed model analysis for covariance adjustment.

For the primary aim of assessing the effectiveness of the intervention on customers' daily intake of FVs, we will use the two-level (individual level and *tienda* level) mixed effects models treating the immediate post-intervention FV intake as the dependent variable. The primary predictor, condition assignment, along with baseline FV intake and significant demographic differences between the two conditions will be placed in the fixed effect part of the models. These covariates

will be adjusted for their influence on the intervention effect. Finally, the *tienda* ID will be placed in the random effect part of the model to adjust for the clustering effects. This model will allow us to compare the effect of intervention on FV intake while adjusting for participants' baseline FV intake. A number of studies have shown that adjusting the baseline outcome (i.e., FV intake) as a covariate has more power and precision than assessing the change over time using the repeated-measure approach [40]. Further, we also expect that the intervention effect on FV intake may differ between men and women [41]. In another model, we will place gender and the gender \times condition interaction term in the fixed effect portion of the model to assess the differential response to the intervention by gender. If the interaction term is not significant, we will drop it from the final model. The proposed multilevel models will be fitted using SAS PROC MIXED or PROC GLIMMIX when examining non-normal variables such as a dichotomous outcome.

2.8. Sample size estimation

The intervention was powered to detect a positive difference of 0.90 (0.20) servings of FV intake among intervention versus control *tienda* customers at the 6-month post-baseline measurement time-point. This rate of change was based on our pilot study results [20,21] and considered along with other design elements to determine our *tienda* and customer sample sizes: an estimated intraclass correlation of 0.11 to account for *tienda* clustering and a six-month retention rate of 90%. To achieve 80% power, we recruited 16 *tiendas* and approximately 23 customers per *tienda* for a total sample size of 369 customers.

2.9. Process evaluation

An extensive process evaluation protocol, similar to that used in our pilot study [20], is being implemented including logs completed by the intervention staff member prior to, during, and after each food demonstration; logs completed by the intervention staff member at each POP campaign maintenance visit; attendance logs at employee trainings and training attendee satisfaction surveys; randomly selected independent observations of employee trainings by a process evaluator; and intervention exposure questions asked of the customers and managers at the 6- and 12-month time points. Ultimately our process evaluation will address questions related to dose delivered, dose received, and fidelity at the *tienda* and customer levels.

3. Results to date

Recruitment of *tiendas* and *tienda* managers occurred in three waves, in part, for staffing reasons. *Tiendas* were pair-matched at recruitment to ensure equivalency across *tienda* characteristics randomized to condition (e.g., presence of a prepared food department; number of cash registers and number and size of aisles). Thus, once a *tienda* was recruited, a second *tienda* from the list was recruited that was similar in size and characteristics to the recruited *tienda* but sufficiently at a distance from the recruited *tienda* to minimize cross-contamination. After all baseline assessments were completed within the pair-matched *tiendas*, and with their respective *tienda*

managers and customers, one *tienda* was randomly assigned to the intervention condition and the second to the wait-list control condition.

Eighty-four *tienda* managers were approached for participation; 12% ($n = 10$) refused to participate without hearing about the study and an additional 18% ($n = 11$) refused after hearing about the study (see Fig. 1). Three *tiendas* (4%) were immediately determined ineligible (not Latino or going out of business), and after further screening, 11% ($n = 7$) more were excluded for various reasons, among them not having a majority Latino clientele, changing the format to a 99 cent store, or being the former manager of a participating *El Valor tienda*. In 17% ($n = 14$) of the *tiendas*, eligibility was undetermined because recruitment ended before eligibility was finalized. Two *tiendas* went out of business before being presented the study.

From among the remaining 37 stores screened for eligibility, 51% ($n = 19$) agreed to participate, 14% ($n = 5$) refused, 19% ($n = 7$) were ineligible for similar reasons and 14% ($n = 5$) were eligible but not enrolled because recruitment goals were met prior to an agreement being reached. One *tienda* went out of business during recruitment. Thus, the recruitment rate based on eligible-agreed/eligible-refused was 79%. After initially agreeing, one *tienda* refused to continue participation, and one *tienda*, and by extension its pair, were dropped during customer recruitment given concerns for staff safety. The final *tienda* sample size is 16.

Among the reasons given for participating, *tienda* managers noted that they appreciated the opportunity to receive resources and staff training. Others wanted to help members of their community. Among reasons given for refusing to participate, *tienda* managers reported that they were too busy or not interested, their *tiendas* were undergoing changes during the upcoming months or they felt the business was too unstable to be involved. However, other managers reported that because customers were not interested in health, it would be a waste of time for their *tienda* and their employees to participate. Depicted in Tables 2 and 3 are customer, manager, and *tienda* characteristics from baseline. Nearly one-third of the customers were male and 36% of the customers had a high school education. Similar percentages were WIC recipients

Table 2
Demographic characteristics of the customers and *tienda* managers/owners.

	Customers (N = 369)	Managers/owners (N = 16)
	% (n) or Mean (SD)	
Demographic characteristics		
Age	42 (12)	40 (14)
Male	30% (110)	88% (14)
Latino/Hispanic	100% (369)	47% (7) ^a
High school educated or greater	36% (132)	88% (14)
Employed full-time	60% (128)	94% (15)
Financial assistance		
WIC recipient	33% (120)	NR ^b
SNAP recipient	33% (120) ^c	NR ^b
Primary aim		
Daily fruit and vegetable intake (cups)	3 (2)	NR ^b

^a Missing ethnicity information for managers: ($n = 1$).

^b NR = not reported.

^c Missing SNAP recipient information: ($n = 1$).

and/or SNAP recipients. FV consumption averaged three cups daily. Few differences were observed between intervention versus control condition customers. Intervention condition customers were more likely to live in poverty (78%) compared with control condition customers (65%; $p < 0.005$) and they were less likely to be homeowners (14% versus 25% respectively; $p < 0.01$). Intervention condition customers were also more likely to be traditional or Spanish language dominant compared with control condition customers (71% versus 59%, respectively; $p < 0.05$). *Tienda* managers were mostly male (88%), employed full-time (94%), and had a high school education or greater (88%). The intervention and control *tiendas* were similar on a number of dimensions including number of aisles, cash registers, employees, and departments. On average, between seven to 25% of weekly sales are attributed to sales of fresh FVs, an aspect of the *tiendas* that we are examining further.

4. Discussion

This paper describes a cluster randomized controlled trial to test an innovative social and structural intervention designed to promote the availability and accessibility of FVs in small-to-medium-sized Latino food stores (*tiendas*), as well as purchasing and consumption among *tienda* customers. The primary outcome is customer-reported daily consumption of FVs. The six-month intervention involves changes in the manner in which FVs are marketed to customers, including changes in the

display, marketing, and promotion of FVs by employees and managers. In addition to evaluating changes among a cohort of *tienda* customers over a 12-month period, changes are being examined among *tienda* managers and within the *tiendas* themselves. An extensive process evaluation protocol examines dose delivered, dose received and fidelity. To our knowledge and based on several reviews [16,19,42], El Valor is among one of two studies [43] to test a social and structural intervention to promote FVs.

Tiendas are an innovative setting in which to conduct health promotion research involving US Latinos. Among Latinos, particularly among traditional Latinos, *tiendas* are frequented more often than supermarkets [44]; Latinos also have greater access to these types of food stores in their communities [45], and recent evidence suggests that they could serve as an ideal venue to promote FVs [24]. They do not introduce the same challenges in the promotion of fresh FVs as convenience stores given no existing infrastructure in the latter [42]. This is the second of two studies conducted in this setting, the former taking place in a new immigrant-receiving community in North Carolina, an area of the US that offered employment in poultry processing plants and other types of factories [46]. The former study helped us learn that *tiendas* in new immigrant receiving communities are gateways of entry into the US [20,21]. *Tiendas* serve as a hub where immigrants can obtain information about community resources and sources of employment; they are also places where immigrants can send home remittances and stay connected to their countries of origin, for example,

Table 3

Tienda and manager employment characteristics based on observed and manager-reported data.

	Total (N = 16)	Intervention (n = 8)	Control (n = 8)
	% (n) or Mean (SD) or Median (range)		
Observed data during a baseline audit			
Aisles	4 (2–9)	4 (3–9)	4 (2–7)
Cash registers	3 (1–5)	3 (1–5)	3 (1–5)
Serviced bakery or <i>tortilleria</i>	25% (4)	25% (2)	25% (2)
Serviced prepared foods dept.	38% (6)	38% (3)	38% (3)
Have <i>tienda</i> flyer	56% (9)	63% (5)	50% (4)
Manager-report on <i>tienda</i>			
Years <i>tienda</i> in operation	20 (2–70)	14 (2–50)	20 (18–70)
Full time employees	6 (2–40)	5 (3–40)	8 (2–30)
Part-time employees	3 (0–20)	3 (0–8)	4 (2–20)
Sales floor in sq. footage ^a	3500 (1080–20,000)	5000 (1800–20,000)	3500 (1080–12,000)
Number of SKUs ^b	5,000 (500–120,000)	4,000 (500–120,000)	7,000 (575–100,000)
Produce distributors	6 (2–15)	6 (3–8)	6 (2–15)
Certified WIC vendor	69% (11)	63% (5)	75% (6)
Weekly sales in \$ ^c	28,500 (8000–100,000)	22,000 (17,500–100,000)	37,500 (8000–75,000)
Weekly produce sales in \$ ^d	6500 (1500–19,000)	4000 (1500–19,000)	10,000 (2600–10,500)
Customers on typical weekday	550 (150–1450)	600 (250–1450)	450 (150–1250)
Manager-report on self			
<i>Tienda</i> owner	50% (8)	63% (5)	38% (3)
# of other food stores owns	1 (1–13)	1 (1–2)	2 (1–13)
Years managed this <i>tienda</i>	5 (1–24)	4 (1–24)	6 (1–20)
Hours works in typical day	8 (4–16)	8 (4–16)	8 (7–12)

^a Sales floor square footage missing: intervention (n = 1) and control (n = 1).

^b SKUs missing: control (n = 1).

^c Weekly sales missing: control (n = 4).

^d Weekly produce sales missing: intervention (n = 1) and control (n = 5).

through foods purchased. Similarly, in established immigrant receiving communities, they are an access point for maintaining culturally-derived food habits through the types of foods and beverages available for purchase. In addition, customers will find an employee or manager who speaks Spanish. Importantly, *tiendas* are visited more frequently than supermarkets or big box stores, in part because the types of shopping trips that occur involve ‘fill-in’ or ‘quick-trip for a meal’ activities. Among Latinos living on the US–Mexico border, approximately 33% of a family’s weekly food basket was purchased from *tiendas* [44].

4.1. Limitations

A few limitations of the study are acknowledged. Although funding was requested for the collection of biomarkers, this evaluation protocol was dropped after a 25% reduction in funding from study inception. This limits our ability to determine, with more precision than is afforded with a food screener, the clinical meaningfulness of study findings. Similarly, employee data collection was reduced after the first wave of *tiendas* given continued funding reductions in subsequent years. This limits our ability to determine whether any possible changes observed in the customers are, in part, due to changes observed in the employees. Finally, challenges remain in our ability to collect sales data; at study end we will have it for a limited number of *tiendas* and periods of time; the validity of the data also will be examined. Collection of sales data is a common problem and has been identified by previous researchers conducting intervention work in stores, even supermarkets [19]. Smaller stores are less likely to have point-of-sale systems that allow easy access to sales data by product category. Independent store managers and owners are also wary of providing sales data to outsiders. Thus, this examination will be limited but it will provide much needed evidence on the impact of the intervention on store sales.

4.2. Conclusions

Dietary intake of FVs is not meeting USDA guidelines and this is more pronounced among Latino males versus females [2], and more generally, among racial/ethnically diverse individuals compared with whites [1]. Evidence-based interventions are needed that affect change in settings in which diet-related decisions are made, such as during food purchasing in food stores [19], a precursor to sustaining changes in dietary intake. The *El Valor* study has the potential to inform industry and public health practice on effective methods for modifying their food stores to promote purchasing of FVs among their customers.

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