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A randomized controlled trial of orthodontist-based brief advice to prevent child obesity☆

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ABSTRACT

Objective: We conducted a randomized controlled trial to test whether brief exercise and diet advice provided during child patient visits to their orthodontic office could improve diet, physical activity, and age-and-gender-adjusted BMI.

Methods: We enrolled orthodontic offices in Southern California and Tijuana, Mexico, and recruited their patients aged 8–16 to participate in a two-year study. At each office visit, staff provided the children with “prescriptions” for improving diet and exercise behaviors. Multilevel models, which adjusted for clustering, determined differential group effects on health outcomes, and moderation of effects.

Results: We found differential change in BMI favoring the intervention group, but only among male participants ($p < 0.001$; Cohen's $d = 0.085$). Of four dietary variables, only junk food consumption changed differentially, in favor of the intervention group ($p = 0.020$; $d = 0.122$); the effect was significant among overweight/obese ($p = 0.001$; $d = 0.335$) but not normal weight participants. Physical activity declined non-differentially in both groups and both genders.

Conclusion: The intervention, based on the Geoffrey Rose strategy, had limited success in achieving its aims.

Implications: Orthodontists can deliver non-dental prevention advice to complement other health-practitioner-delivered advice. Higher fidelity to trial design is needed to adequately test the efficacy of clinician-based brief advice on preventing child obesity and/or reversing obesity.

☆ All co-authors have reviewed and approved the manuscript for submission.

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[1] Melbourne F. Hovell served as PI, oversaw all administration and the fidelity of the trial, and contributed to manuscript preparation and approval.

[2] Katharine E. Schmitz was the full-time research coordinator, and contributed to analyses and manuscript writing.

[3] Sandy Liles coordinated data management, conducted statistical analyses, and led manuscript writing.

[4] Kristi Robusto handled all of the DXA X-rays and validation measurements, and edited the manuscript for possible publication.

[5] C. Richard Hofstetter participated in the design of the study and oversaw data management and statistical analytical procedures.

[6] Jeanne F. Nichols oversaw all PA measures, promotion of PA, and exercise testing.

[7] Cheryl L. Rock provided overview of all dietetic measures and edited the manuscript.

[8] Veronica Irvin compiled and refined data collection instruments, and supervised data collection, management, and analysis.

[9] Melanie Parker and Santiago Surillo served as a pilot participating orthodontist and assisted with recruitment of additional offices and patients.

[10] David Noel helped recruit offices.

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1. Introduction

About 19% of children aged 6–19 in the United States (US) were obese in 2011–2014 [1]. While obesity rates vary by race, socioeconomic status, geographic region, age and gender, obesity is common across demographic groups [1,2]. The prevalence of obesity, as well as the negative impact on health, quality and length of life, warrants preventive intervention [3,4].

Obesity interventions have occurred in schools, homes, clinicians' offices, workplaces, and community settings. Changes have been made to the physical environment, such as improving bike paths and walking trails, and to public policy, such as restricting foods of minimal nutritional value on school campuses. The Behavioral Ecologic Model [5] argues that intervention is needed at many of these levels to be effective and sustainable. For example, nutrition education in a community that is lacking in healthy grocery choices will likely have little impact. A nutrition education program occurring concurrently with increased availability of healthy food choices has a better chance of success. If clinicians and schoolteachers were to additionally encourage and reinforce such purchases, the added layers of support would theoretically further increase the efficacy of interventions. In short, a coherent ecology of supporting contingencies of reinforcement for healthy eating and activity should prevent excess weight gain and sustain fitness.

However, most approaches follow the “medical model” of waiting until individuals acquire excessive weight, putting them at elevated risk of morbidity and premature death, or even until disease such as Type II diabetes or CHD manifests, before applying medical or behavioral treatment. While treatment is necessary, it is costly to society and patients, results in modest change in risk for those treated even if treatment is “successful” and sustained, and offers no risk reduction benefit for the majority who are not (yet) obese [6].

An alternative approach is the prevention strategy advocated by Geoffrey Rose, which addresses disease risks well in advance of disease onset. This approach focuses on relatively inexpensive interventions designed to benefit the whole population, as opposed to the medical model of intensive treatment only for those at high risk or ill [6]. The Rose model targets a downward shift in the entire population distribution of weight by changing what is socially accepted as “normal” weight, to reduce the likelihood that individuals will move into the upper extreme of the distribution. Following the Rose logic, efforts to constrain progress toward obesity among all members of a population—e.g., environmental changes, social media messages, or brief clinician counseling of all patients—may have a greater effect in reducing disease prevalence than intensive treatment for the minority of obese. Prevention measures for reducing the incidence of obesity are particularly indicated because overweight is difficult to reverse. The more a person weighs the more likely they are to gain additional weight, in what has been termed the “runaway weight gain train” [7]. This means early intervention is especially important, making childhood the appropriate time for initiating prevention and control efforts.

This paper describes the outcome of *Healthy Smiles: An Orthodontist Program*, an NIH-funded, randomized, controlled trial of an orthodontist-delivered clinical intervention among 8–16 year old youth aimed at forestalling excess weight gain by improving dietary intake and increasing physical activity (PA) in the experimental condition, and at reducing tobacco use initiation and secondhand smoke exposure in the control condition. The frequency of orthodontist contact enabled the study to serve as a model of clinician intervention emulating the impact of a health system where multiple clinicians offer brief counseling that could cumulatively affect risk practices such as unhealthy eating and physical inactivity. If this could be achieved in the context of routine dental and medical care, cost would be minimal and the possible population effects large.

2. Methods

2.1. Data source

Orthodontic practices in San Diego, Orange, and Riverside Counties in Southern California, United States (US) and along the Northern border region of Baja California, Mexico (MX) were recruited to the study between 2009 and 2013. Orthodontists were selected because they have more frequent contact with young clients than most other medical specialties, thereby providing a powerful test of the preventive efficacy of health messages. US orthodontists were identified from the American Association of Orthodontist membership listing and online searches. MX pediatric orthodontists were identified from telephone directory advertisements and referrals from participating orthodontists. About 8% (n = 33) of contacted offices enrolled. Reasons for not enrolling included unsuccessful contact; ineligibility due to retirement, practicing too few days a week or belonging to a shared practice, and refusals.

Participating offices informed their patients of the study by letter or personal contact. Patients allowing contact by study personnel were then screened for study inclusion. Eligible patients from US offices were between the ages of 8–14 years. Patients from MX offices were eligible up to age 16 years, to reflect the generally later start of orthodontic treatment in MX. Patients from either country were excluded if they had participated in organized sports or PA three or more times per week for nine or more months of the past year, had been prohibited by a physician from engaging in regular PA, were unable to care for themselves, had been diagnosed with an eating disorder or severe depression, had less than one year of orthodontic treatment remaining, or planned to move within a year.

At an initial in-person visit the parent and child signed consent and assent forms, completed self-administered questionnaires that included demographics, and had their heights and weights measured by research personnel. Families were later contacted by telephone to complete additional baseline measures, which were repeated at mid- and post-intervention. At baseline, mid-intervention (12 months), and post-intervention (18 months), children provided prior day recalls of diet and PA on three separate days of computer-assisted telephone interviews. At each orthodontic visit, office staff measured child height and weight, for computing BMI. The consent process and interviews were conducted in English, Spanish, or Vietnamese according to participant preference. Incentives ($10 to $20) were provided to encourage interview completion. All study procedures were approved by the San Diego State University Institutional Review Board. Fig. 1 shows participant flow through the study.

Dietary recalls were based on the 2005 and 2007 California Health Interview Survey [8,9] and PA recalls were adapted from the Previous Day Physical Activity Recall [10,11]. Parents confirmed their child's report of dietary intake. Dietary recalls estimated servings of foods and beverages consumed on the prior day, including fruits, fruit juices, vegetables, dairy, soda or other sugar sweetened beverages, chips, fries and sweets [8,9].

PA recalls assessed bouts of PA occurring during specified blocks of time (a) for school days: before leaving for school, after arriving at school but before classes started, during recess, during physical education (PE), after school but before dinner, and after dinner; (b) for weekend days or non-school weekdays: before breakfast, after breakfast but before lunch, after lunch but before dinner, and after dinner. Children reported the types of PA they performed, but not duration or intensity due to concern with the validity of reports of these features by children [11].

2.2. Interventions

Enrolled offices were randomly assigned to the PA and nutrition (PAN) intervention condition or to the parallel tobacco use/exposure

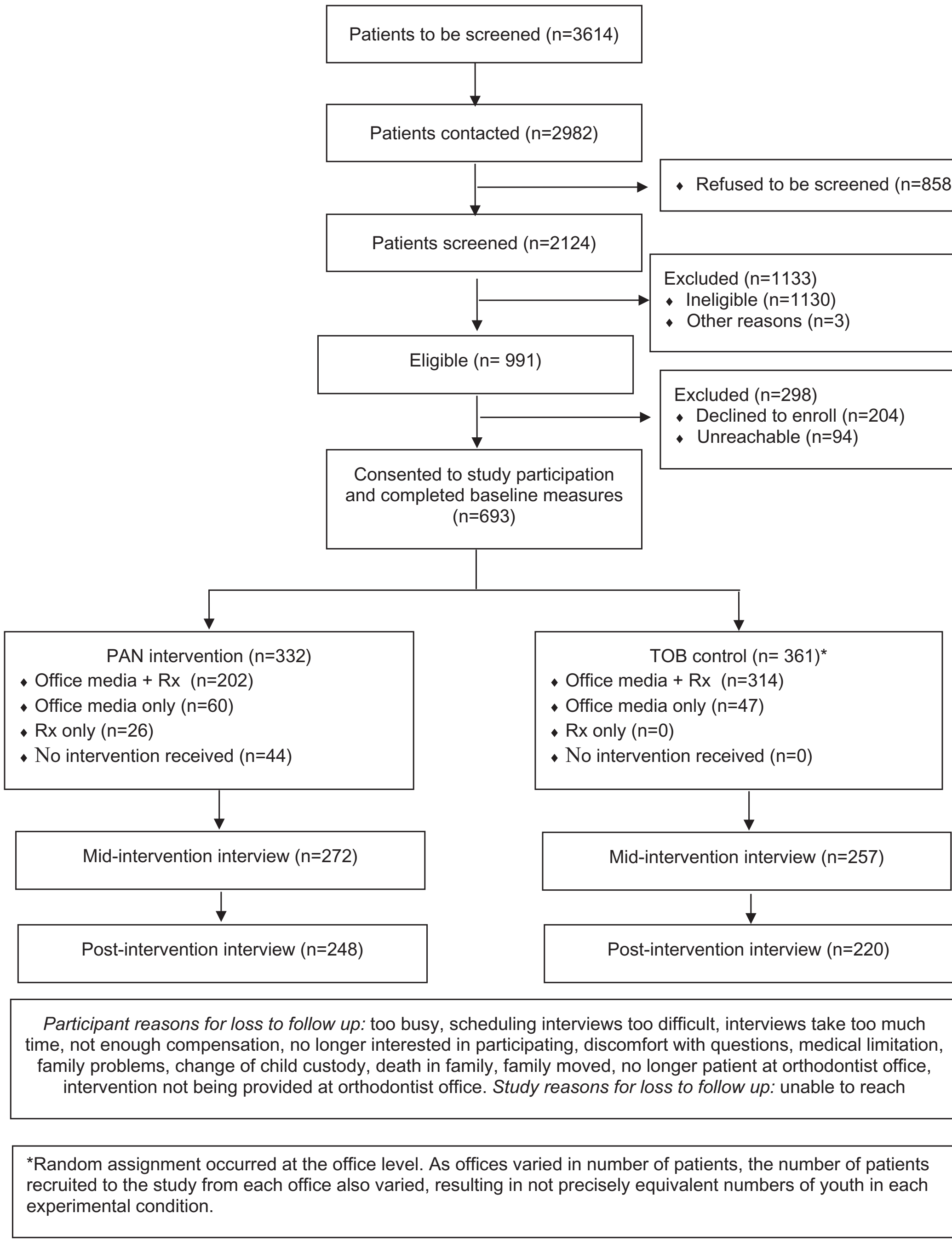

Fig. 1. Participant flow chart.
Healthy Smiles CONSORT diagram.

(TOB) control condition. At baseline and mid-intervention, offices were trained and retrained to implement their specific intervention. At baseline, offices received a 90-minute in-person training delivered by research staff that described the study purpose, goals, components and procedures; shared current recommendations relevant to their specific intervention; discussed and role-played opportunities to engage in patient education and discussion; reviewed behavior modification strategies such as goal setting and the provision of positive reinforcement; and provided instruction on the height and weight measurement protocol. At mid-intervention, offices received an in-person refresher training that reviewed study procedures and solved problems as needed. Health topics within each condition (Fig. 2) changed every six to eight weeks, to coincide with the typical interval between patient visits, resulting in an intervention period of 18–24 months. With each new topic, offices received additional assistance with intervention delivery, in the form of discussion points and detailed information specific to that topic.

The interventions consisted of three main components: health message “prescriptions” and related discussion, office media, and parent education materials. The prescriptions were personalized for each orthodontic office, included space for the patient's name and doctor's signature, and for the PAN condition, space for a personal goal and a rating of the achievement of the last goal set. Prescription messages changed with each topic rotation (Fig. 3). Twelve different prescription health messages were available for distribution, with the goal of one prescription being delivered at each patient visit, approximately

PAN Condition Health Topics	TOB Condition Health Topics
Healthy eating and PA: benefits and recommendations overview	Consequences of tobacco use
Goal setting and monitoring	Secondhand and thirdhand smoke
Social support and PA recommendations	Tobacco industry tactics and regulations
Increasing fruit and vegetable intake	Peer influence and smoking
Reduction of sedentary activities	Other tobacco products (hookah, smokeless tobacco, e-cigarettes, etc.)
Healthy snacking	Smoking depicted in media
Outdoor activities	Tobacco-related litter and the environment
Healthy beverage choices	Tobacco's effect on oral health
Food labels and serving sizes	Smoke-free policies
Advocating for PA and nutrition	Tobacco prevention advocacy
Healthy food choices outside the home	Tobacco sponsorship and sports
Whole grains	Secondhand smoke and pets

Fig. 2. Health topics by condition.

every six to eight weeks. Orthodontic staff were instructed to have brief discussions with their patients regarding the health topic, to assist patients with goal setting, and to reinforce positive behavioral changes as each prescription was being delivered. Prescriptions were only delivered to patients enrolled in the study. Offices received $1.50 for each prescription delivered.

Office media consisted of brochures, posters, counter-top displays, 3-D models, and related patient giveaways. Parent education materials were available in the waiting area of each office and included information relating to each health topic and suggestions as to how to create physical and social environments supportive of the desired behavior changes. Prescriptions and parent education materials were available in English, Spanish and Vietnamese. Office media were available in English and Spanish. Patients enrolled at PAN offices in the US additionally received newsletters through the mail, once every 3–4 months.

2.3. Statistical analyses

2.3.1. Process measures

To assess intervention fidelity, research staff visited orthodontist offices every 6–8 weeks to gather duplicate copies of prescriptions delivered to patients and to complete observational checklists of media being displayed. Participants who were given at least one prescription *and* whose orthodontic office displayed *any* media during the study were considered to have been delivered the intervention as designed.

2.3.2. Outcome measures

To assess possible effects of the intervention, we measured:

(1) Body Mass Index (BMI), computed from weight and height measured at each office visit according to the standard formula: weight [kilograms] / (height [meters])^2; age and gender adjusted BMI z-scores (the primary outcome) were computed based on the CDC 2000 reference standard [12].
(2) Composite variables for four dietary categories were created at each measurement point by averaging the three prior day assessments of consumption of food items: dairy (milk, cheese, yogurt); sugar sweetened beverages; junk food (French fries, chips, sweets); and fruits & vegetables (fruit, 100% fruit juice, vegetables, potatoes). For example, the number of servings of milk, cheese, and yogurt consumed in a day were summed in order to create the composite variable "dairy".
(3) Reports by children of the physical activities they engaged in during each block of time were coded for intensity based on the MET values assigned to those activity types in the 2011 Compendium of Physical Activities [13]. Bout intensity was categorized as light, moderate, or vigorous. Bout duration was not assessed. Mean daily counts of light, moderate, and vigorous PA bouts, obtained by averaging across the 3 prior day recalls, were computed at each of the 3 measurement points (baseline, 12 months, 18 months), separately for school days and non-school days.

2.3.3. Moderating factors

We evaluated potential moderation of group by time effects on outcomes by testing 3-way interactions among group, days, and factor for each of five dichotomous candidate factors: child ethnicity (Hispanic or Latino/a vs not), gender of child (female vs not), age of child ($\geq$12 years vs $<$ 12), family income ($\geq$\$70,000 vs $<$ \$70,000), and child overweight/obese status (BMI percentile $\geq$85 vs $<$ 85) [14].

2.3.4. Sensitivity analyses

Intent-to-treat analysis [15] was used unless otherwise specified. However, to more strictly test our primary intent-to-treat analyses, we recomputed our outcome and moderation analyses, limiting cases to those participants who had data at all three assessment points (a "consistent cohort"), to control for the possibility that participants lost to follow-up systematically differed by condition from those retained. For example, suppose that among participants who dropped out before the second or third assessment point, those in the PAN group had a higher average baseline rate of eating junk food than those in the TOB group. Then, due to drop-out alone, the PAN group would show a greater decrease in junk food consumption over time than the control group.

For the BMI outcome, it proved impossible to define a consistent cohort. This was because no participant had height and weight data at all 12 planned orthodontist office assessment points during the course of the study. So we had to select a different type of subsample for our sensitivity analysis of the BMI outcome. Since the PAN intervention aimed to prevent ***excess*** weight gain, it seemed appropriate to

Sample PAN prescription messages
"Make a list of all the physical activities you like to do, for example, jumping rope, playing tag, dancing, soccer. Put the list where you can see it every day. Pick 1 or more activities off the list to do each day."
"What types of drinks do you drink? Replace an unhealthy drink (like soda, fruit punch, sweetened coffees or teas, energy drinks) with a healthy drink (water, non-fat or low-fat milk, small amounts of 100% fruit juice) at least once a day. Ask your family NOT to keep unhealthy drinks at home. Help your friends or family to make healthy drink choices too. Keep working to cut out the unhealthy drinks until they are just an occasional treat."
Sample TOB prescription messages
"Secondhand smoke is smoke from someone else's cigarette. If you see or smell cigarette smoke, you are breathing it. Chemicals from cigarettes can land on your hair & clothes, making you smell. Get up and walk away if someone lights up a cigarette near you. Why would you want to smell like a smoker, if you're not one???"
"Tobacco companies spend 35 million dollars per day on cool advertisements & promotions knowing that 3,500 kids try a cigarette every day in the U.S. Next time you see a tobacco ad in a store or in a magazine, think about who they are targeting and how. Be smarter than the tobacco companies, don't fall for their tricks."

Fig. 3. Sample health "prescriptions".

investigate the subsample for whom a substantial increase in BMI might constitute an increase in health risk. If a child with an already quite low BMI were to gain weight and attain a more nearly normal BMI, we wouldn't consider that an increase in health risk. Therefore, we omitted the 75 children (11% of the sample: 40 TOB, 35 PAN) who had a baseline BMI z-score of less than negative one, and ran our sensitivity analysis on the remaining 89% subsample.

2.3.5. Dose of intervention

To assess whether dose of the intervention mediated intervention effects, we used four measures: the number of prescriptions received by a participant 1) for PA, 2) for nutrition, 3) for PA or nutrition; and 4) the average number of PAN media displayed in each orthodontic office over the span of the intervention. However, none of our 4 measures of intervention dose were significantly correlated with any outcome for which a significant effect was found, thereby failing a necessary condition for mediation of effect [16]. Thus, we found no evidence of a dose-response relationship.

2.3.6. Analytic procedures

Hierarchical analytical models were used to account for intra-class correlation due to clustering by orthodontic office and by repeated measures within individuals across time. Many children reported half or quarter servings of dietary items, so food variables could not be analyzed as count data. However, these variables presented good approximations of the normal distribution when log transformed, so we used the transformed variables for analyses. Group by time effects were determined in Stata using the *xtmixed* procedure for continuous BMI and diet outcomes, and *mepoisson* for PA count outcomes. For BMI, we tested models with and without random coefficients for time (number of days from baseline), and found that specifying random coefficients (slopes) substantially improved fit of the data, according to Bayesian information criteria (BIC) and Akaike information criterion (AIC) values. Therefore, a model with both random intercepts and random coefficients was specified.

All analyses were computed using robust standard errors. Effect sizes were computed using a procedure for linear models having three or more time points [17]; estimates were based on a one-year study duration. Analyses were performed using SPSS version 23 (IBM, Inc., Armonk, NY) and Stata version 13 (StataCorp, College Station, TX).

3. Results

3.1. Sample characteristics

Of 2982 families contacted, 2124 (71%) were screened, 991 (33%) qualified, and 693 (23%) completed the study consent process and enrolled between 2010 and 2013, yielding a 70% (693/991) enrollment rate. At enrollment, children's mean age was 12.1 years old (SD 1.9), 56% were female, 41% non-Hispanic White, 40% Hispanic, 5% non-Hispanic Asian/Pacific Islander, 5% non-Hispanic multi-racial, 2% non-Hispanic Black or African American, 3% White with no ethnicity reported, and 3% of unknown race or ethnicity. Eighty percent (551) of participants attended US offices while 20% (142) attended MX offices; 14% of participants were overweight (85th to 95th percentile BMI) and 10% were obese at baseline [18].

Demographic variables and baseline values of outcome variables were tested for differences by experimental group (Table 1). The only significant difference was an imbalance in assignment to experimental group by country of orthodontic office: 56.1% of participants in the US were in the TOB control group, as opposed to 36.7% in Mexico.

3.2. Analyses of outcome variables

Tests of group by time interaction and moderation effects, and plots of predicted values of the regression model for each outcome, were based on intent-to-treat analyses; i.e., they included all available data at each time point on individuals. Results of sensitivity analyses computed on subsets are reported separately.

3.2.1. BMI outcome

As duration of participant time in the study increased, BMI z-scores decreased for the PAN group and increased for the TOB group. Differential change was small and nonsignificant ($p = 0.301$).

3.2.2. Moderation of BMI outcome

A significant 3-way interaction was found for gender ($p = 0.013$), indicating moderation of the group by time effect on BMI by this factor (Fig. 4). Among females, the group by time effect on BMI was not significant; among males, intervention group BMI declined while control group BMI increased ($p < 0.001$). The estimated effect over a year of study participation was a difference of 0.093 BMI z-scores lower (Cohen's $d = 0.085$).

3.2.3. Diet outcomes

The only significant group by time effect on the four dietary outcomes—dairy, sugar sweetened beverages, junk food, and fruits & vegetables—was for junk food ($p = 0.020$). PAN participants decreased junk food intake over time relative to TOB participants. The estimated difference was 0.122 fewer junk food items consumed in the intervention group after a year in the study ($d = 0.118$).

3.2.4. Moderation of diet outcomes

The four diet outcomes were tested for moderation by each of the five potential moderating variables. The only significant 3-way interaction was among group, time, and overweight/obese status for the junk food outcome ($p = 0.009$), indicating moderation of effect. Among normal weight participants, the group by time effect was not significant. Among overweight/obese participants, junk food consumption declined in the PAN group relative to those in the TOB group ($p = 0.001$). See Fig. 5. This equates to an average of 0.292 fewer junk food items consumed per day by the overweight/obese PAN participants after a year in the study relative to their counterparts in the TOB group ($d = 0.335$).

3.2.5. PA outcomes

There were no group by time effects for PA on either school days or non-school days. Moderate/vigorous PA counts declined over time in both groups, both on school days ($p < 0.001$) and on non-school days ($p < 0.001$). Fig. 6 illustrates these declines, as well as the substantially lower frequency of PA on non-school days than on school days. We found no moderating effects for any of the five candidate factors.

3.2.6. Effect of gender on PA

Levels of PA were higher for males ($p < 0.001$). The declines in PA over time on school days for both males ($p < 0.001$) and females ($p < 0.001$) did not differ significantly by gender (Fig. 7). The results for non-school days were similar.

3.2.7. Sensitivity analyses

For all significant effects in the foregoing analyses, the applicable sensitivity analyses also found significant effects, with a single exception: the significant 3-way interaction of group, time, and overweight/obese status for the junk food outcome was only near significant ($p = 0.075$) when restricted to a consistent cohort. However, among the overweight/obese participants in that consistent cohort, junk food consumption still declined significantly in the PAN group relative to the TOB group ($p = 0.009$). It is reassuring that, in general, sensitivity analyses confirmed results of our intent-to-treat analyses, especially since power was attenuated due to the smaller size of the subsamples used.

Table 1
Participant demographics and baseline outcome measures (n = 693[a]).

	Control (n = 361)		Intervention (n = 332)	
Country of orthodontic office				
United States	85.6%		72.9%	
Mexico	14.4%		27.1%	
Median income of orthodontic office census tract[b]				
Below median for county of office	61.2%		55.0%	
Above median for county of office	38.8%		45.0%	
TC[c] is female	55.4%		56.6%	
TC age, years				
≥8 to < 10	17.2%		14.8%	
≥10 to < 12	29.6%		27.1%	
≥12 to < 14	38.2%		40.7%	
≥14 to 16	15.0%		17.5%	
TC race/ethnicity				
Hispanic	35.7%		45.2%	
Non-Hispanic White	47.1%		40.1%	
Non-Hispanic other[d]	17.2%		14.8%	
Family income				
Less than $20,000	14.6%		20.8%	
$20,000 to $69,999	25.1%		25.1%	
$70,000 to $134,999	42.0%		33.6%	
More than $135,000	18.3%		20.5%	
TP[e] education				
High school diploma or less	23.8%		26.3%	
> High school, < 4 year college degree	34.0%		33.7%	
4 year college or graduate degree	42.2%		40.0%	
TP is employed	68.5%		69.4%	
TP is a single parent	15.6%		19.0%	
	Mean	SD	Mean	SD
TP BMI (mean, standard deviation)	27.25	6.02	27.79	5.92
TC BMI z-score (age & gender adjusted; mean, standard deviation)	0.22	1.08	0.26	1.12
Diet (number of servings; geometric mean, 95% confidence interval)	Geometric mean	95% CI	Geometric mean	95% CI
Dairy	1.71	(1.59, 1.83)	1.76	(1.64, 1.89)
Sugar sweetened beverages (SSB)	0.67	(0.61, 0.72)	0.66	(0.60, 0.72)
Junk food	1.23	(1.15, 1.31)	1.25	(1.16, 1.34)
Fruits & vegetables	2.45	(2.27, 2.64)	2.32	(2.14, 2.52)
Moderate/vigorous physical activity count	Median	IQR	Median	IQR
School day	1	(0, 2)	0	(0, 1)
Non-school day	1	(0, 2)	0	(0, 1)

CI = confidence interval; IQR = interquartile range (25th & 75th percentiles).
[a] Enrolled sample.
[b] TC = target child.
[c] TP = target parent.
[d] Not assessed for Mexico.
[e] Non-Hispanic other includes Black, Asian, Pacific Islander, and Native American.

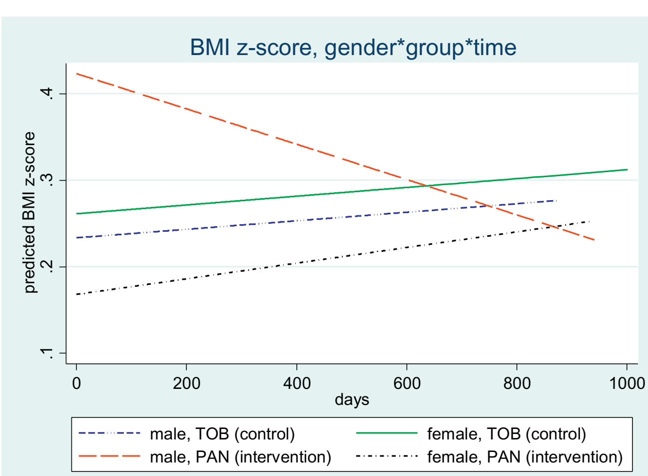

Fig. 4. Change in BMI by group and gender.

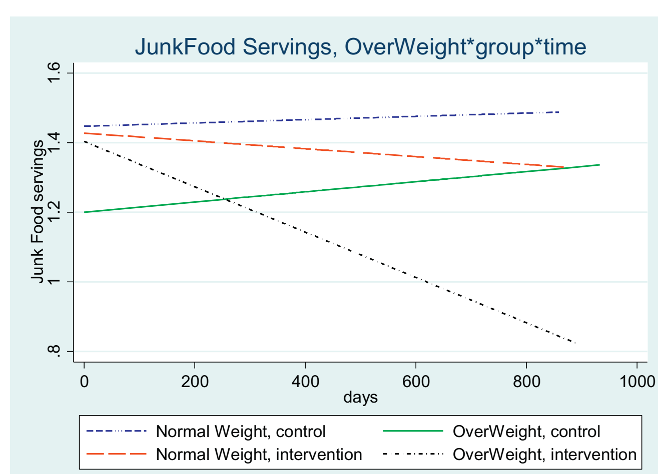

Fig. 5. Change in junk food consumed, by group and overweight/obese status.

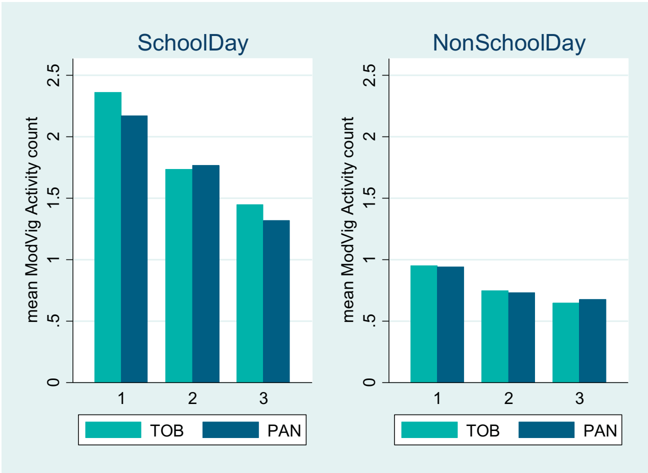

Fig. 6. Change in PA counts by group, for school days and non-school days.
Note: Outcomes are mean daily counts of moderate/vigorous physical activity. X-axis numbers indicate points of measurement: 1 = baseline; 2 = 12 months; 3 = 18 months.
Because distributions for the two groups were quite similarly skewed at each of the 3 measurement points, the mean, while not an optimal indicator of central tendency, is informative for group comparisons.
TOB = control condition; PAN = intervention condition.

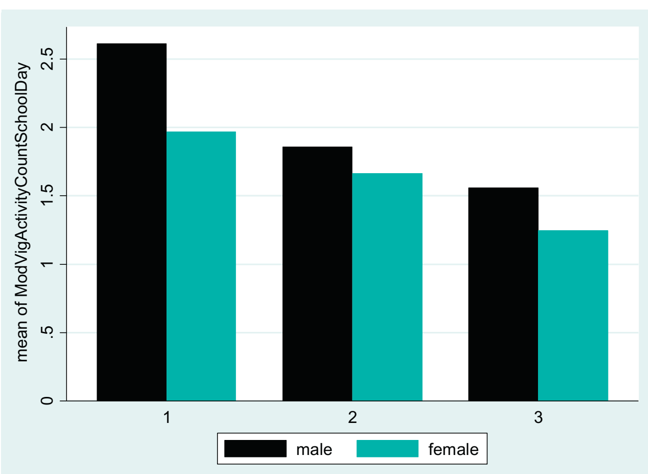

Fig. 7. Change in PA by gender, for school days.
Note: Outcomes are mean daily counts of moderate/vigorous physical activity. Because distributions for the two genders were quite similarly skewed at each of the 3 measurement points, the mean, while not an optimal indicator of central tendency, is informative for comparisons by gender.
X-axis numbers indicate points of measurement: 1 = baseline; 2 = 12 months; 3 = 18 months.

4. Discussion and conclusion

4.1. Discussion

4.1.1. Summary of findings

Over time, BMI increased for both genders in the control group, while in the intervention group female BMI increased and male BMI decreased, suggesting the intervention was effective only among male participants.

For junk food, consumption declined more strongly among intervention participants. Moderation analysis revealed that the significant differential effect between experimental conditions occurred within the overweight/obese subset. It is perhaps welcome that those in greatest need of weight reduction were affected the most. It may be that those in the normal weight range, with less need for weight reduction, were less motivated to reduce their junk food intake.

These findings of statistically significant effects for BMI and junk food consumption were in general supported by sensitivity analyses—which provided more stringent tests of relationships. The sensitivity analyses serve as reliability tests, enhancing the probability that our significant findings were real, rather than just artifacts of our particular sample of participants. This evidence of the robustness of our results bolsters confidence in the implication that the beneficial outcomes seen in our child sample indicate results that would be obtained in a population intervention with youth.

No effects on PA levels were seen that might be attributed to the intervention. Irrespective of gender or experimental condition, physical activity decreased over time, consistent with reports in the literature [19] and consistent with results from our earlier PA trial [20]. Though this may be due in part simply to the aging of participants over the approximately two-year duration of their participation in the study, it is nevertheless worrisome given the considerable evidence of health benefits from adequate exercise. It was also noteworthy that more than twice as much PA was reported on school days as on non-school days, implying that kids may depend on scheduled, organized, or even mandatory activities for much of their exercise. If this is true, students may not be well prepared for obtaining PA independently.

4.1.2. Limitations

Study fidelity was less than optimal, due to incomplete compliance with the planned intervention by some offices. Only 61% of the PAN intervention group received at least one prescription *and* attended an office that displayed at least some PAN media at any point during the study. A full 13% of that group received no measureable intervention. Offices cited lack of time, forgetfulness, and patients missing appointments as barriers to prescription delivery, and space availability and conflicts with office décor as barriers to media display. Protocol was for staff to record height and weight data on the triplicate-copy prescription. For participants not provided an Rx at an office visit, or when height and weight measurements were not recorded by orthodontic staff, participant data were missing for that visit.

Random assignment of offices to condition resulted in different proportions of participants in the PAN treatment group in the US versus Mexico. This occurred due to the widely varying number of patients in each office and differing rates of success in enrolling patients.

Families recruited into our study had a somewhat higher than average income level, possibly limiting the generalizability of findings to the general youth population. While the intervention should be tested on a larger and more representative sample, the same mechanisms of behavior change should operate for any group of children, regardless of their demographic characteristics.

4.1.3. Prior studies

The literature on diet and PA interventions in primary care to combat obesity is extensive; the number of relatively recent review articles is indicative of the research volume [21–29]. Among these, only two reviews dealt with children, and the studies were primarily of overweight/obese individuals. Vine et al. [27] reviewed 63 child interventions, of which only 20 had a statistically significant effect on participants' weight or weight status. The meta-analysis by Sim et al. [28] found the effect of brief child obesity interventions in primary care on BMI was only marginal, and of doubtful clinical significance.

Moreover, interventions in Sim et al., though nominally “brief”, were generally more involved than ours. Our study may be best characterized as a “very brief intervention”, as described in Pears et al. [30], which found weak, inconclusive evidence for the effectiveness of very brief PA interventions.

Even two recent reviews of interventions with overweight/obese children that were not restricted to brief trials or to primary care settings were sobering about prospects of desirable outcomes. Mead et al. [31] found an average effect across 37 diet and PA trials on BMI z-score of only 0.06 units. Nooijen et al. [32] found no evidence that interventions could increase PA.

Given these limited results, it is less surprising that findings in our study were not more encouraging.

4.2. Conclusion

Based on our original power and sample size analysis for the study, our targeted sample size was 1700 child participants. Though we made repeated and vigorous efforts to encourage orthodontists to enroll their offices in the program, the orthodontist participation rate was low, and we were able to identify only 991 qualified children. So despite a 70% enrollment rate, our final sample was only 693 child orthodontic patients (41% of the target). Nevertheless, we were able to detect small but significant effects in the desired/expected direction for changes in junk food consumption and for BMI among males. The effect on patients' behavior change based on the input from a single type of clinician would not be expected to be large. The rationale of the Rose logic, as we argued in the Introduction, is by having many types of healthcare practitioners provide their clients with encouragement to exercise and eat nutritious food, the density of reinforcement for positive health behaviors would be sufficiently great to exert a salubrious effect on obesity. In spite of limitations, the findings of our study of orthodontic practices, which have more frequent contact with clients than most other medical specialties, lend modest, cautious support to the credibility of that logic.

While changes in behavioral and health outcomes were small, and significant only in a couple of instances, results hint at what could be accomplished to a greater extent should more clinicians be involved in prevention efforts or if the intervention were delivered with higher fidelity and at a higher dose.

4.3. Implications

Orthodontists in both arms of our intervention were moderately successful at delivering non-oral health prevention advice and counseling. Orthodontists can serve as another key source of prevention, normalize discussions of healthy diet and activity, and add to the cumulative population effect if all medical, dental, and school providers participated in such interactions.

We also recruited orthodontic patients in an earlier trial aimed at preventing adolescent smoking initiation [33,34]. That trial resulted in the successful recruitment of orthodontic offices (154 enrolled) and clear, statistically significant results, albeit small effects in reduced smoking incidence rates.

The current trial found limited and small effects in the context of fewer offices (33 enrolled) than planned and thus fewer adolescents than targeted. We suspect that economic circumstances were more favorable during the previous trial, when competitive practice pressures were less fierce. Moreover, in the previous trial 64.4% of the intended 8 prescriptions per child were delivered, as compared to only 35.8% of the targeted 12 prescriptions in the current trial. Thus, our limited significant findings are encouraging in light of our previous success with orthodontic offices.

Adolescent patients in orthodontia remain a promising clinical population for demonstrating population prevention effects. However, future trials may require greater funding in order to recruit and train enough orthodontists to obtain and faithfully intervene with a sufficiently large child patient sample. Future studies may require more intensive (even if brief/minimal) interventions in order to increase and sustain physical activity. This might be possible by including micro-incentives both for orthodontists' prescriptions to increase physical activity and for patients' increased activity [35].

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Compliance with ethical standards

All procedures performed involving human participants in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The San Diego State University Committee for the Protection of Human Subjects approved all procedures for this study. Informed consent was obtained from all adult participants included in the study. Informed assent was obtained from all child participants included in the study. The authors confirm that all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details provided.

Compliance with publication standards

This manuscript has not been published previously, and is not under submission elsewhere. The content is solely the responsibility of the authors and does not necessarily represent the official views of the funding agency. All authors declare that they have no conflicts of interest in relation to this manuscript. All authors participated materially in the conduct of the research, and all have reviewed and approved the manuscript for publication. If accepted, the manuscript will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

Registration number and name of trial registry

NCT01510483; ClinicalTrials.gov.

Where the full trial protocol can be accessed

https://clinicaltrials.gov/ct2/show/record/NCT01510483?term=Healthy+Smiles&rank=1.

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