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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-genderadiusted 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.

 $[\]stackrel{\star}{\sim}$ 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.

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

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