ORIGINAL REPORT: EPIDEMIOLOGIC RESEARCH

Randomized Trial Based on the Common-Sense Model of Self-regulation to Increase Child Dental Visits

S. Nelson¹, P. Milgrom², J.M. Albert³, D. Selvaraj¹, J. Cunha-Cruz², S. Curtan¹, T. Copeland¹, M. Heima⁴, M. Rothen², G. Beck⁵, G. Ferretti⁴, and C. Riedy⁶

Abstract: Introduction: School screening and the note home (pinned to a backpack) informing parents/caregivers that their child needs to see a dentist have not been effective.

Objectives: The Family Access to a Dentist Study (FADS) evaluated the effectiveness of school interventions based on the common-sense model of self-regulation (CSM) among K–4 children needing restorative treatment.

Methods: FADS was a multisite double-blind randomized controlled trial with 5 arms. FADS tested a CSM-driven referral letter and dental information guide (DIG) to move caregivers from inaccurate to accurate perceptions of dental caries. Six school districts from Ohio and Washington (14 schools) participated in school years 2015 to 2016 and 2016 to 2017. A total of 611 caregivers were randomized, and 86% (n = 597 children) completed the exit examination. The

primary outcome was receipt of care based on a change in oral health status determined clinically within 1 school year.

Results: In accordance with our primary aims, 5 arms were collapsed into 3: CSM letter and reduced CSM letter (combined), CSM letter + DIG and reduced CSM letter + reduced DIG (combined), and standard letter. Among all sites, 39.7% received restorative care (237 of 597). Combined analysis of sites revealed that the CSM referral letter (with and without the DIG) did not increase dental visits when compared with the standard letter. However, for combined sites (East Cleveland, Ohio; Washington), the CSM + DIG increased dental visits when compared with standard letter in univariate analysis (51.3% vs. 40.9%), indicating 1.6-times increased odds of a dental visit (95% CI, 0.97 to 2.58) after imputation and adjustment for covariates. The CSM + DIG group had 1.9-times increased odds

(95% CI, 1.21 to 3.08) of care when compared the CSM letter alone.

Conclusion: A CSM-driven approach to informing caregivers of the chronic nature of caries with resources in an illustrative manner can increase the benefit of school oral health screening (ClinicalTrials.gov NCT02395120).

Knowledge Transfer Statement: A school dental referral (note home) that tells a parent that the child has cavities has not been effective. In this trial, a referral based on the common-sense model of self-regulation increased follow-up care for children with restorative needs.

Keywords: illness behavior, models/psychological, self-care, dental caries, clinical trial, oral health

Introduction

School screening for tooth decay and subsequent standard referral (i.e., a note

DOI: 10.1177/2380084419830662. ¹Department of Community Dentistry, School of Dental Medicine, Case Western Reserve University, Cleveland, OH, USA; ²Department of Oral Health Sciences, University of Washington, Seattle, WA, USA; ³Department of Population and Quantitative Health Sciences, School of Medicine, Case Western Reserve University, Cleveland, OH, USA; ⁴Department of Pediatric Dentistry, School of Dental Medicine, Case Western Reserve University, Cleveland, OH, USA; ⁵Department of Quantitative Health Sciences, Cleveland Clinic, Cleveland, OH, USA; ⁶Department of Oral Health Policy and Epidemiology, Harvard School of Dental Medicine, Boston, MA, USA. Corresponding author: S. Nelson, Department of Community Dentistry, Case Dental School, 10900 Euclid Ave, Cleveland, OH 44106-4905, USA. Email: sxn15@case.edu

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home specifying that the child has cavities and to see a dentist) have not been effective in increasing follow-up dental care for children (Milsom et al. 2006; Nelson et al. 2012). In contrast, the common-sense model of self-regulation (CSM) has been a useful theoretical framework for developing behavioral interventions (e.g., informational letters and brochures) for care seeking and treatment adherence among patients with diabetes (McAndrew et al. 2008), asthma (McAndrew et al. 2008), cardiac rehabilitation (Mosleh et al. 2014), and psoriasis (Nelson PA et al. 2017). The CSM is a self-regulatory framework that outlines how individual's cognitive (identity, consequences, cause, timeline, control constructs) and emotional representation/perception of one's chronic illness guides his or her coping and action planning to self-manage the disease (Leventhal and Brissette 2003). Using the CSM theory and the Illness Perception Questionnaire-Revised for Dental (Nelson et al. 2016), we recently showed that parents/caregivers who believed that baby teeth do not matter had a significantly less accurate illness perception of dental caries, a greater proportion of children with cavities, and a lower proportion of children ever having a dental visit as compared with caregivers who believed that baby teeth do matter (Nelson S et al. 2017). However, no study has used the CSM framework to develop dental interventions.

The primary objective of the Family Access to a Dentist Study was to evaluate the effectiveness of new referral interventions (CSM-based referral letter alone, CSM referral letter + dental information guide [DIG]) as compared with a standard referral letter sent home and mailed to parents/caregivers for increasing dental visits among their K–4 children with restorative dental needs. We hypothesized that the CSM-based interventions would increase follow-up dental visits as compared with the standard referral letter.

Methods

The Institutional Review Board of the University Hospitals Cleveland Medical

Center approved the study protocol. Written consent (parent) and assent (children >7 y) was obtained in English or Spanish. This protocol follows the CONSORT guidelines (Lee et al. 2014) and relevant extensions (Montgomery et al. 2013).

Study Design

The Family Access to a Dentist Study was a multisite double-blind randomized controlled trial with 5 parallel arms (Nelson et al. 2015). The sites were Ohio and Washington (WA), with 14 elementary schools participating from 6 school districts. Originally, only 1 school district from Ohio (East Cleveland [EC]) and 4 school districts in WA were planned, with recruitment completed during 1 school year (2015 to 2016), but because of low enrollment in these school districts and the inability to meet the sample size requirements, we added another school district (Bedford [BD]) in Ohio for the 2016–2017 school year. Participants were enrolled between August and October in 2015 and 2016. Final examinations were conducted between May and June in 2016 and 2017.

Participants

All study sites followed a 2-stage process for recruitment during 2 school years: 1) all caregivers of K–4 children (aged 5 to 10 y) who were enrolled in the participating schools (8 schools at the Ohio site, 6 schools at the WA site) were invited to have their children participate in the dental screening; 2) participants were screened, and those caregivers who fulfilled the inclusion criteria were enrolled into the clinical trial. Inclusion criteria for caregivers and their children at the first stage (i.e., dental screening) included the following: signed and dated consent and assent; willingness to comply with all study procedures and availability for the study duration; and child in good general health as evidenced by parent report (including children with special health care needs). Additional inclusion criteria in the second stage (i.e., for trial enrollment and randomization) were

as follows: caregivers were randomized if their child had primary (canines and molars) or any permanent tooth with an International Caries Detection and Assessment System (ICDAS) active lesion score ≥ 2 (localized enamel changes to extensive cavity). Exclusion criteria were caregiver illiteracy, age <18 y, or child with no cavities (ICDAS lesion code <2). Outreach staff were hired from the local community to assist with recruitment at school-based events.

Interventions

The Family Access to a Dentist Study employed a multicomponent strategy (psychosocial and resources) consisting of a CSM-based referral letter and a DIG to move caregivers from inaccurate to accurate perceptions of dental caries to self-manage their children's cavities. The 2 core psychosocial issues addressed in the new letter and DIG were as follows: 1) importance of cavity-free primary teeth for protection of permanent teeth and 2) understanding dental caries as a chronic disease rather than acute. The third core issue addressed providing resources to navigate dental care access (information in a DIG and list of area dentists).

The experimental referral letter and DIG were based on the 5 cognitive constructs of the CSM framework (identity, cause, consequence, timeline, control) and were previously described in detail (Nelson et al. 2015). Based on our primary objective, the study had 3 main arms. The 2 reduced-letter arms (arms 3 and 4) were relatively minor variations of the main arms (arms 1 and 2, respectively) for exploratory purposes.

Arm 1: CSM-based referral letter only—addressed the chronicity of dental caries through the 5 CSM cognitive constructs (Appendix Fig. 1).

Arm 2: CSM-based referral letter + DIG—used the same letter as arm 1 + the DIG. The DIG was presented in English or Spanish as a pictographic brochure providing facts and myths about dental

caries, information on making dental appointments, Medicaid access, transportation, and a list of dentists in the area (Appendix Fig. 1).

Arm 3: reduced CSM-based referral letter only—text of the letter did not contain the timeline construct but included all 4 other CSM construct texts. Since the timeline text related to the chronicity of dental caries, the rationale was that removing this text could allow for the estimation of the effect of this construct itself.

Arm 4: reduced CSM-based referral letter + reduced DIG—included the same letter as arm 3 + a reduced DIG with removal of timeline construct information.

Arm 5: modified standard letter only—based on the “Guidelines for Oral Health Screening in Ohio Schools” (Ohio Department of Health 2007 [no longer available, updated 2018]) and consistent with others used across the country (see Appendix Fig. 2).

The intervention letters were pilot-tested for readability and clarity with caregivers of K–4 children. Both English and Spanish versions were at the sixth-grade reading level or lower. The intervention delivery was as follows: referral letters based on the study arm were sent home with the child on the same day of the dental screening; copy of the letters were also mailed to the caregiver’s address within 24 h of the screening; and outreach staff called the caregivers within 48 h of the screening to ensure that they received the letters. Fidelity monitoring of the receipt of intervention is detailed in the Appendix.

Measures

The primary outcome was receipt of dental care based on a change in the child’s oral health status, as determined by clinical examinations between baseline screening (beginning of school year) and follow-up at study exit (end of school year). Dental examinations

were conducted in a portable dental chair in the schools by a dental examiner trained and calibrated in the ICDAS. Six examiners (3 for each site) were trained by a gold standard examiner in the ICDAS protocol, in a 4-d training and calibration session prior to the start of recruitment. The interexaminer κ was 0.77 to 0.95, and the intraexaminer κ was 0.78 to 1.0. Examiners did not utilize dental radiographs.

The decision rules for determining the receipt of dental care are given in Appendix Table 1. In general, a child was classified as having received dental care if she or he had any tooth at follow-up with an ICDAS sealant code (1 or 2), restoration code (3 to 8), or extraction code (X), previously identified at baseline as an active ICDAS lesion code ≥ 2 . All extracted teeth were assumed to have been lost to primary caries. At least 2 attempts were made to complete the ICDAS baseline screening and follow-up examination to avoid missing data.

Moderators and Covariates

Caregivers completed a baseline questionnaire to assess moderators and covariate variables. These included child’s grade, race, previous dental visit, and caregiver sociodemographics (age, race, education, occupation, marital status) with standard questions from National Health and Nutrition Examination Survey III (Centers for Disease Control and Prevention n.d.).

Additionally, postintervention at 2 wk and exit, caregivers were asked debriefing questions pertaining to their child’s receipt of dental care. This information was used qualitatively to describe whether the child received care, whether treatment was completed, and, if not, whether a follow-up appointment had been made and what helped or hindered the caregiver to take the child to the dentist.

Sample Size

The following assumptions were made for sample size calculation: 19% rate of dental care receipt for standard letter (Nelson et al. 2012), 37% rate for

new letter alone (based on Medicaid utilization among children; US General Accounting Office 2008), 57% rate for new letter + DIG (based on 57% who reported in a pilot study that they took their children to the dentist or had an appointment after receiving the intervention; unpublished data). Then, with a 2-sided Z test for equal proportions and to account for any dropouts, a sample size of 306 subjects per site ($N = 660$) would provide $\geq 80\%$ power to detect rate differences of 1) standard versus new and 2) new versus new + DIG for each site, in addition to each comparison with the combined sample.

Randomization

Caregivers of children with restorative needs were randomized and allocated to 1 of the 5 study arms in a ratio of 17:17:2:2:17. The 2 reduced-letter arms had a lower sample size (12 caregivers per arm per site) randomized to these conditions, while the other 3 main arms each had 102 caregivers per arm per site. Stratified randomization was based on school and grade. The caregivers with multiple children received the same treatment based on the school and grade of 1 of their first eligible children. Permuted blocks were used to ensure approximately the targeted treatment proportions within strata. Specifically, we used multiple Latin squares to obtain close to the targeted allocation ratios marginally for each grade, school, and site while also using, through the permuted blocks, a random order of interventions within each stratum (grade within school within site).

Blinding

Only the biostatistician and data manager were aware of the blocking scheme and the actual assignments. All other study staff members, examiners, and participants were blinded. To maintain the blinding, all referral letters were generated by the data manager according to study arm and either enclosed in packages to be delivered at school or sent by mail to caregiver. At

follow-up, the examiners did not have access to the results of the baseline examinations to avoid detection bias.

Statistical Methods

The primary outcome analysis was to compare dental care receipt among the study arms, overall and separately for study sites. We assessed 3 main treatment comparisons: CSM referral letter versus standard letter (arms 1 and 3 vs. arm 5), CSM referral letter + DIG versus standard letter (arms 2 and 4 vs. arm 5), and CSM referral letter alone versus CSM referral letter + DIG (arms 1 and 3 vs. arms 2 and 4). An alpha level of 0.05 was used to determine statistical significance.

Descriptive statistics included frequencies by intervention group for categorical variables. Pearson chi-square tests were performed as initial, and unadjusted, tests for group differences. The focus was on 3 intervention groups obtained by combining related arms (1 and 3; 2 and 4). The primary analysis utilized generalized estimating equations (GEEs) with a logit link for the binary dental care receipt outcome. This approach allowed for clustering of children (i.e., siblings) by caregiver via an exchangeable working correlation structure or an independence structure, in cases where convergence with the former was not obtained. The GEE analysis was conducted with dental care receipt outcomes as restorative care alone (ICDAS codes ≥ 3) as well as combined preventive (i.e., sealants) and restorative care (ICDAS codes ≥ 1). Models were fit separately to the overall data (all sites combined), the combined EC and WA sites (based on our original plan of 2 predominantly low-income school districts), and the BD schools alone. Each model included, as covariates, indicator variables for intervention, site (except for the model with BD alone), child grade, and caregiver demographic variables (race, education, marital status). Wald tests or generalized score tests for multivariate hypotheses were conducted to test for intervention and other covariate effects.

Corresponding estimated odds ratios and 95% CIs were also computed.

To assess the sensitivity of results to missing covariate data, we used a multiple imputation approach in conjunction with the GEE analyses. Specifically, we used a fully conditional specification with logistic regression imputation to produce 20 independent completed data sets and combined GEE results to provide overall inference (e.g., for intervention effects; Rubin 1976).

Results

A total of 1,333 parents/caregivers with 1,681 K–4 children consented to participate in the baseline dental screening at the beginning of the school year (phase 1). Out of 1,584 children screened, 694 had untreated cavities that needed restorative care. The caregivers of these children ($n = 611$) were randomized to the 5 arms of the study (Figure). About 86% of the children ($n = 597$) completed the exit dental examination. The analysis sample was 597 children who completed baseline and exit dental examinations. The participants were similar to nonparticipants in all child and caregiver characteristics except that Medicaid coverage was significantly greater among nonparticipants (Appendix Table 2).

In accordance with our primary aims, the 5 arms of the study were collapsed into 3 main arms since the 2 smaller reduced-letter arms were exploratory: CSM letter and reduced CSM letter combined ($n = 202$), CSM letter + DIG and reduced CSM letter + reduced DIG combined ($n = 209$), and standard letter ($n = 186$). Table 1 indicates that the participants randomized to the 3 arms were similar in all child and caregiver characteristics. There were no baseline differences in mean number of decayed primary and permanent teeth among the groups. A total of 257, 205, and 135 children belonged to EC, WA, and BD school districts, respectively. The original 2 school districts (EC and WA) selected for the study were chosen for enrolling predominantly low-income

and diverse racial/ethnic groups, and as expected, the school districts were significantly different in terms of race, ethnicity, education, and marital status. But EC and WA were similar in Medicaid participation (indicating lower socioeconomic status) as compared with BD, which was added later (Table 2), justifying the analysis of BD separately.

Among all sites (Table 3), 39.7% of participants (237 of 597) received restorative care. In the analysis of EC and WA combined, 42.9% received restorative care (198 of 462); for BD, 28.8% received care (39 of 135). Bivariate analysis (Table 2) indicated no significant differences in restorative care received among the 3 arms when all sites were combined. But stratification of sites (i.e., EC and WA combined and BD separately) indicated important differences. In EC and WA combined, a significantly greater proportion (51.3%) received restorative dental care in the CSM + DIG group as compared with the standard group (40.9%), but there was no difference in the CSM letter alone as compared with the standard group. In BD, there was a trend toward significance for the CSM letter alone (42.1%) versus the standard group (29.6%), but no differences were found between the CSM + DIG group and the standard group.

Covariate data were missing for 121 participants among all sites (95 in EC and WA combined and 26 in BD). The GEE model (Table 3) for all sites without imputation for covariates (race, grade, education, marital status, site), resulting in a lower analysis sample, indicated no significant differences in the restorative care receipt among the 3 arms, a 2-fold increased odds of the CSM + DIG group receiving restorative care as compared with the CSM letter alone for EC and WA, and 69% lower odds of receiving care with CSM + DIG versus the CSM letter alone for BD.

The GEE model with imputation for covariates, by taking advantage of the entire sample (Table 3), indicated 1.6 increased odds of restorative care receipt ($P = 0.065$) for the CSM + DIG arm versus the standard group for the EC and WA sites combined. The CSM + DIG group

Figure. Flowchart of recruitment, allocation, and follow-up. CSM, common-sense model of self-regulation; DIG, dental information guide.

had significantly increased restorative care (odds ratio = 1.93, 95% CI: 1.21 to 3.08) as compared with the CSM group for the EC and WA sites, but for BD schools, CSM + DIG group had significantly lower dental care (odds ratio = 0.29, 95% CI: 0.10 to 0.83) versus the CSM group. When dental care receipt included sealants and restorative treatment, there were no significant differences in any of the analyses (Appendix Table 3).

Discussion

This is the first study to utilize a theory-based referral letter with the CSM framework to improve dental utilization among elementary schoolchildren. Letters were sent home with the child and also mailed. Previous behavioral interventions to increase dental visits or improve oral health behaviors used other health behavior theories (e.g., social cognitive

theory) and focused on oral health behavior modifications through changing parental oral health knowledge, beliefs, and attitudes (Cooper et al. 2013; Gao et al. 2013; Hull et al. 2014). Oral health education and motivational interviewing have been most often used as behavioral interventions to improve dental access, but they have been largely ineffective or the results inconclusive (Yevlahova and Satur 2009; Cascaes et al. 2014).

Table 1.

Descriptive Analysis Based on Study Arms in the Family Access to a Dentist Study.

	CSM Letter (<i>n</i> = 202)	CSM Letter + DIG (<i>n</i> = 209)	Standard Letter (<i>n</i> = 186)	<i>P</i> Value
Child				
Grade				>0.99
1 (kindergarten)	20.8 (42)	18.7 (39)	21.0 (39)	
2 (first)	19.8 (40)	21.5 (45)	22.0 (41)	
3 (second)	20.3 (41)	20.1 (42)	19.9 (37)	
4 (third)	19.3 (39)	21.1 (44)	20.4 (38)	
5 (fourth)	19.8 (40)	18.7 (39)	16.7 (31)	
Caregiver				
Education				0.35
1 (>high school)	53.0 (90)	53.9 (98)	46.6 (75)	
0 (≤high school)	47.1 (80)	46.2 (84)	53.4 (86)	
Marital status				0.33
1 (married)	32.2 (55)	25.1 (46)	27.6 (45)	
0 (other)	67.8 (116)	74.9 (137)	72.4 (118)	
Race				0.77
1 (Black)	61.1 (99)	57.2 (99)	58.6 (92)	
0 (not Black)	38.9 (63)	42.8 (74)	41.4 (65)	
Ethnicity				0.24
1 (Hispanic)	20.2 (22)	15.9 (18)	11.5 (11)	
0 (not Hispanic)	79.8 (87)	84.1 (95)	88.5 (85)	
Age, y	33.9 ± 7.0 (152)	34.4 ± 9.5 (170)	32.9 ± 8.3 (151)	0.29
Child: clinical				
Decayed teeth at baseline, <i>n</i>				
Primary	2.0 ± 1.9 (202)	1.8 ± 1.9 (209)	2.0 ± 2.0 (186)	0.49
Permanent	0.6 ± 1.0 (202)	0.8 ± 1.2 (209)	0.8 ± 1.1 (186)	0.06
Child: dental visits and coverage				
Ever had a dental visit				0.85
Yes	90.6 (155)	89.1 (163)	89.0 (145)	
No	9.4 (16)	10.9 (20)	11.0 (18)	
Any dental insurance				0.83
Yes	83.3 (135)	85.6 (149)	83.9 (135)	
No	16.7 (27)	14.4 (25)	16.2 (26)	
Medicaid coverage				0.92
Yes	81.4 (105)	80.1 (113)	79.4 (100)	
No	18.6 (24)	19.9 (28)	20.6 (26)	

Values are presented as % (*n*) and mean ± SD (*n*).

CSM, common-sense model of self-regulation; DIG, dental information guide.

Table 2.

Descriptive Analysis Based on Sites in the Family Access to a Dentist Study.

	East Cleveland (<i>n</i> = 257)	Washington (<i>n</i> = 205)	Bedford (<i>n</i> = 135)	<i>P</i> Value
Child				
Grade				0.051
1 (kindergarten)	24.5 (63)	17.1 (35)	16.3 (22)	
2 (first)	19.1 (49)	24.4 (50)	20.0 (27)	
3 (second)	17.1 (44)	21.5 (44)	23.7 (32)	
4 (third)	21.8 (56)	22.0 (45)	14.8 (20)	
5 (fourth)	17.5 (45)	15.1 (31)	25.2 (34)	
Caregiver				
Education				<0.001 ^a
1 (>high school)	37.7 (78)	54.2 (104)	71.1 (81)	
0 (≤high school)	63.3 (129)	45.8 (88)	29.0 (33)	
Marital status				<0.001 ^a
1 (married)	8.2 (17)	49.7 (97)	28.1 (32)	
0 (other)	91.8 (191)	50.3 (98)	71.9 (82)	
Race				<0.001 ^a
1 (Black)	96.2 (203)	1.2 (2)	78.0 (85)	
0 (not Black)	3.8 (8)	98.8 (170)	22.0 (24)	
Ethnicity				<0.001 ^a
1 (Hispanic)	1.8 (2)	30.4 (41)	11.1 (8)	
0 (not Hispanic)	98.2 (109)	69.6 (94)	88.9 (64)	
Age, y	33.0 ± 8.3 (191)	33.7 ± 7.2 (184)	35.5 ± 10.3 (98)	0.053
Child: clinical				
Decayed teeth at baseline, <i>n</i>				
Primary	2.2 ± 2.0 (257)	1.6 ± 1.7 (205)	2.1 ± 2.0 (135)	0.002 ^a
Permanent	0.7 ± 1.1 (257)	0.9 ± 1.2 (205)	0.6 ± 1.0 (135)	0.004 ^a
Child: dental visits and coverage				
Ever had a dental visit				0.32
Yes	88.4 (182)	92.0 (185)	87.3 (96)	
No	11.7 (24)	8.0 (16)	12.7 (14)	
Any dental insurance				0.22
Yes	83.6 (168)	82.1 (156)	89.6 (95)	
No	16.4 (33)	17.9 (34)	10.4 (11)	
Medicaid coverage				<0.001 ^a
Yes	88.5 (139)	82.6 (123)	62.2 (56)	
No	11.5 (18)	17.5 (26)	37.8 (34)	

Values are presented as % (*n*) and mean ± SD (*n*).^a*P* < 0.05.

Table 3.

Dental Care Received and GEE Analysis Based on Restorations in the Family Access to a Dentist Study.

	Dental Care: Received, % (n)	P Value	OR ¹ (95% CI)	P Value	OR ² (95% CI)	P Value
All sites (n = 597)						
CSM (n = 202)	37.6 (76)	0.47				
CSM + DIG (n = 209)	43.1 (90)					
Std (n = 186)	38.2 (71)					
GEE model ^c			n = 476		n = 597	
CSM vs. Std			0.78 (0.48 to 1.27)	0.31	0.97 (0.62 to 1.50)	0.88
CSM + DIG vs. Std			1.05 (0.65 to 1.68)	0.85	1.26 (0.82 to 1.93)	0.30
CSM + DIG vs. CSM			1.35 (0.83 to 2.19)	0.22	1.30 (0.85 to 1.99)	0.23
EC + WA (n = 462)						
CSM (n = 164)	36.6 (60)	0.03 ^a				
CSM + DIG (n = 156)	51.3 (80)					
Std (n = 142)	40.9 (58)					
GEE model ^c			n = 367		n = 462	
CSM vs. Std			0.67 (0.39 to 1.15)	0.15	0.82 (0.50 to 1.33)	0.42
CSM + DIG vs. Std			1.35 (0.79 to 2.31)	0.28	1.58 (0.97 to 2.58)	0.065 ^b
CSM + DIG vs. CSM			2.01 (1.18 to 3.41)	0.01 ^a	1.93 (1.21 to 3.08)	0.006 ^a
Bedford alone (n = 135)						
CSM (n = 38)	42.1 (16)	0.054 ^b				
CSM + DIG (n = 53)	18.9 (10)					
Std (n = 44)	29.6 (13)					
GEE model ^c			n = 109		n = 135	
CSM vs. Std			1.42 (0.47 to 4.27)	0.53	1.89 (0.69 to 5.15)	0.21
CSM + DIG vs. Std			0.45 (0.14 to 1.38)	0.16	0.56 (0.21 to 1.49)	0.24
CSM + DIG vs. CSM			0.31 (0.10 to 0.98)	0.047 ^a	0.29 (0.10 to 0.83)	0.020 ^a

CSM, common-sense model of self-regulation; DIG, dental information guide; GEE, generalized estimating equation; OR¹, odds ratio without imputation for covariates; OR², odds ratio with imputation for covariates; Std, standard.

^aP < 0.05.

^b0.05 < P < 0.10.

^cAdjusted for covariates (race, child grade, education, marital status, site).

Traditional approaches to oral health education (i.e., disjointed information giving) has also been ineffective to improve specific behaviors (Yevlahova and Satur 2009), as parents/caregivers fail to understand the chronicity of dental

caries to initiate follow-up dental care for their children's cavities, especially in the primary teeth. Our study intervention focused on helping caregivers understand the chronic nature of dental caries so that their perception of baby teeth

would improve and subsequently initiate follow-up care on receipt of a referral.

The combined analysis of all sites did not demonstrate that the theory-based new CSM referral letter (with and without the DIG) significantly increased

dental care receipt as compared with the standard letter. However, there were important findings when the data from school districts were stratified. First, based on our original sites (EC and WA), the CSM + DIG significantly increased dental visits as compared with standard letter in univariate analysis, with 1.6-times increased odds of a dental visit after imputation and adjustment for covariates. Also, the CSM + DIG group had 1.9-times significantly increased odds of restorative care receipt versus the CSM letter alone. The DIG not only depicted the CSM facts pictorially but also included resources, such as website links for Medicaid, transportation options, and a list of dentists in the area who actively participated in Medicaid. The pictorial information may have been useful for parents/caregivers in EC and WA, where the majority had high school education or lower, and the resources may have been helpful for addressing barriers. Second, for BD schools, univariate analysis indicated that the CSM letter showed a trend toward significance for increased restorative care visits (42%) as compared with the CSM letter alone (19%) or the standard letter (30%), but the adjusted GEE analysis did not show significance. The interesting finding was that the CSM + DIG group had significantly lower odds of receiving restorative care than the CSM letter group. A greater proportion of caregivers in BD schools had more than a high school education and were probably able to understand the contents of the new referral letter without the pictorial DIG. However, for the BD school district, our results may have been influenced by a small sample size. Finally, our findings indicate that for a predominantly lower-income population with a high school education or less, a standard referral letter, as is now used, is not helpful to stimulate follow-up dental care. Parents/caregivers need to be informed of the chronic nature of caries with resources in an illustrative manner for increasing follow-up dental care.

The utilization of the CSM framework is a new way of addressing oral health facts and communication in the dental field.

The CSM framework was previously used to help patients improve their cognitive and emotional perception/representation of their medical illness, with a clearer rationale for treatments, thereby changing self-management behavior (e.g., increasing adherence to medications, attending follow-up health care visits; McAndrew et al. 2008; Mosleh et al. 2014; Nelson PA et al. 2017). A well-designed CSM theory-based leaflet was instrumental in improving patients' understanding of the complexity of psoriasis, suggesting that changing perception of disease may be a precursor to behavior change (Nelson PA et al. 2017). One of the challenges in behavioral trials that utilize letters and brochures is whether the participant read the information. As part of fidelity monitoring, confirmation of the receipt of intervention was obtained through phone calls, a self-addressed postcard sent home, or responses to questions in the final questionnaire inquiring if they received the intervention letter and whether they read and understood it. The majority of parents/caregivers responded (463 of 611 = 76%) and confirmed the receipt of letters.

There are 3 main limitations of this study. First, we were not able to recruit the full sample size of 660 parents/caregivers for 80% power, because of lower-than-expected enrollment in the school districts. Therefore, with a sample size of 611 parents/caregivers, we could detect a trend toward significance between the CSM + DIG and standard letter in the EC and WA school districts. Also, the imputation for covariates, which included the entire sample size, clearly showed the restorative care receipt trending toward significance in favor of the new letter, while it was not significant without imputation and a much reduced sample size. Second, the outcome in this study was determined clinically and visually. Although we trained and calibrated our examiners, it was difficult even for gold standard examiners to detect tooth-colored fillings and sealants. So, our outcomes may have been underestimated in all arms. The examiners were blinded to group

allocation to reduce the possibility of detection bias. Finally, since our outcomes were clinically determined, it is possible that parents may have taken their child to the dentist but did not complete all necessary treatments. The parents/caregivers did complete a survey at the exit examination, which inquired whether they took the child to the dentist postintervention. The comparison of clinical data with parent-reported data indicated that for those children who received restorative care detected through clinical examinations, 73% of their parents reported taking the child to the dentist. For those children where restorative care was not detected clinically, 53% of the parents reported that they took the child to the dentist—in which case, either they indeed did so but without completing necessary treatment, or they simply said as much because of social desirability bias. Additionally, we did not look at parallel changes in parent/caregiver perception of caries (i.e., CSM constructs) as a result of the intervention. In a future study, our plans are to report this secondary objective of our trial.

In summary, our findings suggest that a new CSM-based referral letter + DIG was instrumental in increasing follow-up restorative care among children. This information encouraged parents/caregivers to view children's dental caries as a chronic condition; it informed them that caries can be present without symptomatic pain; and it advised timely dental care for cavity-free baby teeth to protect permanent teeth. In our previous school-based study (2007 to 2010), only 19% of parents/caregivers sought follow-up care for their elementary-aged children when a standard referral letter was sent home (Nelson et al. 2012). In our present study, 30% to 41% of children (depending on the site) received restorative care with a standard referral letter. The rates in the control group overall were much higher than originally anticipated, perhaps due to the 2010 enactment of the Affordable Care Act and increased eligibility and efforts to enroll children in Medicaid.

Author Contributions

S. Nelson, P. Milgrom, contributed to conception, design, data acquisition, analysis, and interpretation, drafted and critically revised the manuscript; J.M. Albert, contributed to conception, design, data analysis, and interpretation, drafted and critically revised the manuscript; D. Selvaraj, contributed to data acquisition, analysis, and interpretation, drafted and critically revised the manuscript; J. Cunha-Cruz, S. Curtan, M. Heima, contributed to data acquisition and interpretation, critically revised the manuscript; T. Copeland, M. Rothen, contributed to data acquisition, critically revised the manuscript; G. Beck, G. Ferretti, C. Riedy, contributed to conception, design, and data interpretation, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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