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Research Article

A Randomized Controlled Clinical Trial of Prenatal Oral Hygiene Education in Pregnancy-Associated Gingivitis

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Introduction: Research shows there is a significant increase in gingival inflammation during pregnancy. This study was conducted to determine if an oral health intervention (OHI), including oral hygiene education delivered by nurse-led staff and an advanced over-the-counter (OTC) oral home care regimen, improved gingival inflammation in pregnant women with moderate-to-severe gingivitis compared with a standard oral hygiene control group.

Methods: This was a multicenter, randomized, controlled, single-masked, parallel group clinical trial conducted in obstetrics clinics of 2 medical centers. A total of 750 pregnant women between 8 and 24 weeks of pregnancy with at least 20 natural teeth and moderate-to-severe gingivitis (>30 intraoral bleeding sites) were enrolled. Participants were randomized to either the OHI group, which included oral hygiene instructions supplemented with an educational video and advanced OTC antibacterial/mechanical oral hygiene products, or the control group receiving oral hygiene instructions and standard products. Both groups received oral hygiene instructions from nurse-led staff. Experienced, masked examiners measured whole mouth gingival index (GI) and periodontal probing depths (PDs) at baseline and months 1, 2, and 3.

Results: Participants enrolled in this study presented with moderate-to-severe gingivitis at baseline. Both the OHI and control groups exhibited significant reductions in GI ($P < .001$) and PD ($P < .03$) from baseline that persisted throughout the study period. The OHI group exhibited modest, yet statistically greater, reductions in GI ($P \leq .044$) compared with the control at all time points. The reduction in PD directionally favored the OHI group, but between-group differences were small (<0.03 mm) and not statistically significant ($P > .18$).

Discussion: Significant gingivitis was prevalent among participants in this study and identifies an opportunity to improve gingival health during pregnancy by providing oral health education during the course of prenatal care when coupled with an advanced OTC oral hygiene regimen.
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Keywords: pregnancy, oral health, gingivitis, inflammation, education, prenatal care

INTRODUCTION

Gingivitis is the most prevalent oral disease, affecting a majority of dentate adults.[1] Dental plaque is the primary etiologic factor in the development of gingivitis, and hormonal and other factors can influence the onset or severity of gingival inflammation.[2,3] There is a reported increase in the extent and severity of gingival inflammation during pregnancy[3–6] affecting 36% to 100% of pregnant women.[6,7] Inadequate oral hygiene contributes to plaque accumulation and subsequent gingival inflammation,[8] but significant qualitative differences in the composition of the biofilm are not uniformly associated with the increased inflammation seen in pregnancy.[9–12] The hormonal changes during pregnancy alter and increase the inflammatory response to the dental plaque biofilm, resulting in an increase in gingival inflammation without changes in oral hygiene habits.[13–15]

According to the 2017 World Workshop on the classification of periodontal disease,[2] pregnancy-associated gingivitis is diagnosed as dental plaque-induced gingivitis modified by systemic factors and associated with sex steroid hormones. The increase in severity and extent of pregnancy-associated gingivitis is self-limiting and transient. As the hormonal changes of pregnancy decline during the postpartum period, gingival inflammation levels return to prepregnancy levels, if oral hygiene is unaltered.[5,16] After a systematic review of studies of women with gingival inflammation during pregnancy, we found that a significant increase in gingival inflammation occurs throughout pregnancy when compared

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Quick Points

- Pregnancy-related hormonal changes elicit an inflammatory response to dental plaque biofilm, leading to gingival inflammation without any changes to the dental hygiene routine.
- Moderate-to-severe gingivitis during pregnancy was prevalent among participants in this clinical trial, across study sites, and in population subgroups.
- Advanced oral hygiene education regimens delivered by nurse-led staff in conjunction with perinatal pregnancy counseling is an effective new strategy to improve the oral health of pregnant women.

with nonpregnant women. The increase in gingivitis is not associated with an increase in differences in plaque accumulation between pregnant and nonpregnant groups and appears to be proportional to systemic hormone levels and inflammatory biomarkers.[11]

Gingivitis is optimally treated by the daily meticulous removal of biofilm from the gingival sulcus.[17] Although hormonal and inflammatory changes during pregnancy influence the development of clinical gingivitis, Geisinger et al have shown that pregnancy gingivitis is rare in instances of exceptional plaque control and, moreover, that the condition can be reversed through an intensive oral home care regimen, despite the influence of sex steroid hormones.[18,19] Furthermore, it has been established that pregnancy offers a distinctive opportunity in which women are more likely to adopt and continue positive health behaviors.[20–22] Given the low prevalence of optimal oral health behaviors in the general population, intervention during pregnancy may represent a particularly effective time for midwives and other prenatal providers to deliver health education and to improve oral home care habits.[23,24]

Periodontal disease in pregnancy has also been reported to be associated with adverse pregnancy outcomes, including low birth weight and preterm birth.[25–29] The hypothesized underlying mechanisms for these relationships include systemic microbial exposure and subsequent inflammatory burden from periodontal diseases. However, the efficacy of periodontal treatment on pregnancy outcomes has been inconsistent.[25,30,31] Furthermore, improved maternal oral hygiene during pregnancy and beyond as well as attendance of prenatal care visits has also been linked to improved oral health status in offspring, including lower rates of early childhood caries.[32,33] A further advantage of the approach we describe here is the accessibility of its implementation as an integral part of perinatal health care.

Given the potential effect of optimizing oral health habits and dental plaque biofilm removal during pregnancy on oral and overall health, the investigation of alternative mechanisms to enhance oral home care at this critical time was assessed in 2 pilot studies.[18,19,34] The first study showed that a nonalcohol cetylpyridinium chloride (CPC) oral rinse was associated with decreased incidence of preterm birth among women with periodontal disease who declined dental care.[34] The second pilot study expanded the intervention to include education and a combination of advanced oral hygiene products in pregnant women with moderate-to-severe gingivitis.[18,19] Findings showed the intervention improved the women's periodontal health. Based on these collective findings, and those from related research on the effects of oral hygiene combination therapy on oral health,[35] this randomized controlled trial was undertaken. The primary aim of this multicenter randomized controlled trial was to determine if an oral health intervention (OHI) that included an advanced over-the-counter (OTC) oral home care regimen, oral hygiene instructions delivered by nurse-led staff, and supplemental educational video content improved gingival inflammation in pregnant women with moderate-to-severe gingivitis.

METHODS

Design

This was a multicenter randomized, controlled, single-masked, 2-treatment, parallel group clinical trial to assess gingivitis and maternity outcomes in up to 750 participants assigned to 2 different daily oral hygiene routines. The perinatal outcomes are being summarized separately and are not included in this report. This study was approved by The University of Alabama at Birmingham (UAB) and the University of Pennsylvania (UPenn) Institutional Review Boards and was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013. The study was registered at ClinicalTrials.gov (NCT01549587).

Setting and Sample

The research setting included 2 prenatal care clinic centers, one at the Center for Women's Reproductive Health at UAB in Birmingham, Alabama, and the other at Penn Ob/Gyn and Associates in affiliation with UPenn in Philadelphia, Pennsylvania.

Each center targeted women for participation who were between 8 and 24 weeks' gestation and were at least the age of legal consent, had at least 20 natural teeth, and had moderate-to-severe gingivitis (at least 30 intraoral bleeding sites). Potential participants were excluded from the study if they had multifetal gestations, a history of HIV infection, AIDS, autoimmune diseases, or diabetes mellitus (other than gestational diabetes). Participants were also excluded if they had an indication for use of antibiotic premedication prior to dental procedures, systemic corticosteroid or immunosuppressive therapy within one month of baseline, a history of allergies or hypersensitivity to mouth rinse products containing CPC, severe periodontal disease or other conditions requiring urgent dental care needs, or other factors that in the opinion of the investigator could interfere with the safe completion of the study.

Prior to the study, sample size was estimated for perinatal (eg, gestational age) endpoints based on results from both

pilot studies involving an oral regimen treatment during pregnancy.[18,34] The initial sample size based on the power calculations was to enroll 750 in order to complete 600 evaluable participants. Three hundred participants per group were selected to ensure there were enough participants enrolled in the study and to increase power for subset analyses. This sample size was sufficient to yield at least 90% power to detect a 0.05 between-group difference in gingivitis with an estimated variability of 0.185 using 2-sided testing at an $\alpha = 0.05$ level. Per the study protocol, an interim analysis was planned using the first 184 participants. The final sample size was adjusted by enrolling up to 150 more participants to achieve a maximum total of 750 subjects overall to (1) replace nonevaluable subjects, (2) account for increased variability from the interim analyses versus the initial estimate of variability, and (3) increase power for certain subset analyses.

Enrollment began in April 2012, and the last dental visits were completed by April 2014. All participants underwent an informed consent process that was approved, along with the protocol, by the respective institutional review boards at UAB and UPenn. Eligible participants were randomly assigned to one of 2 oral hygiene regimens using a computer-generated program provided by the study sponsor that balanced for groups based on history of preterm birth, current smoking status, and number of gingival bleeding sites (<60, ≥ 60). Separate randomizations were generated for each study center. The baseline sample included 295 participants at UAB and 353 at UPenn.

Procedures

The study consisted of 4 scheduled oral health visits: (1) baseline visit with oral hygiene treatment randomization, (2) 4-week (month 1) visit, (3) 8-week (month 2) visit, and (4) 12-week (month 3) visit. All visits were performed in conjunction with monthly perinatal care. Masked examiners who underwent a calibration exercise performed comprehensive oral examinations, including assessment of plaque deposits and clinical periodontal parameters. Pregnancy outcomes were assessed by a masked examiner.

At each study site, participants were randomized to either the OHI group or a standard control group. Participants in the OHI group received an oral hygiene kit that included a power toothbrush (Oral-B ProfessionalCare, Series 1000 with the Oral-B Precision Clean brush head), 0.454% stannous fluoride toothpaste (Crest Pro-Health), 0.07% alcohol-free CPC rinse (Crest Pro-Health Multi-Protection), and deep cleaning dental floss (Glide Pro-Health Deep Clean). In addition, OHI participants received a supplemental educational video on oral hygiene (as a DVD), approximately 4 minutes long, detailing 2-minute twice daily usage of the assigned brush and toothpaste and daily use of rinse and floss during pregnancy. The standard care control group kit contained a flat trim soft manual toothbrush (Oral-B Indicator regular), 0.243% sodium fluoride toothpaste (Crest Cavity Protection), and dental floss (Oral-B Essentials). Participants assigned to the control group also received oral and written instructions for brushing at least twice daily and daily flossing. Intervention and control group products (except for brushes) had new generic labels applied to disguise the product identity, and all products and instructions were dispensed in identical masked test kits. It was not possible to mask the identity of the test toothbrushes because one was electric and one was manual.

The nurse-led staff at each obstetric clinic were trained as dental health educators and delivered basic oral hygiene instructions to participants in both groups at each prenatal visit. They also supervised the initial use of the oral hygiene materials by participants. The participants in the OHI group also watched the educational video on oral hygiene at the study center at the baseline and month 3 visits, and the DVD was also available in their kit to view at home. All other use of study materials was at home and unsupervised. Oral hygiene kits for both OHI and control groups were resupplied monthly through month 3. The final monthly kit was sufficient to provide the participants oral hygiene supplies until they had given birth.

Clinical examinations at baseline and at months 1, 2, and 3 assessed, in order, oral safety, gingivitis and bleeding sites, and periodontal probing depth. The clinical safety examination consisted of a standard oral and perioral examination of soft and hard tissues. Adverse events, if any, were classified by site, severity, and causality. The level of gingival inflammation was measured per tooth, using the Löe and Silness Gingival Index (LSGI),[6,36] and number of bleeding sites was determined from individual tooth site scores (LSGI ≥ 2). Full-mouth periodontal probing depth (PD), measured from the free gingival margin to the base of the periodontal pocket, was recorded to the nearest millimeter with a periodontal probe. Each measurement was assessed at 6 gingival areas per tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and distolingual) and averaged to obtain a whole mouth average gingivitis score.

Dentists who were masked to treatment assignment and uninvolved with oral hygiene education or product use training carried out all oral health examinations and measurements. Oral health examinations were conducted in a dental unit located in the prenatal care clinics. Prior to study initiation, potential examiners received a single, common clinical training program and conducted a calibration exercise to ensure consistency in determining gingival inflammation, bleeding, and safety assessments. Data were monitored as collected to assess examiner qualification, and follow-on training was conducted to train new or replacement examiners. When logistically possible, examinations were conducted by the same examiner at each study site.

Analysis

After study completion, the database was monitored prior to unmasking of treatments and statistical analyses. Relative to baseline, within-treatment differences in gingivitis (LSGI) scores were tested versus zero at each visit from an analysis of covariance (ANCOVA) model. Similar analyses were conducted for change from baseline for the total number of bleeding sites and probing depth (PD) at each visit. LSGI was considered the primary gingivitis endpoint. Between-group differences in LSGI, bleeding site, and PD change from baseline scores were tested using an ANCOVA with the analogous gingivitis baseline as the covariate and study center and gestational age at enrollment, along with all potential 2-way interactions as factors in the statistical model. Interactions

were maintained in the model if significant at the 10% level. Because the month 3 scores were of primary importance, the month 3 model for each dental endpoint was used for the analogous month 1 and 2 analyses. One participant was identified as a statistical outlier at month 3 using Dixon's test,[37] and their LSGI data were not used in the analyses. Additionally, 95% CIs were generated on the treatment difference for the average change from baseline scores.

Demographic and baseline variables were summarized by treatment group, and adverse events reported during the study were documented, listed, and coded by treatment group. The categorical demographic variables were analyzed for treatment group differences using either Fisher's exact test or Cochran-Mantel-Haenszel test, and the continuous variables were analyzed using Wilcoxon rank sum test. All statistical tests were be carried out using SAS version 9 (SAS Institute Inc, Cary, NC).

RESULTS

Study Participants

Informed consent was obtained from 817 participants. Of these, 71 were ineligible, including 59 women who did not meet protocol criteria. A total of 746 participants met enrollment criteria and received baseline evaluations and treatment randomization (Figure 1). An additional 80 participants at one center (40 in the OHI group and 40 in the control group) were excluded from analyses due to a protocol deviation at the initial baseline assessment. This left a baseline sample of 648 participants eligible for inclusion in outcome analyses. Other factors affecting evaluability, such as missed visits or pregnancy loss or completion (dental examinations were limited to active pregnancies), resulted in loss of evaluable participants in the final analysis of dental outcomes. Although attendance differed slightly at the month 1 and 3 visits, most participants completed the dental examination at month 1 (548) and month 3 (532).

The baseline study participants sample exhibited considerable diversity. Mean (SD) age was 27.6 (5.92) years, ranging from 18 to 46 years; mean (SD) gestational age at enrollment was 17.0 (3.65) weeks, ranging from 8 to 24 weeks. Black women comprised approximately two-thirds of the study sample. Treatment groups were balanced ($P \geq .12$) overall with respect to demographic, economic, and other pertinent factors at baseline (Table 1A).

Table 1A. Demographic Characteristics Between Intervention and Control Groups (N = 648)

Characteristic	Intervention (n = 322)	Control (n = 326)	*P* Value[a]
Maternal age, y			.452
Range	18-44	19-46	
Mean (SD)	27.4 (5.94)	27.8 (5.91)	
Ethnicity, n (%)			.477
American Indian	0 (0)	2 (0.6)	
East Asian	13 (4.0)	8 (2.5)	
Black	223 (69.3)	217 (66.6)	
White	70 (21.7)	73 (22.4)	
Hispanic	7 (2.2)	13 (4.0)	
South Asian	4 (1.2)	5 (1.5)	
Multiracial	5 (1.6)	8 (2.5)	
Insurance type, n (%)			.854
Private	149 (46.3)	159 (48.8)	
Medicaid	10 (3.1)	9 (2.8)	
None, self-pay	20 (6.2)	13 (4.0)	
None, unable to pay	134 (41.6)	138 (42.3)	
Military/VA	4 (1.2)	4 (1.2)	
Unknown/declined	4 (1.2)	5 (1.5)	
Tobacco use during pregnancy, n (%)			.329
Yes	22 (6.8)	29 (8.9)	
Gestational age, wk			.118
Range	8-24	8.3-24.1	
Mean (SD)	16.8 (3.78)	17.2 (3.50)	

Abbreviation: VA, Veterans Affairs.
[a] Categorical demographic variables were analyzed for treatment group differences using either Fisher's exact test or Cochran-Mantel-Haenszel test, and the continuous variables were analyzed using Wilcoxon rank sum test.

Study Center Differences

Study center differences were evident at baseline for several demographic parameters. The 2 study centers differed significantly ($P < .001$) with respect to age, ethnicity, dental insurance coverage, and tobacco use, but they did not differ for baseline obstetric or dental variables. Study centers did not differ statistically on gestational age at baseline enrollment ($P = .22$) or baseline number of bleeding sites ($P = .37$), with each averaging more than 50 bleeding sites (Table 1B).

All participants had gingivitis at baseline (≥ 10% of tooth sites with gingival bleeding as defined by the 2017 World Workshop on the Classification of Periodontal and Peri-impant diseases and Condidtions).[38] The overall whole mouth LSGI mean (SD) score was 1.3 (0.10), the mean (SD) number of bleeding sites was 51.1 (15.89), ranging from 30 to 144 sites, and whole mouth mean (SD) probing depth averaged 2.5 (0.32) mm. Treatment groups were well-balanced ($P > .45$) on periodontal clinical parameters at baseline (Table 2).

Gingivitis Assessment

The number of bleeding sites was the variable used to categorize gingivitis severity at baseline to understand the relationship between gingivitis and other baseline status variables. Using regression analysis, both study center and maternal age at baseline were significantly ($P < .02$) related to the number of baseline bleeding sites. In contrast, gestational age at enrollment and ethnicity were not significantly ($P > .32$) related to baseline bleeding. Relative to baseline, both treatment groups exhibited significant ($P < .001$) reductions in gingivitis beginning at month 1. For number of bleeding sites, this represented a 35% to 39% improvement versus initial bleeding after one month of treatment use. Participants exhibited continued improvement in the number of bleeding

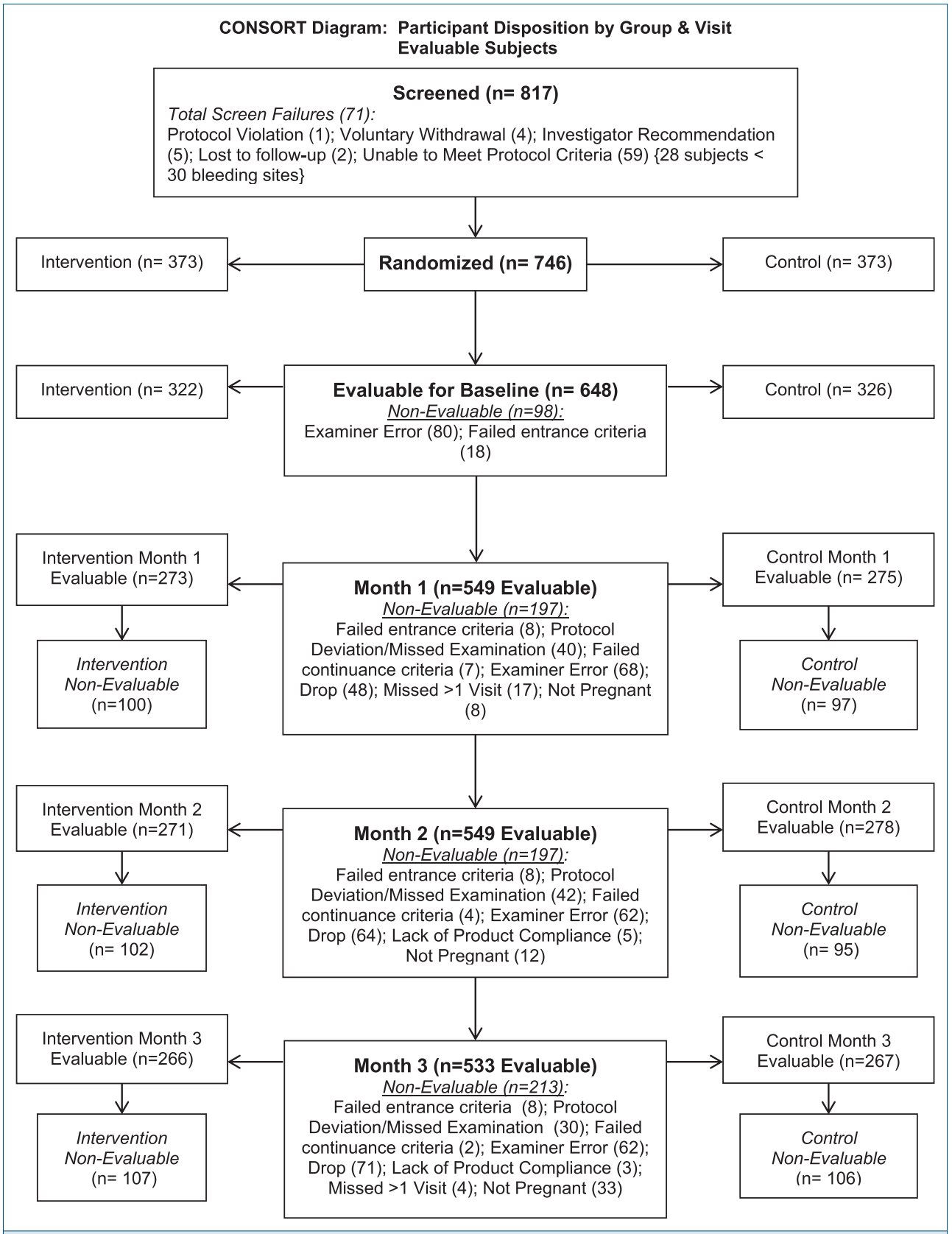

Figure 1. CONSORT Diagram: Participant Disposition by Group and Visit

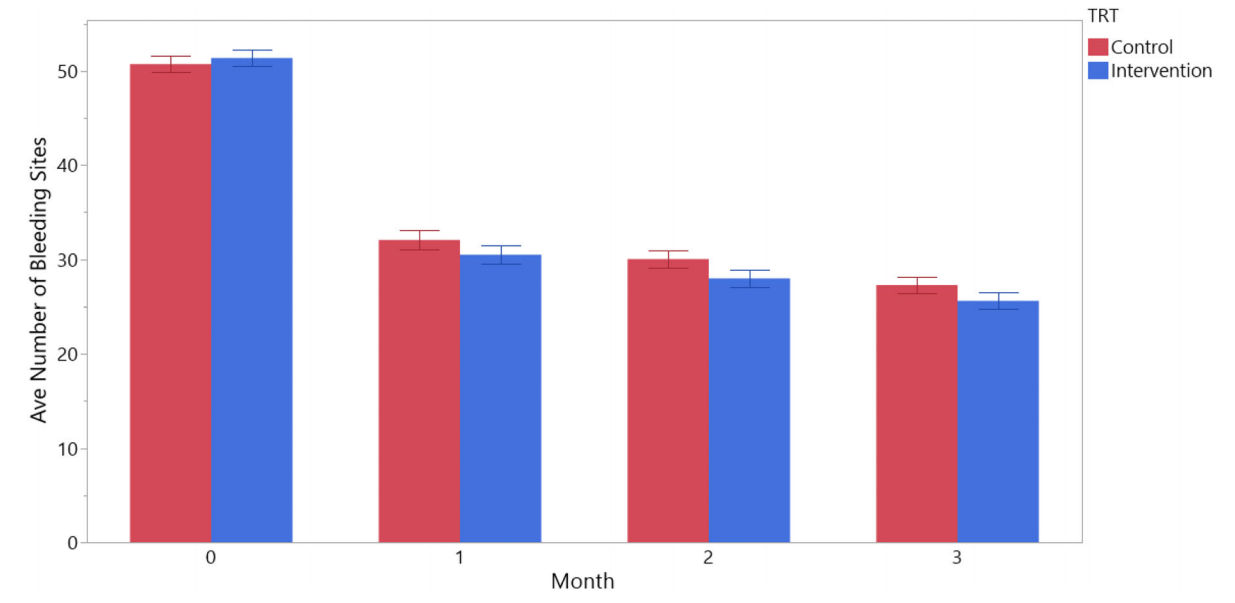

Figure 2. Average (SE) Number of Gingival Bleeding Sites by Month and Treatment

sites through month 3, reaching 43% to 47% improvement (Figure 2). Both groups exhibited significant ($P < .03$) whole mouth probing depth reductions beginning at month 1 and continuing through month 3.

Comparing treatments, the OHI group exhibited significantly higher ($P < .05$) reductions in gingivitis, as measured by whole mouth LSGI, beginning at month 1 and continuing through month 3 (Table 3). We observed similar outcomes for number of bleeding sites, with treatments differing significantly at months 1 and 3. Probing depth directionally favored the OHI group, but between-group differences were small (<0.03 mm) and not statistically significant ($P > .18$) at any postbaseline time point.

Adverse events reported or determined with oral examination were collected irrespective of causality at each dental visit. There were a total of 81 participants with 91 oral or perioral adverse events. Of these, there were 18 different adverse event types from multiple participants (Table 4). Oral mucosal exfoliation, tooth fracture, and tooth discoloration were the most common adverse events by type. Occurrence was more common in the OHI group (15% vs 10% of participants with at least one oral or perioral adverse event). Study groups differed significantly ($P < .05$) with regard to oral adverse event occurrence overall and oral mucosal exfoliation occurrence. Oral/perioral adverse events were generally mild in severity and were not factors in study dropout during the 3 months of routine dental monitoring and examination.

DISCUSSION

Clinical examination of participants showed moderate-to-severe gingivitis to be common at baseline, with 96.6% of screened participants demonstrating at least 30 bleeding sites. Gestational age at baseline did not appear to be related to level of gingivitis as measured by the number of bleeding sites. Participants did not receive a clinical periodontal examination prior to pregnancy or after parturition. It is notable that at

Table 1B. Demographic Characteristics of Participants Between Study Sites (N = 648)

Characteristic	UAB (n = 295)	UPenn (n = 353)	*P* Value[a]
Maternal age, y			<.001
Range	19-43	18-46	
Mean (SD)	24.0 (4.22)	30.7 (5.39)	
Ethnicity, n (%)			<.001
American Indian	0 (0)	2 (0.6)	
East Asian	0 (0.0)	21 (5.9)	
Black	271 (91.9)	169 (47.9)	
White	16 (5.4)	127 (36.0)	
Hispanic	8 (2.7)	12 (3.4)	
South Asian	0 (0)	9 (2.6)	
Multiracial	0 (0)	13 (3.7)	
Insurance type, n (%)			<.001
Private	12 (4.1)	295 (84.8)	
Not private/none	278 (95.9)	53 (15.2)	
Tobacco use during pregnancy, n (%)			<.001
Yes	47 (7.3)	4 (0.6)	
Gestational age, wk			.219
Range	8-24	8.3-24.1	
Mean (SD)	16.8 (3.77)	17.2 (3.54)	
Bleeding sites, n			.366
Range	30-144	30-129	
Mean (SD)	50.4 (14.12)	51.6 (17.23)	

Abbreviations: UAB, The University of Alabama at Birmingham; UPenn, University of Pennsylvania.
[a] Categorical demographic variables were analyzed for treatment group differences using either Fisher's exact test or Cochran-Mantel-Haenszel test, and the continuous variables were analyzed using Wilcoxon rank sum test.

Table 2. Baseline Gingivitis, Bleeding, and Probing Depth by Treatment Group (N = 648)

Characteristic	Overall (N = 648) Mean (SD)	Intervention (n = 322) Mean (SD)	Control (n = 326) Mean (SD)	Group Differences 95% CI	*P* Value[a]
Gingivitis index, LSGI	1.32 (0.103)	1.32 (0.101)	1.31 (0.107)	(−0.011 to 0.021)	.536
Bleeding sites, n	51.1 (15.89)	51.4 (15.41)	50.7 (16.36)	(−1.80 to 3.10)	.604
Probing depth, mm	2.54 (0.323)	2.55 (0.334)	2.53 (0.312)	(−0.031 to 0.069)	.458

Abbreviation: LSGI, Löe and Silness Gingival Index.
[a] Analyzed using a 2-sample *t* test.

Table 3. Efficacy Outcomes Change from Baseline Treatment Comparisons by Visit (N = 648)

Outcome	Participants	Mean Treatment Reduction[a] (SE) Intervention (n = 266-273)	Mean Treatment Reduction[a] (SE) Control (n = 267-278)	Adjusted Mean Treatment Difference (SE)	95% CI	*P* Value[b]
Gingivitis index, LSGI						
Month 1	548	0.125 (0.0045)	0.112 (0.0045)	0.013 (0.0064)	(0.0004 to 0.026)	.044
Month 2	548	0.137 (0.0045)	0.124 (0.0044)	0.014 (0.0063)	(0.001 to 0.026)	.031
Month 3	532	0.154 (0.0046)	0.141 (0.0046)	0.013 (0.0065)	(0.0005 to 0.026)	.042
Gingival bleeding sites, n						
Month 1	549	19.85 (0.712)	17.86 (0.709)	1.98 (1.005)	(0.011 to 3.958)	.049
Month 2	549	21.66 (0.712)	19.73 (0.701)	1.93 (0.998)	(−0.029 to 3.891)	.054
Month 3	533	24.02 (0.696)	22.04 (0.691)	1.98 (0.977)	(0.061 to 3.898)	.043
Probing depth, mm						
Month 1	549	0.056 (0.0139)	0.060 (0.0139)	−0.004 (0.0188)	(−0.041 to 0.033)	.836
Month 2	549	0.063 (0.0155)	0.035 (0.0155)	0.028 (0.0208)	(−0.013 to 0.069)	.186
Month 3	533	0.073 (0.0159)	0.059 (0.0158)	0.013 (0.0213)	(−0.029 to 0.055)	.538

Abbreviation: LSGI, Löe and Silness Gingival Index.
[a] Reduction indicates improvement in the measure from baseline.
[b] Between-group differences were tested using an analysis of covariance model.

baseline examinations, participants universally demonstrated moderate-to-severe gingivitis regardless of gestational age. This observation is consistent with findings of increased gingivitis prevalence and severity in pregnancy.[3–6]

Participants at the 2 study centers in this investigation, one of the largest of its kind in recent years, differed appreciably with respect to age, ethnicity, and socioeconomic factors, including, specifically, insurance coverage. Despite the differences, participants at both centers demonstrated a ubiquitous presence of gingivitis at the baseline examination, with a mean of 50 bleeding sites. Socioeconomic factors are widely recognized to play a key role in access to care, including access to preventive dental care, and as such, underserved groups typically present with greater disease prevalence. Furthermore, it is notable that Alabama is one of 3 states that does not provide dental services to adults receiving Medicaid medical insurance. Individuals recruited at the UAB site over the age of 21 were unlikely to have access to comprehensive dental care if they had Medicaid insurance.[39]

Gingivitis is a reversible, site-specific inflammatory condition initiated by dental biofilm accumulation and characterized by gingival erythema, edema, and the absence of periodontal attachment loss.[38] Furthermore, pregnancy gingivitis is modified by the systemic inflammation. Thorough daily removal of dental plaque biofilm is critical in the treatment of pregnancy gingivitis. An initial pilot investigation was performed by our group to evaluate the benefit of nurse-directed education coupled with an intense oral hygiene therapy for pregnancy gingivitis. This intervention resulted in a statistically significant reduction in plaque and gingivitis[18] and a reduction in inflammatory mediators.[19] In the current study, both the OHI and control groups resulted in a marked improvement of oral health as evidenced by a significant reduction in bleeding sites and probing depths compared to baseline levels. The gingivitis reductions were statistically greater in the OHI group, although the intergroup differences may not have been clinically meaningful.

Implications for Practice

Pregnancy presents a unique opportunity for behavior modification. Pregnant individuals are more likely to cease negative health behaviors and comply with advice from health care providers than their nonpregnant counterparts.[40] Furthermore, the adoption of positive health care behaviors following instruction by dental professionals has been reported.[41] Pregnancy is also a period when individuals require significantly more health care visits than at most other times.[42] This period

Table 4. Oral and Perioral Adverse Event Occurrence by Treatment Group and Type (N = 648)

Category/Occurrence	Intervention n (%)	Control n (%)	*P* Value[a]
All participants	322 (100)	326 (100)	
Participants with oral/perioral adverse events	49 (15.2)	32 (9.8)	.04
Oral adverse event type (2+ participants)			
Dental fistula	1 (0.3)	1 (0.3)	.99
Device damage	0 (0.0)	2 (0.6)	.99
Dysgeusia	2 (0.6)	0 (0.0)	.50
Gingival abscess	1 (0.3)	2 (0.6)	.99
Gingival hyperplasia	2 (0.6)	0 (0.0)	.25
Gingival injury	1 (0.3)	1 (0.3)	.99
Gingival pain	2 (0.6)	2 (0.6)	.99
Lymphadenopathy	0 (0.0)	2 (0.6)	.50
Mouth ulceration	1 (0.3)	1 (0.3)	.99
Oral mucosal exfoliation	10 (3.1)	1 (0.3)	.006
Sensitivity of teeth	4 (1.2)	1 (0.3)	.21
Stomatitis	1 (0.3)	1 (0.3)	.50
Tongue disorder	2 (0.6)	1 (0.3)	.62
Tooth abscess	1 (0.3)	1 (0.3)	.99
Tooth discoloration	6 (1.9)	2 (0.6)	.17
Tooth fracture	5 (1.6)	6 (1.8)	.99
Tooth impacted	1 (0.3)	1 (0.3)	.99
Toothache	4 (1.2)	3 (0.9)	.72

[a] Analyzed using Fisher's exact test.

offers an opportunity for multidisciplinary interactions to improve health care behaviors. In the current study, oral health care education, including oral home care instructions and dispensing of the oral hygiene kits, was performed by trained nurse-led staff at the same time as prenatal care visits.

Access to dental care is not universal. Factors that influence access to dental care include ethnicity, age, income level, education level, perceived need, insurance coverage, and sociodemographic differences.[43–45] Given that access to dental care for adult patients across the United States is variable, the importance of preventive care is elevated, particularly in groups with lower access to care. It is well established that oral health education is a powerful adjunctive, cost-effective tool to an oral hygiene regimen that can improve oral health.

Currently, oral health education is not included in global guidelines for prenatal care, resulting in significant disparities in maternal oral health experiences.[46] An impactful mechanism to facilitate improved oral and overall health may include delivery of oral health education as part of pregnancy counseling.[47] Obstetric nurses, midwives, and other perinatal care providers are well-positioned to incorporate oral health care education into perinatal care, particularly among underserved populations.[23] Having a positive effect on the oral health of high-risk populations may result in overall improvement of maternal health and the oral health of subsequent offspring. Evidence exists that maternal periodontal disease and oral inflammation are associated with preterm birth and low birth weight in newborns.[27,48–50] Previous large-scale interventional trials for periodontal disease have been largely ineffective in reducing preterm birth rates.[31,51] This lack of effect may reflect a focus on timing and effectiveness of treatment delivery as well as limited focus on reducing gingival inflammation through patient-delivered home care. The residual inflammation reported after intervention for pregnancy gingivitis demonstrates that the treatment endpoints may not have been appropriate.[51] In previous pilot studies, gingival inflammation and other oral clinical indicators of periodontal disease were reduced by an intervention focused on oral health education, coupled with plaque control treatments.[18,19,34] These findings are supported by the results of this study, which demonstrated improvement in gingival health outcomes following oral health education and use of advanced oral hygiene home care products.

Strengths and Limitations

Strengths of this research include the multicenter, randomized, controlled, parallel group study design and the inclusion of OTC oral hygiene products that are widely accessible to the population. Additionally, the coordination of oral hygiene counseling with obstetric visits and the delivery of oral health education by perinatal health care providers allowed circumvention of barriers to dental care that may exist for some pregnant women. The heterogeneity of the study population is another strength with important implications for generalizability of the findings. However, it is simultaneously a limitation, as it required larger sample sizes for subgroup comparisons and makes it difficult to ascertain contributing factors, unrelated to pregnancy, for the gingivitis prevalence across study sites. This unexpected finding could indicate a phenomenon of "severity without disparity," or it could be a function of selection bias or other unknown factors. Replication of the study with a standardized gestational age upon enrollment would further elucidate the role of oral health education and daily plaque control in prenatal care.

CONCLUSION

In this study, we demonstrated near universal prevalence of gingivitis with significant severity among study participants relatively early in pregnancy. These gingivitis levels were evident across study sites and demographic and socioeconomic subgroups. Oral hygiene education delivered by nurse-led staff resulted in an improvement of gingival inflammation and bleeding during pregnancy. A modest but statistically significant additional improvement was noted when an intentional oral hygiene educational intervention, including an educational video, was combined with use of a powered toothbrush, 0.454% stannous fluoride toothpaste, dental floss, and 0.07% CPC mouth rinse compared with a control oral hygiene regimen and standard written instructions. Oral hygiene education delivered in conjunction with prenatal

pregnancy counseling may offer a novel approach for the improvement of maternal oral health.

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CONFLICT OF INTEREST

Drs. Doyle and Grender are employed full-time by the Procter & Gamble Company. Dr. Gerlach is a former employee of the Procter & Gamble Company. They provided logistics and data analysis support for the study but did not participate in data collection. Dr. Geisinger has participated in the Procter & Gamble Speaker's Bureau.

REFERENCES

1. Stamm JW. Epidemiology of gingivitis. *J Clin Periodontol*. 1986;13(5):360-366. doi:10.1111/j.1600-051x.1986.tb01473.x
2. Chapple ILC, Mealey BL, Van Dyke TE, et al. Periodontal health and gingival diseases and conditions on an intact and a reduced periodontium: consensus report of workgroup 1 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. *J Periodontol*. 2018;89(1):S74-S84. doi:10.1038/sj.bdj.2018.614
3. Silness J, Löe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. *Acta Odontol Scand*. 1964;22:121-135. doi:10.3109/00016356408993968
4. Cohen DW, Friedman L, Shapiro J, Kyle GC. A longitudinal investigation of the periodontal changes during pregnancy. *J Periodontol*. 1969;40(10):121-125. doi:10.1902/jop.1969.40.10.563
5. Gürsoy M, Pajukanta R, Sorsa T, Könönen E. Clinical changes in periodontium during pregnancy and post-partum. *J Clin Periodontol*. 2008;35(7):575-583. doi:10.1111/j.1600-051x.2008.01236.x
6. Löe H, Silness J. Periodontal disease in pregnancy. I. Prevalence and severity. *Acta Odontol Scand*. 1963;21:533-551. doi:10.3109/00016356309011240
7. Orban B, Maier AW. Histopathology of pregnancy gingivitis. *J Dent Res* 1947;26(6):451.
8. Carrillo-de-Albornoz A, Figuero E, Herrera D, Cuesta P, Bascones-Martínez A. Gingival changes during pregnancy: III. Impact of clinical, microbiological, immunological and socio-demographic factors on gingival inflammation. *J Clin Periodontol*. 2012;39(3):272-283. doi:10.1111/j.1600-051x.2011.01800.x
9. Adriaens LM, Alessandri R, Spörri S, Lang NP, Persson GR. Does pregnancy have an impact on the subgingival microbiota? *J Periodontol*. 2009;80(1):72-81. doi:10.1902/jop.2009.080012
10. Carrillo-de-Albornoz A, Figuero E, Herrera D, Bascones-Martínez A. Gingival changes during pregnancy: II. Influence of hormonal variations on the subgingival biofilm. *J Clin Periodontol*. 2010;37(3):230-240. doi:10.1111/j.1600-051x.2009.01514.x
11. Figuero E, Carrillo-de-Albornoz A, Martin C, Tobías A, Herrera D. Effect of pregnancy on gingival inflammation in systemically health women: a systematic review. *J Clin Periodontol*. 2013;40(5):457-473. doi:10.1111/jcpe.12053
12. Raber-Durlacher JE, van Steenbergen TJ, Van der Velden U, de Graaf J, Abraham-Inpijn L. Experimental gingivitis during pregnancy and post-partum: clinical, endocrinological, and microbiological aspects. *J Clin Periodontol*. 1994;21(8):549-558. doi:10.1111/j.1600-051x.1994.tb01172.x
13. Laine MA. Effect of pregnancy on periodontal and dental health. *Acta Odontol Scand*. 2002;60(5):257-264. doi:10.1080/00016350260248210
14. Mariotti A, Mawhinney M. Endocrinology of sex steroid hormones and cell dynamics in the periodontium. *Periodontol 2000*. 2013;61(1):69-88. doi:10.1111/j.1600-0757.2011.00424.x
15. Wu M, Chen SW, Su WL, et al. Sex hormones enhance gingival inflammation without affecting IL-1β and TNF-α in periodontally healthy women during pregnancy. *Mediators Inflamm*. 2016;2016:4897890. doi:10.1155/2016/4897890
16. Tilakaratne A, Sorry M, Ranasinghe AW, Corea SM, Ekanayake SL, de Silva M. Periodontal disease status during pregnancy and 3 months post-partum in a rural population of Sri-Lankan women. *J Clin Periodontol*. 2000;27(10):787-792. doi:10.1034/j.1600-051x.2000.027010787.x
17. Geisinger ML, Kaur M, Basma H. Nonsurgical periodontal therapy: a review of current standards of care and innovations to improve gingival and periodontal health. *Curr Oral Health Rep*. 2019;6:177-187. doi:10.1007/s40496-019-00224-7
18. Geisinger ML, Geurs NC, Bain JL, et al. Oral health education and therapy reduces gingivitis during pregnancy. *J Clin Periodontol*. 2014;41(2):141-148. doi:10.1111/jcpe.12188
19. Kaur M, Geisinger ML, Geurs NC, et al. Effect of intensive oral hygiene regimen during pregnancy on periodontal health, cytokine levels, and pregnancy outcomes: a pilot study. *J Periodontol*. 2014;85(12):1684-1692. doi:10.1902/jop.2014.140248
20. Davis AM, Wambach KA, Nelson EL, et al. Health behavior change in pregnant women: a two-phase study. *Telemed J E Health*. 2014;20(12):1165-1169. doi:10.1089/tmj.2013.0374
21. Olander EK, Smith DM, Darwin Z. Health behaviour and pregnancy: a time for change. *J Reprod Infant Psychol*. 2018;36(1):1-3. doi:10.1080/02646838.2018.1408965
22. Zinsser LA, Stoll K, Wieber F, Pehlke-Milde J, Gross MM. Changing behaviour in pregnant women: a scoping review. *Midwifery*. 2020;85:102680. doi:10.1016/j.midw.2020.102680
23. Haber J, Dolce MC, Hartnett E, Altman S, Silk H. Improving oral health during pregnancy: a call to action. *J Midwifery Womens Health*. 2022;67(2):167-169. doi:10.1111/jmwh.13357
24. Worthington HV, MacDonald L, Poklepovic Pericic T, et al. Home use of interdental cleaning devices, in addition to toothbrushing, for preventing and controlling periodontal diseases and dental caries. *Cochrane Database Syst Rev*. 2019;4(4):CD012018. doi:10.1002/14651858.cd012018.pub2
25. Chambrone L, Guglielmetti MR, Pannuti CM, Chambrone LA. Evidence grade associating periodontitis to preterm birth and/or low birth weight. I. A systematic review of prospective cohort studies. *J Clin Periodontol*. 2011;38(9):795-808. doi:10.1111/j.1600-051x.2011.01755.x
26. Ide M, Papapanou PN. Epidemiology of association between maternal periodontal disease and adverse pregnancy outcomes—systematic review. *J Clin Periodontol*. 2013;40(14):S181-S194. doi:10.1111/jcpe.12063
27. Jeffcoat MK, Geurs NC, Reddy MS, Cliver SP, Goldenberg RL, Hauth, JC. Periodontal infection and preterm birth: results of a prospective study. *J Am Dent Assoc*. 2001;132(7):875-880. doi: 10.14219/jada.archive.2001.0299
28. López NJ, Smith PC, Gutierrez J. Higher risk of preterm birth and low birth weight in women with periodontal disease. *J Dent Res*. 2002;81(1):58-63. doi:10.1177/002203450208100113
29. Offenbacher S, Katz V, Fertik G, et al. Periodontal infection as a possible risk factor for preterm low birth weight. *J Periodontol*. 1996;67(10):1103-1113. doi:10.1902/jop.1996.67.10.1103
30. López NJ, Uribe S, Martinez B. Effect of periodontal treatment on preterm birth rate: a systematic review of meta-analyses. *Periodontol 2000*. 2015;67(1):87-130. doi:10.1111/prd.12073

31. Michalowicz BS, Gustaffson A, Thumbigere-Math V, Buhlin K. The effects of periodontal treatment on pregnancy outcomes. *J Clin Periodontol*. 2013;40(14):S195-S208. doi:10.1111/jcpe.12081
32. de Souza PMDES, Proença MAM, Franco MM, Rodrigues VP, Costa JF, Costa EL. Association between early childhood caries and maternal caries status: a cross-section study in São Luís, Maranhão, Brazil. *Eur J Dent*. 2015;9(1):122-126. doi:10.4103/1305-7456.149659
33. Xiao J, Alkhers N, Kopycka-Kedzierawski DT, et al. Prenatal oral health care and early childhood caries prevention: a systematic review and meta-analysis. *Caries Res*. 2019;53(4):411-421. doi:10.1159/000495187
34. Jeffcoat M, Parry S, Gerlach RW, Doyle MJ. Use of alcohol-free antimicrobial mouth rinse is associated with decreased incidence of preterm birth in a high risk population. *Am J Obstet Gynecol*. 2011;205(4):382.e1-382.e6. doi:10.1016/j.ajog.2011.07.016
35. Biesbrock AR, Bartizek RD, Gerlach RW, Terézhalmy GT. Oral hygiene regimens, plaque control, and gingival health: a two month clinical trial with antimicrobial agents. *J Clin Dent*. 2007;18(4):101-105. doi:10.1111/j.1601-5037.2008.00327.x
36. Löe H. The Gingival Index, the Plaque Index, and the Retention Index systems. *J Periodontol*. 1967;38(6):610-616. doi:10.1902/jop.1967.38.6.610
37. Barnett V, Lewis T. *Outliers in Statistical Data*. John Wiley & Sons; 1978.
38. Trombelli L, Farina R, Silva CO, Tatakis DN. Plaque-induced gingivitis: case definition and diagnostic considerations. *J Periodontol*. 2018;89(1):S46-S73. doi:10.1002/jper.17-0576
39. Center for Health Care Strategies, Inc. *Medicaid Adult Dental Benefits: An Overview*. Center for Health Care Strategies, Inc; 2019. Accessed February 1, 2021. https://www.chcs.org/media/Adult-Oral-Health-Fact-Sheet_091519.pdf.
40. Crozier SR, Robinson SM, Borland SE, Godfrey KM, Cooper C, Inskip HM, SWS Study Group. Do women change their health behaviours in pregnancy? Findings from the Southampton Women's Survey. *Paediatr Perinat Epidemiol*. 2009;23(5):446-453. doi:10.1111/j.1365-3016.2009.01036.x
41. Al Khamis S, Asimakopoulou K, Newton T, Daly B. The effect of dental health education on pregnant women's adherence with toothbrushing and flossing—a randomized control trial. *Community Dent Oral Epidemiol*. 2017;45(5):469-477. doi:10.1111/cdoe.12311
42. Magriples U, Kershaw TS, Rising SS, Massey Z, Ickovics JR. Prenatal health care beyond the obstetrics service: utilization and predictors of unscheduled care. *Am J Obstet Gynecol*. 2008;198(1):75.e1-75.e7. doi:10.1016/j.ajog.2007.05.040
43. Azofeifa A, Young LF, Alverson CJ, Beltrán-Aguilar E. Oral health conditions and dental visits among pregnant and nonpregnant women of childbearing age in the United States, National Health and Nutrition Examination Survey, 1999-2004. *Prev Chron Dis*. 2014;11:E163. doi:10.5888/pcd11.140212
44. Hwang SS, Smith VC, McCormick MC, Barfield WD. Racial/ethnic disparities in maternal oral health experiences in 10 states, pregnancy risk assessment monitoring system, 2004-2006. *Matern Child Health J*. 2011;15(6):722-729. doi:10.1007/s10995-010-0643-2
45. Marchi KS, Fisher-Owen SA, Weintraub JA, Yu Z, Braverman PA. Most pregnant women in California do not receive dental care: findings from a population-based study. *Public Health Rep*. 2010;125(6):831-842. doi:10.1177/003335491012500610
46. *WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience*. World Health Organization; 2016.
47. Adams SH, Gregorich SE, Rising SS, Hutchison M, Chung LH. Integrating a nurse-midwife-led oral health intervention into centering pregnancy prenatal care: results of a pilot study. *J Midwifery Womens Health*. 2017;62(4):463-469. doi:10.1111/jmwh.12613
48. Heimonen A, Janket SJ, Kaaja R, Ackerson LK, Muthukrishnan P, Meurman JL. Oral inflammatory burden and preterm birth. *J Periodontol*. 2009;80(6):884-891. doi:10.1902/jop.2009.080560
49. Kunnen A, van Doonaal JJ, Abbas F, Aarnoudse JG, van Pampus MG, Faas MM. Periodontal disease and pre-eclampsia: a systematic review. *J Clin Periodontol*. 2010;37(12):1075-1087. doi:10.1111/j.1600-051x.2010.01636.x
50. Wimmer G, Philstrom BL. A critical assessment of adverse pregnancy outcome and periodontal disease. *J Clin Periodontol*. 2008;35(8):380-397. doi:10.1111/j.1600-051x.2008.01284.x
51. Offenbacher S, Beck JD, Jared HL, et al. Effects of periodontal therapy on rate of preterm delivery: a randomized controlled trial. *Obstet Gynecol*. 2009;114(3):551-559. doi:10.1097/aog.0b013e3181b1341f