

# Effectiveness of a family-centered behavioral and educational counselling approach to improve periodontal health of pregnant women: a randomized controlled trial

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## Research article

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# Abstract

**Objectives:** Poor oral hygiene and higher hormone levels during pregnancy always lead to poor periodontal health. Oral health education of the pregnant women to improve the periodontal outcomes might be ineffective and inconsistent. The aim of this study was to assess the effectiveness of a family-centered behavioral and educational counselling program on the pregnant women's periodontal health and long-term effect after delivery.

**Methods:** A randomized controlled trial was conducted among first-time pregnant women (10~20th gestational-week) in Hong Kong. Participating families were randomized into test and control group. The intervention in test group included: explanation on oral health education pamphlets, oral hygiene practice training by the "tell-show-do" technique, individualized feedback, and proposed solutions to overcome barriers on self-care. Reinforcement was implemented by interview, phone call or messaging to assess performance, identify barriers and to encourage participants on self-care, in around 32nd gestational-week and 6 months after delivery. Main outcomes assessed were periodontal health measurement including bleeding on probing (BOP), periodontal-pocket (Poc) and loss of clinical attachment levels (LoA); oral hygiene status was assessed by visible plaque index (VPI). The dental examinations were carried out at baseline, 32nd gestational-week and 12-months post-delivery.

**Results:** 589 pregnant women were recruited and 369 completed all three visits (test 188; control 181). Mixed-effect model ANOVA indicated that in test group, % sites with visible plaque decreased from the baseline to the 32nd gestational-week and maintained to 12-months post-delivery while in control group the effect could not be sustained ( $p < 0.001$ ). Both groups showed significant decrease in BOP over time, and significantly lower % sites with BOP was found in test group than in control group at 12-months post-delivery ( $p < 0.001$ ). Generalized linear mixed model (GLMM) showed that there was significant less in sites with Poc and LoA in the both groups over time at 12-months post-delivery than during pregnancy ( $p < 0.001$ ), whereas there was no significant effect between the two groups ( $p > 0.05$ ).

**Conclusions:** Providing family-centered, behavioral and educational counselling to pregnant women at early stage of pregnancy and reinforcements can improve their oral hygiene and periodontal health, the effect can be sustained over a longer period.

## Introduction

Good oral health is essential for healthy pregnancy. Pregnancy induced hormonal changes can affect periodontal tissues. Higher hormone levels during pregnancy amplifies the inflammatory response of gingiva to dental plaque which causes the gingiva to swell and bleed more easily.<sup>1-3</sup> The prevalence of pregnancy gingivitis reported in different studies is 36–100%,<sup>4-7</sup> the changes are transient and the severity of gingival inflammation always increases from 16 to 40 weeks of pregnancy and then decreases after parturition.<sup>8,9</sup> Some studies have reported greater periodontal pocket depths or attachment loss during pregnancy.<sup>3,8,10</sup> However, the difference in the study design (e.g., the variability of

pre-existing periodontal status at baseline, the lack of a non-pregnant comparison group or short follow-up period) would make it unclear to conclude if pregnancy exacerbates periodontal destruction.<sup>11</sup>

It is notable that since periodontal diseases are initiated by dental plaque, and untreated gingivitis can lead to further destruction of the periodontal tissue, educating pregnant women to perform effective plaque removal is important for the prevention and control of periodontal disease in this vulnerable group. Despite this, reported studies on oral health promotion targeting pregnant women are few. A recent systematic review reported that most of these studies mainly delivered dental knowledge on infant oral health and rarely addressed pregnant women's oral health.<sup>12</sup> There were only two studies that reported the periodontal health outcomes and no convincing conclusion could be drawn from their findings because periodontal treatments were also provided and the follow-up was short-term (e.g., after 4–8 weeks).<sup>13,14</sup> In addition, participants in these two studies were pregnant women who had a gingival index score >2 at half or more of the examined tooth sites while excluding pregnant women with normal gingival conditions at baseline.

There still remains a research gap to provide evidence on the effectiveness of oral health education on pregnant women. The aim of this clinical trial was to evaluate the effectiveness of a family-centered behavioral and educational counselling approach on improving periodontal health among pregnant women, and to see if this could be sustained post-parturition. It was hypothesized that the approach applied in this study would improve the periodontal health of pregnant women.

## Materials & Methods

This study was part of a randomized controlled trial titled “Family-centered oral health promotion for new parents and their infants: a randomized controlled trial” with aims to decrease the prevalence of early childhood caries (ECC). A family-centered approach was proposed in providing behavioral and educational counselling to new parents to help establish the self-efficacy of the parents in their own oral health care, and to improve the self-efficacy in taking care of their infants' oral health as well. Comprehensive data of mothers, fathers and their babies were collected through dental examinations, biological sample collection and questionnaire surveys at the 10–20 gestational weeks of pregnancy ( $T_0$ ), 3<sup>rd</sup> trimester of pregnancy ( $T_1$ ), babies' at 1-year-old ( $T_2$ ), babies' at 2-years-old ( $T_3$ ), and babies' at 3-years-old ( $T_4$ ). Findings reported in this paper was the periodontal health of pregnant women after oral health promotion at  $T_1$  and  $T_2$ . The study protocol was approved by the Institutional Review Board of the University of Hong Kong (ethical approval: UW 13–163) and the Research Ethics Boards at each of the participant recruiting sites, as well as registered in [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02937194) (#NCT02937194).

### *Study population and subject recruitment:*

The pregnant women and their spouses were recruited from Obstetrics & Gynecology (O&G) department of the three public hospitals under the Hospital Authority and two Maternal and Child Health Centers (MCHC) under the Department of Health in Hong Kong. The potential participants were approached

during their prenatal visits with minimal disturbance to the routine care at the MCHCs and O&G and with recruiting advertisement. The inclusion criteria were pregnant women with 1) first-time pregnancy; 2) between 10 and 20 weeks of gestation; 3) being 18 years or older at enrolment; and 4) could understand written and spoken Cantonese. Families were excluded if they were 1) not of Chinese ethnicity; 2) pregnant women with severe systemic disease. Written informed consent was obtained from both the husband and wife. The recruitment lasted between June 2014 and June 2016.

#### *Randomization and blinding:*

This study was a randomized controlled trial with parallel design, and was compliant with the CONSORT statement (CONSORT Group 2010). The participants were randomly assigned to one of two parallel intervention groups after the baseline data collection which included a questionnaire survey and dental examination conducted by dentists not involved in the intervention. The random number sequence was generated by an independent statistician prior to recruitment. Block randomization with a block size of 4 was adopted. Opaque sealed envelopes were used to conceal the allocation. Research assistants who enrolled participants, collected the questionnaire information and dental examiners were blinded to the participants' group allocation.

#### Intervention:

The intervention to the test group was family-centered behavioral and educational counselling, which occurred in the early stages of pregnancy ( $T_0$ ), reinforced in the late stage of pregnancy ( $T_1$ ) and 6-months after delivery. The process of intervention was a dynamic (versus static) design, and supported participants to progress toward their goals—being healthy both for themselves and their babies. The pregnant women received specific, action-oriented advice to achieve goals rather than general information on healthy behaviors.

At  $T_0$ , 20–40 minutes individualized counselling was given by trained dental auxiliary staff to both the expectant mothers and their spouses. The whole process was as follows:

1) Face-to-face explanation of two OHE pamphlets: each family was given two OHE pamphlets produced by the Department of Health of the Hong Kong government. The first OHE pamphlet entitled "*Cleaning your teeth by toothbrushing*" was intended for the general public and included: i) knowledge of etiology and pathological progress of dental caries and periodontal disease; ii) description of plaque, tooth anatomy and how the oral bacteria caused the oral disease; iii) best oral health home care including brushing teeth at least twice daily, using fluoridated toothpaste, and daily flossing; iv) illustrations on toothbrushing and flossing. The second OHE pamphlet entitled "*Oral health for the expectant mother*" introduced the changes in oral health during pregnancy, the potential link between periodontitis and adverse birth effects, appropriate dental visit time during pregnancy. The information about the perceived benefits of toothbrushing and flossing and the impacts of not performing the oral hygiene practice well during pregnancy was emphasized (e.g. susceptibility to poor periodontal health, association of systemic disease, increase the risk of preterm delivery and bacteria vertical transmission related to children's ECC).

After this part of education, the pregnant women got to know themselves to be susceptible to periodontal disease (perceived susceptibility); considered periodontal disease to have potentially serious consequences (perceived severity) e.g. preterm delivery; believed that their oral hygiene practice would produce positive outcomes (perceived benefits) e.g. to reduce the vertical transmission of oral cariogenic bacteria to children.

2) Demonstration of toothbrushing and dental flossing: manual toothbrushing technique (Bass method as recommended by ADA) was demonstrated on a teeth model. *"Tell-show-do"* technique was used with the participants listening to the explanation and observing the proper technique for toothbrushing and flossing, then the participants were encouraged to do it on the models.

3) Proposing the possible ways of overcoming barriers related to toothbrushing and flossing during pregnancy: we proposed the best practices for oral health hygiene if experiencing frequent nausea/vomiting. For example, *"if brushing makes you feel sick, try using a soft small-headed toothbrush designed for children"*; *"brush later in the morning when you may not gag as much"*; *"concentrate on your breathing as you clean your back teeth"*; *"brushing without toothpaste, rub or smear fluoride toothpaste over your teeth after brushing and don't rinse it off"*. Through the above step 2 and 3, the communication with oral health educator provided the participants opportunity to raise and solve the problems they encountered (perceived and solved barriers).

4) Individualized feedback based on the dental checkup findings, and to answer the questions raised from participants: e.g., *"Is it safe to use mouthwash during pregnancy?" "Is an electric toothbrush better than a manual toothbrush?" "Should I switch to fluoride-free toothpaste to decrease the potential harm to my fetus?"* etc.

At the 32<sup>nd</sup> gestational week (T<sub>1</sub>) followup, the expectant mothers provided feedback on performing the toothbrushing and flossing, the instruction were reinforced if the participants reported their self-efficacy on oral hygiene practice was not good enough. The oral health education on infant oral health care was also delivered to the parents. The details will be reported in another paper.

After the babies were born and reached 6-months-old (between T<sub>1</sub> and T<sub>2</sub>), the mothers in the test group were contacted through phone calls or message for arranging the next appointment. Reinforcement of maintenance of proper oral hygiene practice for themselves and their children was carried out. Assessment on performance, barrier identification, tips for behavior motivation and encouragement was sent to participants in response to their feedback.

The intervention to the control group was only delivery of the oral health education pamphlets for adults and pregnant women as same as the test group. There was no further reinforcement after baseline data collection.

### *Data collection*

Data was collected from the participants through dental examination and a questionnaire at T<sub>0</sub>, T<sub>1</sub> and T<sub>2</sub>. Oral hygiene status was recorded by using the Visible Plaque Index (VPI) which reflects the overall level of plaque accumulation.<sup>15</sup> The presence or absence of visible plaque on the buccal and lingual surfaces of six indexed teeth (tooth 16, 21, 24, 36, 41, 44) was recorded. Periodontal status was measured following the periodontal examination methods and indices recommended by World Health Organization (WHO) (Oral health surveys: basic methods, 4th ed., 1997. At our initial stage of data collection, the 5th edition is not online yet.). The CPI probe with a 0.5mm ball-ended tip and scale marked at 3.5/5.5mm was used to probe the WHO recommended index teeth (one tooth in each sextant).<sup>16</sup> For each tooth, the highest code that corresponds with the most severe condition among six probing sites would be recorded. One score represents one sextant. The gingival inflammation was detected by the Bleeding on Probing index (BOP). The presence or absence of bleeding by probing was recorded. Periodontal pocket score (Poc), measured from the free gingival margin to the base of the periodontal pocket, and loss of attachment (LoA), measured from the cemento-enamel junction to the base of the periodontal pocket, was recorded to the nearest 3.5 or 5.5mm mark of CPI probe.

The baseline and follow-up examinations on oral hygiene and periodontal status was conducted by two calibrated examiners trained by an experienced epidemiologist prior to the study initiation. In each examination, duplicate examinations were conducted on 5% of participants. The inter-examiner reproducibility was good (Kappa = 0.77 for oral hygiene status, Kappa = 0.76 for bleeding and Kappa = 0.80 for pocket depth and loss of attachment). The intra-examiner reproducibility was good for both examiners (all the Kappa>0.75).

Before each dental examination the participants completed a questionnaire which included three questions on oral hygiene practices (toothbrushing frequency, use of fluoridated toothpaste, and additional oral hygiene measures) and twelve questions on periodontal health knowledge. Information on participants' socio-demographic background, and smoking and alcohol consumption habits was also collected.

In this paper, the primary outcome of the interventions was periodontal health. Percentage of sites with BOP (BOP%), the number of sextants with Poc (NPoc) and the number of sextants with loss of attachment (NLoA) were the primary outcome variables. The secondary outcome was oral hygiene status measured by the percentage of examined tooth surfaces with visible plaque (VPI%).

### Statistical analysis

Statistical analysis was performed using SPSS Statistics for Windows (IBM, (Version 24.0. Armonk, NY: IBM Corp) Data of the participants who attended all three examinations were included in the analysis. To compare the characteristics between two groups and between participants who completed the follow-ups and who did not, Mann-Whitney U tests and  $\chi^2$  tests were performed to assess the differences in the medians of continuous variable and the distribution of categorical variables between groups, respectively.

The effects of study group allocation and time of examination on BOP% and on the VPI% (continuous variables, 0%–100%) were analyzed with a mixed-effect ANOVA model. Since the frequency distribution of the NPoc and NLoA was highly skewed with excessive zero score (negative binomial distribution), generalized linear mixed model (GLMM) on count data was adopted. In the above models, time-points ( $T_0$ ,  $T_1$  and  $T_2$ ) was regarded as the within-subjects factor whereas the group allocation was the between-subjects factor. The between-subjects factor reflected the intervention effect, and the interaction between time-point and group allocation showed whether the intervention effect differed between  $T_1$  and  $T_2$ . Treatment effects at  $T_1$  and  $T_2$  were presented as adjusted mean differences with 95% CIs. The p-values of the pairwise comparison were adjusted by Bonferroni adjustment and 0.05 was considered as the statistical significance level adopted for all overall tests.

### *Sample size calculation*

Sample size calculation for this trial was based on the severity of early childhood caries (ECC) for children at 3-years-old, which was the primary outcome of this family-centered clinical trial. A total of 584 families were considered sufficient to achieve the main objectives of this trial. For evaluating the periodontal outcome of pregnant women in present research, one of the primary outcomes was the mean percentage of sites with BOP. At baseline there were 60% of the sites with BOP among the pregnant women. If an absolute decrease of 20% in BOP was considered clinically significant and using an 80% power, the sample size required would be 102 in each group. Our original sample size calculation based on ECC outcome was sufficient for detecting clinically significant changes in the periodontal health parameters of the pregnant women.

## **Results**

Figure 1 shows the CONSORT flow chart for this RCT. A total of 1,989 pregnant women were approached, 1,203 women met eligibility criteria and 589 participants with complete baseline data were recruited in this study (participation rate 49.0%). After random allocation, 297 and 292 participants were in the test and the control groups, respectively.

Table 1 summarizes the characteristics of women by allocated group at baseline. The mean age of the participants was 31.1 years (SD = 4.0 years) and the mean gestational age at the time of recruitment was 14.4 weeks (SD = 2.6 years). More than 60% the participants had an income of HK\$30,000 or more per month which was above the average level of Hong Kong households (Census and Statistics Department, 2017). More than two thirds (67.1%) of the participants had received tertiary education. Less than half (40.4%) of the participants were covered by adental care scheme. There were no statistically significant differences in the demographic characteristics, dental scheme coverage and alcohol drinking habit between the test and control groups ( $p>0.05$ ), whereas there was a higher proportion of participants with smoking habits allocated to the control group ( $p<0.05$ ).

At baseline, although visible plaque was detected on most (82.5%) of the study participants, only 6.6% of them had visible plaque on more than 50% of the examined tooth surfaces. Mean percentage of tooth surfaces with plaque were similar in both groups at baseline ( $p>0.05$ ). At baseline, almost all (95.2%) of the participants had BOP. Over 70% of the participants had more than 50% indexed tooth surface with BOP. Nearly 90% of the participants were free of POC on the sextants examined. There was no significant difference between the two study groups regarding the percentage of sites with BOP and the number of sextants with POC ( $p>0.05$ ) (Table 1).

Table 2 shows comparison of the characteristics of participants who were followed up with those who were not. Of the 589 participants recruited, 369 (62.6%) attended T1 and T2 follow-up examinations and completed the study questionnaire. Participants who lost to follow-up were younger ( $p<0.01$ ). There was no significant difference ( $p>0.05$ ) on other characteristics between the participants who completed the follow-ups and who did not. Although there were a certain percentage of losses during the follow-up (37% in the test group and 38% in the control group), there was no difference on the distribution of age, gestational age, education level, monthly household income, dental scheme coverage and smoking habit between the test and control among the participants who completed twice follow-ups (all  $p$ -value  $>0.05$ ).

### *Outcomes and estimation*

By a per protocol analysis which exclude the dropout participants, table 3 shows the difference on periodontal conditions between two groups accounting for the time changing. In the mix-designed analysis of variance (ANOVA) on VPI% and BOP% and generalized linear mixed model (GLMM) analysis on count NPoc and NLoA, participants' age, gestational month, education level, monthly income, with dental scheme coverage or not and smoking habit was put into the initial model as confounding factors. These variables had been removed in the final model due to no significant contribution to the coefficient.

At the one-year follow up of this study, more participants had healthy periodontal condition (defined by WHO as VPI = 0 and BOP = 0 and POC = 0 and LoA = 0) than baseline ( $p<0.01$ ). Meanwhile, the test group had more percentage of individuals with healthy periodontal status than the control group one-year post-delivery ( $p<0.01$ ) (Table 3).

There was around 3% of participants who had been detected with VP on more than 50% of the tooth surfaces at  $T_0$ . After intervention in the test group, fewer participants at this condition could be detected at  $T_1$  and  $T_2$  (3.7% to 0.5% to 0%,  $p<0.01$ ), whereas the participants in control group at this condition were more (2.2% to 2.2% to 5%). Throughout the study, people with severe condition of gingival bleeding ( $>50\%$  sextants) was less in both groups, however the prevalence of severe gingival bleeding was lower in the test group than in the control group at  $T_2$  ( $p<0.01$ ). For the severity of condition, the mean VPI% in test group was 19% at  $T_0$  and decreased to 14% at  $T_1$  and remained at the lower level at  $T_2$ . In the control group, the mean VPI% decreased slightly from 19% at baseline to 16% at  $T_1$  but increased to 22% at  $T_2$ . The change tendency of BOP% was similar to the VPI%. In the test group, the mean BOP% was 57% at  $T_0$  and this decreased to 46% and 35% at  $T_1$  and  $T_2$  respectively. The mean BOP% in the control group only

decreased slightly from 58% at baseline to 52% and 46% at T<sub>1</sub> and T<sub>2</sub>. A main effect of time, of intervention and an interaction between time and intervention has been detected (all p<0.05). The difference of VPI% change between groups was statistically significant (p = 0.025), as well as of BOP% change (p = 0.014). Pairwise comparison has carried out with Bonferroni adjustment. As for VPI%, from T<sub>0</sub> to T<sub>1</sub>, the decrease in test group reached statistical significance (p<0.001) whereas it did not in the control group (p>0.05). After 12 months (T<sub>2</sub>), the VPI% of the test group was similar to the corresponding T<sub>1</sub> values and still remained significantly better than baseline (p = 0.01). However, the VPI% was significantly greater in control group at T<sub>2</sub> Compared to the T<sub>1</sub>, the VPI% increment T<sub>2</sub> in control group was 0.06(95% CI: 0.03; 0.08) whereas in the test group was only 0.01(95% CI: -0.01; 0.04). The inter-group difference of increment was significant (p<0.05).

In total, compared with T<sub>0</sub>, more pregnant women had periodontal pocket at the T<sub>1</sub> (p<0.01), and fewer participants with periodontal pocket at T<sub>2</sub> (p<0.001). No significant difference was found between the two study groups at the three time-points (p>0.05). In both the test and the control group, the mean NPoc increased from T<sub>0</sub> (around 0.2) to the T<sub>1</sub> (around 0.3) and then decreased at T<sub>2</sub> (around 0.1). There were significant changes for both groups due to time (p<0.001). There was no significant intervention-time interaction such that the intervention effect did not differ between T<sub>1</sub> and T<sub>2</sub> (p = 0.293). The mean NPoc was greater at the late stage of pregnancy than the early stage, then dropped to the lower level in comparison to baseline one-year later (p<0.001). There was a similar pattern of coefficients of the two groups. No significant differences were found between the two study groups (p = 0.402). There was a similar pattern of coefficients of the two groups in the NLoA. The count of sextants with LoA in T<sub>2</sub> significantly decreased from T<sub>0</sub> and T<sub>1</sub> whereas there was no significant difference between two groups over time (Table 3).

## Discussion

This study sheds light on oral health promotion programs aimed at families with their first pregnancy in a primary care setting, which has been sparse in the literature to date, and the strengths of this trial was with a control group and decent sample size. Findings of this clinical trial showed a behavioral and educational counselling program is helpful on gingival inflammation control without supplementary treatment. Pregnancy does not necessarily lead to more severe gingivitis or periodontitis if they can keep their oral hygiene efficiently. Although the greater hormone level increases the risk of gingivitis during pregnancy, the status of gingivitis would not necessarily become severe in the late pregnancy as long as the plaque is controlled. Even one-year after parturition, the oral hygiene and periodontal status could be well maintained with efficient oral health promotion during pregnancy. On the other hand, based on the “new classification system for periodontal and peri-implant diseases and conditions”<sup>17</sup>, for the disease of periodontitis, the findings indicate that there is not necessarily greater periodontal attachment loss during pregnancy accompanied by elevated hormone levels. Although the intervention in the test group had no additional efficacy in comparison with the control group, and possibly the significant decrease of periodontal pocket and loss of attachment post-delivery was due to the host response related to hormones, we still

cannot ignore the role of oral health education because the destroyed periodontal support tissue during pregnancy will not always completely revert after delivery.

Compared with previous studies, a significantly higher proportion of participants showed a better oral hygiene and periodontal health in this study, and the interventions were just behavioral and educational counselling without additional treatment. In the two previous studies on oral health promotion among pregnant women, they focus on the pregnant women who were with intensive gingivitis but free of periodontal pocket and provided limited clinical treatment in addition to oral health education.<sup>13–14</sup> Although direct comparison between the previous studies and the current study is not justified, this research shows the importance of an effective oral health education approach to the general pregnant women population, which is consistent with the appeal of global action to effectively promote periodontal health by primary and secondary prevention.<sup>18</sup>

There are many kinds of oral health education methods, such as delivered to individual or group, by distribution of pamphlets or giving instructions and audiovisual presentations.<sup>12–14,19</sup> A recent randomized controlled trial found no additional effects in oral hygiene and gingival bleeding improvement in the group who had received a more elaborated education.<sup>20</sup> In contrast, our study shows that a more elaborated and tailor-made behavioral and educational counselling is more effective in improving and sustaining plaque control and periodontal health than the distribution of pamphlets only.

The good effectiveness of this clinical trial may due to a number of reasons. Firstly, the intervention was in majority consistent with essential constructs of a psychological theory-based model, Health Belief Model for promoting health.<sup>21</sup> The process of intervention was a dynamic (versus static) design, and supported participants as they progressed toward their goals—being healthy both for themselves and their babies. Parents received specific, action-oriented advice to achieve goals rather than general information on healthy behaviors. After counselling the pregnant women got to know themselves to be susceptible to periodontal disease (perceived susceptibility); considered periodontal disease to have potentially serious consequences *e.g.* preterm delivery (perceived severity); believed that their oral hygiene practice would produce positive outcomes *e.g.* to reduce the vertical transmission of oral cariogenic bacteria to children (perceived benefits); and the communication with oral health educator during the reinforcements provided opportunity to solve the problems they encountered (perceived barriers). Generally theory-based interventions are proven to be more successful in achieving stable and permanent behavioral changes than non-theory based interventions.<sup>22–24</sup> Secondly, the 2<sup>nd</sup> trimester of pregnancy is a good opportunity to emphasize to the pregnant women the importance of good oral health in this specific period (*e.g.*, some of them had experienced gingivitis, concern of oral–systemic health issues, as well as her baby’s health). If the pregnant women are aware of the impact of the expectant mother’s oral health on infant’s health, it may be easier to translate knowledge into their behavior. Thirdly, there was detailed demonstration of oral hygiene practice and use of “*show-to-do*” in this study. Training the participants on how to master the correct tooth brushing method focusing on gingival margin and proximal areas of the teeth, how to handle nausea/vomiting when brushing teeth and how to use the

additional tooth cleaning methods (e.g., flossing) was delivered to the participants. All these procedures as well as pregnant women providing feedback on performance are particularly useful to improve their capabilities to perform a good oral hygiene practice. Fourthly, first-time expectant mothers at their early pregnancy stage were targeted in this study. Pregnancy, especially the first one, is a major transition in woman that provides an opportunity to “change”, e.g. change of nutrition-related behavior because the woman concerns about the health of herself and her fetus.<sup>25</sup> Similarly, pregnancy with first one also may be a good opportunity to elicit positive behavior changes in oral health-related behavior. It has been also reported pregnant women in their first trimester are easier to register in research projects and are more willing to receive prenatal or other health care.<sup>26</sup>

The findings would be tempered due to some limitations. First, although diverse samples of pregnant women were obtained in different districts in Hong Kong and the participants were recruited from public prenatal care centers, their socio-economic background was above the average in Hong Kong. This may lead to a better response to oral health promotion. More research on interventions delivered in other populations, e.g., low-income people, are required to see if the conclusions on the effects of approach in this study can be generalized. Secondly, there is methodological limitation in adopting the indices for partial periodontal examination methods recommended by WHO (4<sup>th</sup> edition)<sup>16</sup> in this study. Clearly, partial mouth recordings are quicker to undertake than full mouth recordings. This is important and helpful in this study because our participants were pregnant women and the data collection was carried out during their prenatal care with restricted time. However, the partial recording of periodontal parameters might result in underestimating the prevalence of disease<sup>27</sup>. Despite of this concern, this measurement has been recognized as being well suited for identifying individuals who are (and who continue to be) periodontally healthy.<sup>28,29</sup> In this respect, we can conclude that the individualized behavioral and educational counselling indicate more promising findings for maintaining the good periodontal oral health among pregnant women. Thirdly, although fathers were encouraged to attend, the relative high drop-out rate (roughly 30%) restricted highlighting the particularity and benefit of family-based oral health education, which limits the generalizability of the study findings.

Compared to other studies, the oral hygiene status of the participants in this study was not poor. Although 82.5% of them had visible plaque on some of the index tooth surfaces, only around 3% of the participants had visible plaque on half or more of the index tooth surfaces. The oral hygiene of pregnant women in this study was much better than the average level of the middle-aged (35–44 year-old) adults in Hong Kong.<sup>30</sup> There is a potential ‘ceiling effect’ (i.e. the reasonably good oral hygiene at baseline would make further improvement difficult). If the intervention in this study would be delivered to people with poorer oral hygiene, better intervention efficacy could be expected. So, for the pregnant women with higher scores of gingivitis, we hypothesize that gingivitis during pregnancy could be controlled with a simple, convenient and minimally invasive approach - behavioral and educational counselling to improve home care in pregnant patients.

Due to the widespread prevalence of pregnancy gingivitis, whereas many pregnant women did not seek dental care for the misunderstanding of oral health knowledge and other concerns, this paper proved the home self-care strategy after behavioral and educational counselling could be a cost-effective way to treat gingivitis and prevent periodontitis in pregnant women. A pregnant woman should receive adequate information and oral hygiene instructions from dentist or non-dental professionals (e.g., her obstetrician, midwives, nurses) so as to know how to improve her oral health. Psychological theory-based oral health promotion is suggested and could be used in the routine dental care or be integrated into prenatal care to manage pregnant women's periodontal health. Furthermore, if necessary, early in her pregnancy more reinforcement should be scheduled.

## Declarations

*Ethics approval and consent to participate:* Ethical approval was obtained from the five ethics review boards in Hong Kong: Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB, Ref: UW 13–163), Hong Kong East Cluster (HA HKE IRB, Ref: HKEC–2014–087), Kowloon Central & East Cluster (HA KC/KE IRB, Ref: KC/KE–14–0093/FR–2), Kowloon West Cluster (HA KW IRB, Ref: KW/EX–14–177(79–15), as well as ethic review board from Department of Health (Ref: L/M 304/2014). Informed written consent were obtained from all participants.

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*Competing interests:* The authors declare that they have no competing interests in this study. No financial or non-financial interests influenced the interpretation of the data or presentation of the information.

*Consent for publication:* All the authors are aware of and approve the submission of the manuscript.

*Availability of data and material:* The full trial protocol accessed, datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

*Authors' contributions:* Dr. Liu P have made an contribution to the oversight of the project and coordination, data analysis and interpretation, and drafting of the paper; Dr. Wen Weiye has made substantial contributions to the data collection, data analysis and drafting of paper; Liu P and Wen WY have contributed equally to this work. Ms. Yu Kafung made an active contribution to the data collection and analysis; Dr. Gao XL has been involved in study design and critically refined the paper; Professor Lo CM has made contributions to the design of the work, training and calibrating dental examiners, and substantively revised and greatly improved the manuscript; Professor Wong MCM contributed to the conception and design, supervised the data analysis, critical revision of the article, reviewed and approved the final version submitted for publication.

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## Tables

Due to technical limitations, Tables 1 - 3 are only available for download from the Supplementary Files section.

## Figures

Fig. 1. CONSORT diagram of participants on recruitment, randomization and follow-ups

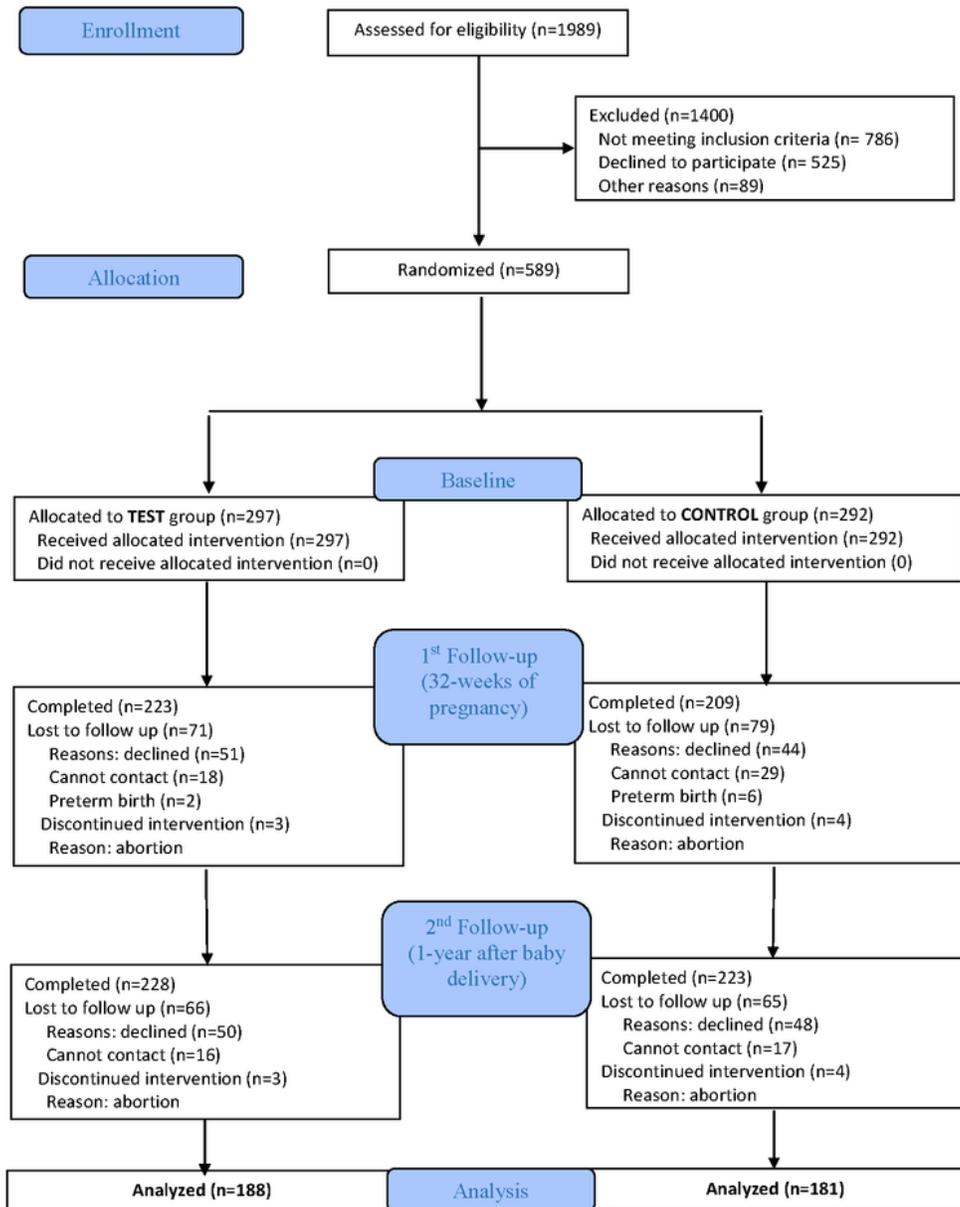


Figure 1

CONSORT diagram of participants on recruitment, randomization and follow-ups. Notes: The number of participants of each follow-up was compared to the baseline, regardless whether they have the completed data. The follow-up rate of each time was more than 75%. The reasons for loss of follow-up were participant refusal, transferring to other health centers, public or private hospitals for antenatal checkup which were different from the ones included in this study, loss of contact, preterm delivery before 32-

gestational week or abortion. The data analysis was based on the participants who completed both the 1st and 2nd follow-ups.

## Supplementary Files

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- [Tables13.docx](#)