**Oral Health Behaviour among Pregnant Women in Kuwait
A Social Cognitive Approach**

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Oral Health Behaviour among Pregnant Women in Kuwait: A Social Cognitive Approach

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ABSTRACT

Background: Oral health is a concern in pregnancy because of local oral effects such as gingivitis and the potential to have an adverse effect on pregnancy outcomes. In Kuwait, evidence suggests that expectant mothers have poor oral health, are fearful of dentistry, have little awareness of oral health and are in need of dental health education (DHE). In order to design an intervention aiming to change the oral health behaviours of pregnant Kuwaiti women, it was important to have contemporary evidence on the relationship between periodontal disease (PD) and adverse birth outcomes (ABOs), and an understanding of the social and cultural context in Kuwait in which oral health behaviours take place.

Aim: The aim of the thesis was to design, implement and evaluate a DHE intervention for Kuwaiti pregnant women. In order to achieve the aim of the thesis three studies were undertaken: 1) A systematic review and meta-analysis to assess the association between PD and ABO, and the efficacy and the safety of non-surgical periodontal treatment (NSPT) during pregnancy to prevent ABOs. 2) A qualitative study amongst Kuwaiti women to investigate perceptions, beliefs, attitudes and expectations about oral health and maintaining and improving oral health during pregnancy. The data were also used to identify social cognition constructs which might be helpful to promote oral health behaviour in this group of women. 3) A randomised controlled trial to assess the efficacy of dental health education (DHE) with or without a planning intervention on adherence to dental health related behaviours amongst Kuwaiti pregnant women.

Results:
Study 1) The majority of individual cohort studies support an association between ABOs and PD, the meta-analyses support the association [(PTB: RR1.63 (95% CI: 1.06, 2.50, P=0.03), LBW: RR 2.35 (95% CI: 1.21-4.57, P=0.01) and PLBW: RR 3.53 (95% CI: 1.51 -8.20, P=0.003)] but are compromised by high levels of heterogeneity associated with the insecurity of definition of periodontal disease. The meta-analyses of 13 RCTs found that NSPT during pregnancy did not prevent PTB and PLBW but may prevent LBW (RR 0.75 (95% CI: 0.56-0.99, P=0.05) and stillbirth (RR 0.48 (95% CI: 0.25-0.90, P=0.02). The meta-analyses for PTB, LBW and PLBW were characterised by high levels of heterogeneity also attributable to uncertainty about definition of periodontal disease. None of the RCTs assessed robustly the safety of the periodontal treatment during pregnancy, though no significant adverse events were reported. There remains uncertainty in relation to the efficacy and safety of NSPT to prevent ABOS.

Study 2) The qualitative study found that women had low levels of oral health knowledge and information. They had unhelpful cultural beliefs concerning oral health during pregnancy, and were unaware of the effect of pregnancy on oral health. Pregnant women lacked motivation to seek dental care even when they considered dental treatment safe during pregnancy. Dentists, unhelpful cultural beliefs, and lack of motivation were identified as barriers to accessing oral health care and seeking oral health knowledge. A number of social cognition constructs were identified from the qualitative study: knowledge; attitudes; subjective norms; barriers; and intentions. These together with the findings from

the first study were used to frame, inform and design the intervention reported upon in study 3).

Study 3) At T1 154 women were eligible and randomly allocated to the three groups respectively: Treatment as Usual (TAU) =53; DHE=53; DHE & Planning=48. At T2 the number of women in each group completing the intervention (N=90) was respectively: TAU=28; DHE=30; DHE&P=32. SCM constructs and self-report of behaviours were assessed at T1 and T2 through a questionnaire assessing knowledge, attitudes, subjective norms, barriers, intentions and self-report of oral health behaviours in relation to oral hygiene. Plaque scores (PI) and gingival scores (GI) were recorded by a trained and calibrated examiner blind to group allocation.

There were no demographic differences between the groups at baseline. The mean age of women was 27.80±SD 5.40, 43% (n=38) had a high school level education and 10% no formal education. Twenty eight per cent were in their first pregnancy, the remainder had 2.06±1.98 or more children. A mixed factor ANOVA analysis demonstrated that all women improved their PI (F=94.343 df=1 p=0.001) and GI (F=73.138 df=1 p=0.001) scores. There were no differences in self-reported oral hygiene and PI and GI by intervention group. The SCM constructs changed over time in all women (N=90) except barriers to attendance (F=1.067 df=1 p=0.305). There were no differences in SCM constructs by intervention group at T2. All women reported increasing the frequency of tooth brushing and flossing.

Conclusion: Providing a basic oral hygiene leaflet was sufficient to motivate women to change their behaviour in relation to tooth-brushing and dental flossing resulting in improved PI and GI scores. In this study where women had very limited oral health knowledge, information giving was as efficacious as an intervention underpinned by SCMs in influencing behaviour change, but these results must be interpreted with caution given the high attrition rates and possible influence of a Hawthorne effect.

DEDICATION

This thesis is dedicated to my father, who always stood behind me and knew I would succeed. Gone now but never forgotten. I will miss you always and love you forever. Thanks for all you did.

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Chapter 1

Introduction

Maintaining optimal oral health during pregnancy is important for the general health of the pregnant woman and the unborn baby (Achtari et al., 2012; Acharya and Bhat, 2009). The literature suggests that periodontal disease is a concern in pregnancy because of local oral effects such as gingivitis (Wrzosek and Einarson, 2009; Ressler-Maerlender et al., 2005; Mills and Moses, 2002) and the potential to have an adverse effect on pregnancy outcomes (Ide and Papapanou, 2013; Chambrone et al., 2011a; Vergnes and Sixou 2007).

In Kuwait, evidence suggests that expectant mothers have poor oral health and have little awareness of the importance of oral health during pregnancy (Honkala and Al-Ansari, 2005). Most women in this 2005 study reported that they had not received information concerning care of the mouth which together with the prevalence of oral problems reported in the study indicated a need for appropriate dental health education (DHE) (Honkala and Al-Ansari, 2005).

The low awareness of oral health in Kuwait was not confined to pregnant women. Two other studies of Kuwaiti adults' oral hygiene habits confirmed that oral health knowledge was poor, with most adults reporting multiple oral health problems (Al-Shammari et al., 2007a; Al-Hussaini et al., 2003). In Kuwait, dental health services mainly provide treatment for pain relief and dental emergencies (Behbehani and Scheutz, 2004). The oral health care system has little focus on disease prevention or DHE for adults. Preventive services are available only for children in kindergartens and primary schools (Behbehani and Scheutz, 2004).

Honkala and Al-Ansari (2005) indicate a need for DHE amongst pregnant women in Kuwait. Any such DHE intervention should be based on a sound understanding of the impact of pregnancy on oral health particularly the possible impact of periodontal disease on pregnancy outcomes. Where

necessary, the safety and efficacy of interventions employed to treat periodontal disease during pregnancy should also be understood. Additional considerations are that the proposed DHE interventions should be sensitive to the social and cultural context of participants and also be underpinned by psychological models of behaviour change (Watt et al., 2001; Kay and Locker, 1996).

This thesis sets out to design, implement and evaluate a DHE intervention for pregnant Kuwaiti women. In order to design an intervention aiming to change the oral health behaviours of pregnant Kuwaiti women, it was important to have a clear understanding of the relationship between periodontal disease (and possible treatment) during pregnancy and adverse birth outcomes (ABOs), and the social and cultural context in which oral health behaviours take place.

In order to achieve the aim of the thesis, three studies were therefore undertaken. The first study involved a systematic review to assess: a) the association between periodontal disease (PD) and adverse pregnancy outcomes (ABOs), b) the efficacy of providing non-surgical periodontal treatment (NSPT) during pregnancy to prevent ABOs, and c) the safety of periodontal treatment during pregnancy.

The second study was a qualitative study, which explored perceptions, beliefs, attitudes and expectations about oral health amongst pregnant Kuwaiti women, and also explored beliefs and attitudes about maintaining and improving oral health amongst Kuwaiti women during pregnancy. Important factors which shape women's behaviour during pregnancy were identified.

The design of the third study was informed by the first and second studies in particular the low knowledge base and lack of motivation for oral health behaviour identified in the qualitative study. The third study was a randomised

controlled trial (RCT) which aimed to assess the efficacy of dental health education (DHE) with or without a planning intervention on adherence to dental health related behaviours amongst pregnant Kuwaiti women, using maternal health clinics.

Chapter 2

Literature Review

2.1 Introduction

This literature review first describes the current evidence with regard to the relationship between pregnancy and oral health. Then a brief description is provided of the oral health of adults and pregnant women in Kuwait. The next section will discuss the relationship between adverse pregnancy outcomes and periodontal disease and identifies any gaps in knowledge, which might have implications for dental health education. Finally, as the central area of interest is an intervention to change oral health behaviours, the health behaviour and psychological models of behaviour change and their application in dentistry will be reviewed.

2.2 Pregnancy and oral health

Pregnancy affects a pregnant woman's body, including several body systems, due to changes in the sex hormones oestrogen and progesterone (Nayak et al., 2012). The physiological changes associated with pregnancy may lead to several symptoms such as nausea, vomiting, nasal congestion, heartburn, food craving, shortness of breath and fatigue (Nayak et al., 2012). Pregnancy may also affect dental health as a result of the hormonal changes that mainly affect the soft tissues (Russell and Mayberry, 2008). Several oral changes have been suggested to occur in the woman's oral cavity during pregnancy including: maternal gingivitis, pregnancy tumour or granuloma, worsening of a pre-existing periodontitis and reduction in saliva pH with increased risk of erosion and dental caries (Achtari et al., 2012; Nayak et al., 2012; Zanata et al., 2008).

It is contended in the dental literature that oral health should be maintained during pregnancy and that preventive oral health care is essential before and during pregnancy (Ressler-Maerlender et al., 2005). The literature highlights the need for routine dental care during pregnancy (Archtari et al., 2012; Nayak et

al., 2012) not only for the woman's oral health but also for her baby's oral health (Chaffee et al., 2014; Archtari et al., 2012). For example the literature suggests an association between early childhood caries through the transmission of bacteria from the mother's oral cavity to the baby (Chaffee et al., 2014; Archtari et al., 2012).

Studies have highlighted the importance of good oral hygiene procedures to prevent maternal gingivitis (Acharya and Bhat, 2009; Adriaense et al., 2009; Ressler-Maerlender et al., 2005). Therefore the main goal of the oral health care provider regarding pregnant women is to establish and maintain good oral health before and during pregnancy. Basic oral hygiene instruction may improve oral health and contribute to improve the quality of life amongst pregnant women (Zanata et al., 2008).

Authors have highlighted the importance of dental health care for women before and during pregnancy. A number of studies have reported an association between poor oral health and adverse birth outcomes (ABOs) such as preterm birth (PTB) and low birth weight (LBW) (Ide and Papapanou, 2013; Chambrone et al., 2011a; Vergnes and Sixou, 2007; Xiong et al., 2007). The American College of Obstetricians and Gynecologists (2010) for example emphasised the importance of providing dental care to women during pregnancy including preventive, diagnostic and treatment dental care services. It also highlighted the safety and benefit of the utilisation of the needed dental radiographs and local anaesthesia during pregnancy (American College of Obstetricians and Gynecologists, 2010). Several dental organisations such as the American Dental Association (ADA) (2000) and the American Academy of Paediatric Dentists (AAPD) (2008) suggest that pregnant women should receive the same level of dental treatment during pregnancy as non-pregnant women.

Pregnancy is thought to be an important and critical period for imparting oral health information and motivating women to adopt positive oral health behaviours (Bates and Riedy, 2012; Russell and Mayberry, 2008).

This view is not universal and some dental authors have suggested that dental treatment may be unsafe during pregnancy and therefore should be avoided or delayed until after delivery (Achtari et al., 2012; Amini and Casimassimo, 2010). Furthermore, the literature highlights the inconsistency between dental care providers' knowledge about safety of dental treatment and the actual dental care provided for pregnant women in practice. A cross-sectional study conducted in the USA, for example, investigated the practice of health care providers (HCPs) and included dentists in the sample studied (n=331) (Strafford et al., 2008). The study found that while most of the dentists encouraged dental attendance during pregnancy, the dentists reported that they were not confident about providing dental treatment during pregnancy (Strafford et al., 2008). Consistent with the latter findings is George et al. (2012) who conducted a systematic review to assess dentists' knowledge, attitude and behaviour concerning dental health care during pregnancy. The review included nine studies from four different countries: the USA, Brazil, Jordan and Australia. Although the findings of the review showed that dentists knew about the importance of regular dental attendance during pregnancy, dentists were also uncertain about the safety of dental treatment and most reported that they provided limited dental care during pregnancy (George et al., 2012).

There is also evidence that pregnant women may avoid dental assessment or treatment during pregnancy due to the lack of oral health awareness and an underestimation of the importance of oral health during pregnancy (Acharya and Bhat, 2009). Pregnant women's knowledge and awareness concerning

maintaining optimal oral health during pregnancy is often inaccurate and incomplete (Hashim, 2012; Ozen et al., 2012; Battancs et al., 2011; Martinez-Beneyto et al., 2011; Detman et al., 2010; Keirse et al., 2010; Scambler et al., 2010; Al-Attas, 2007; Alwaeli and Al-Jundi, 2005; Christensen et al., 2003). Several studies from different Western (the UK: Scambler et al. 2010; Australia: Keirse et al. 2010; the USA: Detman et al. 2010; Spain: Martinez-Beneyto et al., 2011; Hungary: Battancs et al., 2011 and Denmark: Christensen et al., 2003) and Eastern settings (Kingdom of Saudi Arabia: Al-Attas, 2007; Jordan: Alwaeli and Al-Jundi, 2005; United Arab Emirates: Hashim 2012 and Turkey: Ozen et al. 2012) have investigated pregnant women's knowledge, awareness and behaviour concerning oral health during pregnancy. Women from Eastern countries had low oral health knowledge. The exception to these findings was Alwaeli and Al-Jundi (2005) who noted that patients who were pregnant knew that bleeding gums was a sign of gum disease but were not aware what they should do if their gums bled. In contrast, while knowledge was also poor amongst pregnant women in England, the USA, and Australia, there was less of a tendency to provide explanations about oral health derived from cultural beliefs, though the cultural beliefs still played a role. All authors concluded that dental health education (DHE) was needed as a matter of priority.

Additionally, regardless of the Western or Eastern setting, pregnant women avoided seeking dental care during pregnancy, except when dental problems arose. Table 2.1 presents the main findings of studies investigating the oral health knowledge and behaviour of women during pregnancy. Most of the studies use questionnaires and elicit knowledge and behaviour based on arising literature. Only Scambler et al. (2010) allows the opportunity for new knowledge and behaviour to emerge through using a qualitative approach.

Table 2.1 Studies assessing oral health knowledge, attitudes and behaviours of women during pregnancy

Author, Year Country	Study Design	Main Findings
Christensen et al. (2003) Denmark N=1935	Telephone interviews, participants consecutively recruited	33% percevie gingival inflammation. 5% assessed their gingiva as poor. 96% brushed twice a day. '9 out of 10' were regular users of dental care. 26% reported that they responded to symptoms of pregnancy gingivitis by going to the dentist.
Honkala and Al-Ansari (2005) Kuwait N=200	Cross- sectional, questionnaire study Convenience sample	55% reported having periodontal disease. 31% did not know the meaning of periodontal disease. 55% reported dental pain. 40% had dental pain during the previous six months. 7% of participants visited the dental clinic for regular check-ups. Most women reported that they had not received instructions concerning oral health care. 50% had visited the dental clinic while pregnant because of dental pain.
Alwaeli and Al-Jundi (2005) Jordan N=300	Cross- sectional self-administered randomly distributed questionnaires in six maternity units	16% knew what dental plaque was. 88% were aware that bleeding gums indicated presence of periodontal disease. 56% did not think frequency of brushing should be increasing during pregnancy.
Al-Attas (2007) KSA N=528	Cross-sectional, questionnaire study Convenience sample	81 % believed that pregnancy affected the teeth and gums. 72% believed that the foetus took calcium from the mother's teeth during pregnancy. 22% reported that they had received Oral Hygiene Instructions (OHIs) from dentists. 32% thought that a woman lost a tooth for every pregnancy experienced. 58% of women thought that the only indication to attend the dentist during pregnancy was for dental pain.
Battancs et al. (2011) Hungary N=275	Cross-sectional, questionnaire study to volunteers Convenience sample	94% reported they brushed their teeth twice a day. 33% used dental hygiene aids such as dental floss and mouth rinses. 'Many women' reported having gingival bleeding on brushing.
Hashim (2011) UAE N=750	Cross-sectional, questionnaire study Convenience sample	94% reported that they brushed their teeth twice a day. 40% used dental hygiene aids such as dental floss and mouth rinses. 23% reported having periodontal disease. 46% had dental caries. 44% had current dental pain. 60% knew about the effect of pregnancy on oral health. 44% believed that pregnant women might lose a tooth with each pregnancy. 33% reported that they visited the dentist during pregnancy because of dental pain.
Ozen et al. (2011) Turkey N=351	Cross- sectional, questionnaire study. Convenience sample	93% brushed their teeth at least once a day. 8% used dental floss. 14% had regular preventive dental visits during pregnancy. 69% reported having oral health problems during

		pregnancy.
		57 % did not seek dental care during their pregnancy.
		67% did not receive dental instructions during their pregnancy.
		73% believed that they lost calcium from their teeth during foetus development.
		43% believed that pregnant women tended to lose a tooth with each pregnancy.
		47% considered that there was a connection between dental health and gum health.
		75% believed that there was a relationship between oral health and pregnancy.
		31% received oral health instructions from their medical health care providers.
Scambler et al. (2010) UK N=44(9 interviews and 33 focus groups)	Interview (qualitative study)	Women had limited oral health knowledge concerning tooth brushing, sugar consumption, and preventive dental care. Few women reported visiting dental clinics regularly. Some participants made a connection between pregnancy and poor oral health.
Detman et al. (2010) USA N=253	Cross-sectional (Interview and questionnaire) Convenience sample	56% reported having dental problems during pregnancy. 53% did not access dental care before pregnancy. 67% did not access dental care during pregnancy. 60% did not recall receiving dental information during prenatal visits. Barriers to seeking dental care cited by women: • Lack of dental pain or problems. • Low priority of dental care. • Belief that dental treatment was not safe during pregnancy. • Belief that dentists would not treat pregnant women (which was based on information derived from friends, families and prenatal caregivers).
Keirse and Plutze (2010) Australia N=649	Cross- sectional, questionnaire study Convenience sample	65% of the participants had not accessed dental care during pregnancy. 73% did not use dental floss. 41% of the pregnant women reported having experienced gingival bleeding during pregnancy. 38% of the participants with gingival bleeding sought dental treatment.

In conclusion, there is a consensus in the literature with regard to the importance of having and maintaining optimal oral health during pregnancy. There was no doubt about the oral health knowledge of the dental health professionals concerning the importance of dental health attendance during pregnancy. In spite of this, there is still confusion amongst dental health professionals about the safety and efficacy of dental treatment during pregnancy. Pregnant women from Eastern and Western countries lacked oral

health knowledge and were uncertain about the safety of dental treatment during pregnancy. In addition, some pregnant women reported that they were fearful that dental treatment might harm their unborn babies so they would rather avoid any dental treatment during pregnancy (Detman et al., 2010).

The next section will review what is known in relation to the oral health of pregnant women in Kuwait.

2.3 Oral health of adults and pregnant women in Kuwait

Only one study in the capital Kuwait City (Honkala and Al-Ansari, 2005) has reported on oral health practices and behaviours amongst pregnant women. The authors described self-reported oral health, oral hygiene habits, and the frequency of visits to a dentist in pregnant women (N=200) attending a government maternity hospital in Kuwait. Questionnaires were distributed to a convenience sample of 603 pregnant women who were admitted to the government maternity hospital. The questionnaire consisted of five parts: socio-demographic factors, perceived oral health e.g. periodontal disease and dental caries, oral health habits such as dental visits and tooth brushing, instructions relating to oral health care by dentists, and knowledge concerning tooth brushing, fluoride, sugar, and caries causing bacteria. Thirty-one% (31%) of Kuwaiti participants and 21% of non-Kuwaiti said they had very good/excellent oral health. Fifty-five% (55%) of participants were currently in dental pain and reported having gingival/periodontal disease, with 40% having dental pain during the last six months. In terms of visiting the dental office: 50% attended to have dental pain treated; 10% for regular scaling and 7% for regular check-ups. The authors concluded that given the extent of oral health problems experienced by pregnant women in their study there was a great need for dental

health education (DHE). The findings from the study must be treated with some caution as it was a small cross-sectional study undertaken in one urban setting. The response rate was low at 30% and the cross-sectional design meant that it was not possible to assess whether there had been a change in oral health practices attributable to pregnancy. It was also a convenient sample so the results are not representative of all pregnant women attending the maternity unit. Nevertheless, despite its limitations the study gives some insight into oral hygiene practices undertaken by pregnant women in Kuwait. Aside from this study little is known about Kuwaiti women's existing knowledge, attitudes, awareness, and practice of oral health behaviours.

Obviously the Honkala and Al-Ansari (2005) findings are no different from the findings from other international settings with the exception of Denmark described in the previous section. In common with other countries, pregnant women in Kuwait had low oral health knowledge.

Three other studies amongst the adult population in Kuwait, also suggest poor oral health knowledge amongst Kuwaitis. Al-Shammari et al. (2007a) assessed the self-reported oral hygiene habits and oral health problems amongst Kuwaiti adults in a cross-sectional study. The findings suggested that most of the Kuwaiti adults reported several dental health problems that could be prevented through effective dental hygiene and regular preventive dental care. Al-Shammari et al. (2007b) in another study explored the barriers to seeking preventive dental care amongst Kuwaiti adults. In the latter study, more than half of the participants had not received preventive dental care in over a year and participants believed that dental attendance should only be for pain relief. Al-Hussaini et al. (2003) in an earlier study assessed the dental health and oral hygiene knowledge and attitudes amongst students in the Kuwait University

Health Sciences Centre. In this younger group oral health knowledge was low in relation to the causes and the prevention of dental caries and periodontal disease.

Based on these albeit few previous studies, there is evidence that oral health knowledge is poor amongst Kuwaiti adults and amongst pregnant women. These findings are not surprising, given that dental health services in Kuwait do not provide preventive oral care services for adults. Dental preventive services are only provided to children in kindergartens and primary schools (Behbehani and Scheutz, 2004) . In Kuwait, dental care services are mostly based on providing dental treatment and dental pain relief (Behbehani and Scheutz, 2004). It would appear that in Kuwait, women do not receive even the most basic information about how to promote their oral health (Honkala and Al-Ansari, 2005). Appendix A presents the health care provision for expectant mothers in Kuwait.

The existing studies in Kuwait have identified a clear need for DHE in adults, but these studies have limitations because of reliance on the use of convenience samples, small samples, and the cross-sectional design employed. The Kuwaiti studies are further limited by the fact that a questionnaire design is used which limits the possibility of inquiring into the social and cultural context of behaviours in any depth. Simply describing the frequency of particular behaviours is insufficient. In order to understand oral health behaviours of Kuwaiti pregnant women, it is important to have an understanding of the social and cultural context that shapes and forms the oral health behaviours (Sisson, 2007).

In conclusion, pregnant women and adults in Kuwait have low oral health knowledge. The dental health care system in Kuwait mainly provides dental and emergency treatment and does not provide an opportunity to support any type of DHE for adults or pregnant women. This lack of opportunity to access information might explain the low oral health knowledge amongst adults and pregnant women in Kuwait. There is a clear need to address this information gap in pregnant women, as improved oral hygiene practices and dental treatment may mitigate the risk of dental problems during pregnancy.

The next sections will review the evidence in relation to oral health and adverse pregnancy outcomes.

2.4 Oral health and adverse birth outcomes

Preterm birth (PTB) and low birth weight (LBW) are the most common reasons for neonatal mortality (World Health Organization, 2012). PTB is defined as a 'baby born before 37 weeks' gestation' (Mifflin, 2003) and LBW is defined as baby 'weighing less than 2500 grams' (Levene et al., 2000). These are the definitions that will be employed throughout this thesis. It is suggested that 60% to 80% of all newborn deaths are related to LBW (World Health Organization, 2012). It is also suggested that there are about 20 million LBW babies born worldwide every year, with most of the LBWs (96.5%) occurring in developing countries (World Health Organization, 2012).

2.4.1 Description of the condition

Adverse birth outcome (ABO) is a broad term, which covers many disparate conditions including PTB and LBW, PLBW, pre-eclampsia, miscarriage and stillbirth. PTB and LBW are the most well researched ABOs and are thought to be important causes of perinatal mortality and morbidity throughout the world

and are identified as major global public health problems (Vergnes and Sixou, 2007). The specific causes of ABOs are unclear (Goldenberg et al., 2008; Xiong et al., 2007). A widely held view is that inflammatory processes in the foetal/placental unit and/or elevated systemic inflammation may affect pregnancy outcomes (Ide and Papapanou, 2013), though ABOs are acknowledged to be multi-factorial in origin. The speculated risk factors for spontaneous PTB and LBW for example have been reported as: previous PTB or LBW, black race, socio-economic status, low education level, low maternal body mass index, alcohol use and tobacco use (Goldenberg et al., 2008; Vergnes and Sixou, 2007; Jeffcoat et al., 2003). Also implicated are infections of the genital tract (bacterial vaginosis (BV) and intrauterine infection (Goldenberg et al., 2008; Jeffcoat et al., 2011a). There is plausible biological evidence that infections such as BV may be important risk factors for PTB, but subclinical infections distant from the uterus have also been implicated (Rebarber et al., 2002; Schieve et al., 1994). The presence of inflammatory mediators such as interleukin-6 (IL-6) and prostaglandin E2 (PGE) has also been implicated (March of Dimes, 2010). It has also been suggested that short cervical length and raised cervico-vaginal foetal fibronectin concentration are the strongest predictors of spontaneous PTB (Goldenberg et al., 2008).

The pathogenesis of ABOs is thus multifactorial, highly complex and variable (Stamilo et al., 2007).

The incidence of PTB and LBW is reported to be between 12% and 13% of all live births in the USA (Polyzos et al., 2009), though in other populations the incidence can be higher. For example, the estimated proportion of newborn deaths caused by PTB in Kuwait and the neighbouring Kingdom of Saudi Arabia in 2000 was 22% and 31% respectively (World Health Organization, 2006). This

difference in incidence and prevalence across populations and ethnic groups provides a considerable challenge to researchers in determining risk factors.

Many ABOs outcomes co-vary, e.g. a baby born early (thus defined as PTB) is likely to be smaller in weight and meet the criteria for 'LBW'. Whenever possible, researchers suggest that it is preferable to focus on individual outcomes and report combinations of outcomes separately (Ide and Papapanou, 2013).

2.4.2 Periodontal disease and ABOs

Studies have suggested that periodontal disease may be associated with several systematic diseases including: cardiovascular disease, osteoporosis, respiratory disease, diabetes mellitus, and ABOs (Chambrone et al., 2011a; Chambrone et al., 2011b; Agueda et al., 2008; Bassani et al., 2007; Molloy et al., 2004; Rose et al., 2000; Offenbacher et al.,1996; Genco and Loe,1993).

Periodontal disease can be considered a 'continuous pathogenic and inflammatory challenge at a systemic level' (Agueda et al., 2008) due to the large epithelium surface that could be ulcerated in the periodontal pocket. This permits bacteria and their products to reach other parts of the organism. Moreover, some bacteria can directly invade cells and tissues. These bacteria and their products can generate an immuno-inflammatory response with the potential to damage different body organs and systems. During pregnancy, complex physiological changes occur that lead to an increase in oestrogen and progesterone levels (Agueda et al., 2008). These two hormones increase until 33 weeks (month 8) of pregnancy. Oestrogen and progesterone receptors exist in the gingival tissues (Adriaense et al., 2009; Russell and Mayberry, 2008). Gingivitis is the most common oral disease associated with pregnancy. The

incidence of pregnancy gingivitis is reported to range from 35% to 100%, peaking during the second trimester (Adriaense et al., 2009). Xiong et al. (2007) suggested that 20% to 50% of pregnant women could be affected by periodontal disease.

The case definition of 'periodontitis' has been shown to be problematic in reports of interventions involving Non-surgical Periodontal Treatment (NSPT) to prevent ABOs. Manau et al. (2008) suggested that one of the major issues that have been deemed responsible for the inconsistency of the findings in relation to ABOs are the different methods used to assess or define periodontal disease. In their review, Manau et al. (2008) found that over 50 definitions of periodontitis were used in articles exploring the relationship between ABOs and periodontal disease in pregnant women. Some indicators used continuous variables such as bleeding on probing (BOP), while others used dichotomous variables based on the presence of a specified number of teeth with clinical attachment loss (CAL) or with a cut-off probing depth (PPD). In a secondary analysis of data, Manau et al. (2008) found that the prevalence of periodontitis among a sample of women depended on the case definition of periodontitis applied and the statistical significance of the association between periodontitis and ABOs was directly determined by the case definition of periodontitis or the periodontal indicator used in the analysis. For example, Manau at al. (2008) assessed 23 studies and found six periodontal disease case definitions were statistically significant with ABOs: Bassani et al. (2007): severe periodontitis ≥3 sites in different teeth with CAL≥7 mm; Bosnjak et al. (2006): ≥60% of sites with CAL≥4 mm; Cruz et al. (2005): ≥4 teeth with CAL≥4 mm; Goepfert et al. (2004) mild: CAL 3–5 in any one sextant and severe PD: CAL>5 mm in any one sextant; Lopez et al. (2002): ≥4 teeth with≥1 site with PPD ≥4 and with CAL≥3

mm at the same site; and Lunardelli and Peres (2005): ≥4 sites with PPD≥3.5 mm (quoted from Manau at al., 2008).

Thus in the interpretation of the relationship between periodontal disease and ABOs and the efficacy of interventions, it is important to scrutinise the case definition of periodontitis and base the assessment on a secure definition of periodontitis. It is proposed in this thesis to include a systematic review of studies reporting on the relationship between the presence of periodontal disease and ABOs using secure definitions of periodontal disease.

2.4.3 Postulated mechanisms by which periodontal disease might affect pregnancy outcomes

A body of research over the last 20 years has suggested an association between PTB, LBW and clinical periodontal and subclinical infections (Jeffcoat et al., 2011; Michalowicz et al., 2006; Offenbacher et al., 2006; Jeffcoat et al., 2003; Lopez et al., 2002; Jeffcoat, 2000; Offenbacher et al., 1996). It is postulated in the literature that there is an association between periodontal disease and the ABOs: PTB, LBW, PLBW and stillbirth. Three possible mechanisms have been proposed by Offenbacher et al. (2009): 1) metastatic spread and translocation of bacteria and their toxins to the foeto-placental unit 2) induced cell-mediated response (both systemically and locally) in the foetus and placenta, and 3) low IgG maternal response to the presence of periodontal bacteria. It is further hypothesised that by treating periodontal disease and gingivitis, inflammation in the gingiva and periodontal pockets may be reversed or reduced (Kim et al., 2012). There will then be a consequent reduction in inflammatory loading on the pregnant mother and therefore her associated risk of an ABO may be reduced (Kim et al., 2012). Effective oral hygiene has been shown to reduce the extent of gingival inflammation in pregnant women (Turner

et al., 1994). Treatment of periodontal disease through the removal of calculus and effective plaque control could theoretically reduce the reservoir of periodontal bacteria and the number of periodontal bacteria transferred systemically in amniotic and chorionic fluids and contribute to the reduction in systemic inflammatory loading (Polyzos et al., 2009). However, the study of the association between gingivitis, periodontal disease and ABOs is challenging because of the lack of clarity over the case definitions of periodontal diseases in the studies used to search for the associations (Manau et al., 2008) as discussed in the previous section. It is also made challenging by the number of risk factors for ABOs, their tendency to covary and the variation in prevalence of ABOs in different populations. Few studies have reported upon the safety of NSPT during treatment, yet it is a concern of women in both Western and Eastern settings.

2.4.3.1 Systematic reviews to assess associations between ABOs and periodontal disease

A systematic review of the literature is the most appropriate research method to understand and manage the huge amount of studies concerning the association between ABOs and periodontal disease. A systematic review is a high-quality research method that allows the evaluation, combination and summary of the findings of individual studies undertaken in different countries, settings, and with different participants (Higgins and Green, 2011). It involves the development of a clearly formulated question that aims to eliminate bias by identifying, selecting, and assessing the quality of the research design, critical appraisal of the study, and summary of the selected research (Moles et al., 2005). The evidence produced is 'pooled', usually in the form of evidence tables reporting the characteristics of the included studies (participants, intervention,

comparator, outcome), risk of bias and summary of findings (Higgins and Green, 2011; Moles et al., 2005). When there are sufficient suitable data, these may be pooled in a meta-analysis to give the overall effect size and its precision (Moles et al., 2005; Egger and Smith, 1997). This type of review would allow managing and appraising the studies investigating the association between the ABOs and periodontal disease and would allow the synthesis of evidence concerning the association between ABOs and periodontal disease. A focus on more recent studies that might be of higher quality due to more recent adoption of guidelines on reporting such as Consort (2010) and more secure definitions of periodontal disease may produce fewer conflicting results. This is the topic of the first study in this thesis and the findings are described and discussed in detail in Chapter 3.

2.5   Conclusion

In conclusion, oral health knowledge during pregnancy is low amongst pregnant women in general and pregnant Kuwaiti women in particular. The dental health care system in Kuwait does not provide dental health educational opportunities for pregnant women and the system has largely neglected the oral health information needs of pregnant women. There is a need to improve women's oral health knowledge and behaviour during pregnancy and to improve access to oral health services in Kuwait during pregnancy. In this thesis, the author will focus on pregnant women's oral health knowledge and behaviours through the implementation of a DHE intervention. In order to develop an appropriate DHE intervention, there is a need to understand, in depth, the social and cultural context that shapes oral health behaviours. Furthermore, any proposed DHE intervention should be developed to meet Kuwaiti women's information needs and be based on the current evidence.

In addition, reviews of DHE have highlighted the importance of developing interventions based on psychological principles of behaviour change. In order to do this, the next sections will review psychological models of behaviour change and their use in DHE interventions.

2.6   Psychosocial theories of behaviour change

Researchers have highlighted the importance of health behaviour research as a significant approach to understand what behaviour is associated with which disease and also which behaviour might be predictive of mortality (Ogden, 2007). Health behaviour is defined as 'any activity undertaken by a person believing himself to be healthy for the purpose of preventing disease or detecting it at an asymptomatic stage'(Conner and Norman, 2007, p.2). Therefore the goal of health behaviour research is to prevent people from engaging in risky behaviour, in addition, to understanding the psychological and social factors that play a role in the uptake of risk behaviour or the avoidance of preventive behaviour (Morrison and Bennett, 2006). Positive changes in health behaviour may avoid the inception of disease and expand an active lifetime (Conner and Norman, 2007). There are two major factors that are said to enhance the prediction and understanding of health behaviour distribution across a society: distal influence factors such as socio-economic status, age, gender, ethnicity and personality, and proximal influence factors such as beliefs, attitude and peer influence (Conner and Norman, 2007). There are several psychological theories that have been developed to predict, enhance and change health behaviour; the most applied ones are social cognition models (SCMs).

SCMs are psychological models that give a significant framework for understanding the determinants of adherence to specific health behaviour

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(Renz and Newton, 2009). Adherence is defined as 'the extent to which a person's behaviour, such as taking medication, following a diet, and/or executing lifestyle changes, corresponds with recommendations the person has agreed with a healthcare provider' (Asimakopoulou and Daly, 2009, p. 626). SCMs consist of beliefs, thoughts and attitudes that determine whether or not the person undertakes a specific behaviour. The models assume that a person's behaviour is best comprehended by assessing their attitudes and beliefs (Renz and Newton, 2009).

SCMs are defined as 'models of how cognitive factors produce various social behaviours' (Conner and Norman, 2007,p.6). The concern of SCMs is how individuals make sense of social circumstances by focusing on individual cognitions, such as beliefs, attitude and peer influence, as processes in any situation (Conner and Norman, 2007). The models assume 'that a person's behaviour is best comprehended by assessing their attitudes and beliefs' (Renz and Newton, 2009, p. 252). SCMs explain behaviour as a result of logical information processing and place emphasis on individual cognitions rather than the social context of those cognitions. SCMs have been used frequently to predict and explain health behaviour change (Renz and Newton, 2009). Some commonly used SCMs are the health belief model (HBM), protection motivation theory (PMT), theory of planned behaviour (TPB), social cognitive theory (SCT), and implementation intentions.

2.6.1 Social cognition models (SCMs)

The following section will briefly describe the key psychological models of behaviour change. Table 2.2 presents theory constructs and examples of the construct use.

1. **Health belief model (HBM)**

The HBM was primarily developed to predict preventive health behaviours as well as behavioural responses to treatment in patients (Ogden, 2007). This model is widely used in health education to prevent undesirable health behaviours. Recently, the model has been used to predict a multiplicity of health-related behaviours such as healthy lifestyles e.g. exercise, healthy diet and oral health (Ogden, 2007).

The HBM consists of constructs or core beliefs which predict behaviour (Ogden, 2007). The core beliefs are one's perception of susceptibility to disease and the severity of the disease; barriers to or costs of endorsing the behaviour; the benefits of carrying out the behaviour; and cues to action to activate health behaviour which may be internal or external. Additionally, two constructs were added to the core beliefs of the HBM health motivation, which reflects the readiness of the individuals to be concerned about health matters, and perceived control, which was added more recently (1987) to the model.

2. **Protection motivation theory (PMT)**

The PMT was developed by Rogers (1975), who expanded the HBM to include further constructs. The PMT consists of four constructs: severity, susceptibility, response effectiveness and self-efficacy. The constructs of the PMT predict behavioural intention, which is associated with behaviour. In addition, Rogers, added fear to the theory as an emotional response to education and information (Ogden, 2007).

The PMT consists of two appraisals. The first is threat appraisal, appraising the threat including severity, susceptibility and fear. The second appraisal relates to

coping appraisal in response to the threat appraisal, i.e. appraising the individual themselves including response effectiveness and self- efficacy.

The theory considers two types of information sources: environmental, such as verbal persuasion and interpersonal such as prior experience. This information has a role in influencing the constructs of the PMT which then bring out either an adaptive or a maladaptive coping response (Ogden, 2007).

3. Theory of planned behaviour (TPB)

Like most SCMs, the theory of reasoned action (TRA) was used to assess predictors of behaviours. The TRA underlined the role of social cognitions, the individual's representations of their social world, in the form of subjective norms, the individual's beliefs about their social world, and included beliefs and evaluations of these beliefs. The factors of beliefs and evaluation make up the individual's attitudes. The TRA is a significant theory that placed the person within the social situation and suggested a role for the individual's attitude to approach the behaviours (Ogden, 2007).

TPB was developed by Ajzen and colleagues (1985) as an extension of the theory of reasoned action. The theory underlines behavioural intentions as the result of a combination of several beliefs. The TPB proposes that '*intentions should be conceptualized 'as plans of action in pursuit of behavioural goals'* (Ogden, 2007). Behavioural intentions are an outcome of three beliefs (which are constructs of the model): attitude, subject norm and perceived behavioural control. Attitude towards the behaviour could be either a positive or negative evaluation of a specific behaviour and belief about the outcome of the behaviour e.g. '*exercising is fun and will improve my health'.* A subject norm consists of

the perception of social norms and pressures to perform behaviour, as well as an evaluation of whether the individual is motivated to comply with this pressure to perform the behaviour. Perceived behavioural control is a belief that the individual can perform a specific behaviour based upon a consideration of internal (skills and abilities) and external (environmental resources) control factors which relate to past behaviour (Ogden, 2007).

These three factors predict behavioural intentions, which are related to behaviour. Furthermore, the TPB suggests that the third factor (perceived behavioural control) can have a direct effect on behaviour.

4. Social cognitive theory (SCT)

The SCT was developed by Bandura (1982) as a result of the need to include a temporal element in the understanding of beliefs and behaviour. SCT emphasised the significance of self-efficacy which is considered a determinant of both behavioural intentions and self-reports of behaviour (Ogden, 2007).

SCT contains several constructs from the HBM, PMT and TPB; the theory attempts to predict two elements: behavioural intention and actual behaviour. The main difference between SCT and other theories is the distinction between a decision-making motivational stage and an action/maintenance stage. The theory includes temporal and process factors to comprehend the association between beliefs and behaviour. The model consists of two phases; a motivational phase, which revolves around an individual decision on whether or not to carry out the behaviour and the action phase, which is about planning to initiate and maintain the behaviour (Ogden, 2007).

The motivational phase contains: self-efficacy, outcome expectancies, which contain social outcome expectancies, and threat appraisal which includes

beliefs of the severity of a sickness as well as perceptions of individual susceptibility (Ogden, 2007).

The action phase contains three factors: cognitive (volitional), situational and behavioural. A cognitive factor consists of action plans and action control. The situational factor includes social support and the absence of situational barriers. The last two factors determine the individual adherence to the behaviour (Ogden, 2007).

5. Implementation intentions

Implementation intentions are a key cognitive tool in the volitional stage, the stage where concrete plans are made and detailed action is initiated (Glanz et al., 2008). In this stage, the intention to implement such behaviour will change into an actual action. Implementation intentions bind the individuals to a definite course of action by encouraging them to specify exactly when, where, and how they will engage in a specific behaviour (I intended to do x whenever the situational conditions y are met) (Conner and Norman, 2007).

Table 2.2 presents the SCM constructs and provides examples of each construct.

Table 2.2: SCM constructs and examples

SCM	Construct	Example
HBM	Susceptibility	I believe that I am overweight.
	Severity	I believe that high blood pressure is a disease contributed to by being overweight.
	Barriers	Changing my dietary habits when I have children to feed will be difficult and more expensive.
	Benefits	If I lose weight my health will improve.
	Cues to action	Feeling breathless worries me; I should think about going on a weight reducing diet (internal). Information in health education brochures will predict their health behaviours (external).
	Motivation	I was not worried about my weight before but now I have children I am concerned that I should maintain my health.
	Perceived control	I am confident that I can lose weight.

PMT	Severity	High blood pressure is a serious illness.
	Susceptibility	My chances of getting high blood pressure are high.
	Response effectiveness	Changing my diet would improve my health.
	Self-efficacy	I am confident that I can change my diet.
	Fear	An emotional response to education and information.
TPB	Subjective norms	People who are important to me will approve if I lose weight; I want their approval.
	Attitude	Exercising is fun and will improve my health.
	Perceived behavioural control	Can I carry out this behaviour? It is difficult or easy?
	Intentions	I intend to exercise one hour daily.
SCT	Self-efficacy	I can stop smoking.
	Outcome expectancies	Stopping smoking will improve my health. Other people want me to stop smoking. If I stop smoking, I will gain their approval.
	Volitional 1.Action plans 2. Action control	If offered a cigarette when I am trying not to smoke, I will imagine what the tar would do to my lungs. I can survive being offered a cigarette by reminding myself that I am a non-smoker.
	Situational factor: 1.Social support 2.Situational barriers	The existence of friends who encourage non-smokers. Financial support to join an exercise club.
Implementation Intention	I have made a detailed plan of where, when and how one engages in the behaviour.	

2.6.2 SCMs and oral health behaviour

Most dental diseases could be prevented by maintaining good oral hygiene.

Effective oral hygiene through plaque control (tooth brushing and dental

flossing) is able to prevent dental and periodontal diseases (Turner et al., 1994).

Failure to maintain good and effective oral hygiene might lead to dental

diseases and dental and periodontal treatment failure. As a result, the key

messages of dental health professionals is to encourage their patients to follow

a good oral hygiene regime including brushing teeth twice a day with fluoridated

tooth paste, flossing once a day, reducing the consumption of sugar and visiting

the dentist regularly (DH/British Association for the Study of Community

Dentistry, 2009). Table 2.3 provides a summary of research studies that have

applied psychological models to assess oral health behaviour.

Most of the published studies that investigated the efficacy of the HBM in predicting oral health behaviours were a single measure in design (four cross-sectional studies) (Kasmaei et al., 2014; Anagnostopoulos et al., 2011; Buglar et al., 2010; Rayant and Sheiham,1980) and only two were longitudinal studies (Baker, 1994; Kuhner and Raetzke,1989). Two studies included self-efficacy with the HBM to improve the effectiveness of the model in predicting health behaviour (Kasmaei et al., 2014; Buglar et al., 2010). The HBM was not applied consistently, and while the self-efficacy construct was added, some HBM constructs were omitted including motivation, perceived control and cues to action in the three following studies (Kasmaei et al., 2014; Anagnostopoulos et al., 2011; Buglar et al., 2010). Few constructs were consistently confirmed as important across the six studies reporting the use of the HBM as a theoretical model. The studies, however, did suggest that the following HBM constructs could predict oral health behaviour (though not consistently across all six studies reviewed): severity, barriers, benefits, susceptibility, motivation and self-efficacy.

Oral health researchers have rarely applied PMT to underpin oral health behaviour interventions. Only one longitudinal study used PMT as a model to predict adherence to oral hygiene (Beck and Lund,1981). The study results suggested that severity, self-efficacy and intention predict adherence to oral health behaviour.

Most of the studies that investigated the use of TPB as a theoretical model were longitudinal studies (Pakpour and Sniehotta, 2012; Buunk-Werkhover et al., 2009; Defrance et al., 2008), while Lavin and Groake (2005) used a cross-sectional design. All studies assessed oral hygiene behaviour except for Defrance et al. (2008) who assessed dietary habits, dental attendance and oral

hygiene habits. Moreover, Pakpour and Sniehotta (2012) assessed the efficacy of TPB and Implementation Intention theory in predicting oral health behaviour. The TPB-based studies suggested that motivation, seriousness, benefit, susceptibility, perceived behaviour control and intention predicted adherence to oral health behaviour.

Two longitudinal studies assessed the efficacy of SCT in predicting oral health behaviour (Clarkson et al., 2009; Schüz et al., 2006). The latter studies included an 'action plan' in order to enhance oral health behaviour. In both studies SCT was not applied consistently, and some constructs were omitted. Clarkson et al. (2009) omitted risk perceptions, outcome expectations, barriers, and intention and Schüz et al. (2006) omitted barriers. Based on these two studies, constructs were identified which predicted oral health behaviours: risk perceptions, outcome expectations, self-efficacy, intention, and planning.

All studies (Pakpour and Sniehotta, 2012; Suresh et al., 2011; Clarkson et al., 2009; Schüz et al., 2006; Lavin and Groarke, 2005) that used implementation intentions to predict oral health behaviour were longitudinal in design. These studies suggested that the presence of an 'action plan' predicted adherence to oral health behaviour.

In summary, all studies that applied SCMs in oral health sought to describe a relationship between a model of health behaviour and self-reported oral health behaviours, which was sometimes evidenced by an observed clinical status. Most studies focused on assessing the relationship between individual constructs of the model and oral health behaviour using longitudinal studies, while some cross-sectional studies looked at the ability of individual constructs to predict behaviour.

More than a third of the studies in dentistry are cross-sectional in nature, characterised by partial application of the behavioural models and heterogeneity of the measures and outcomes used (Anagnostopoulos et al., 2011; Buglar et al., 2010; Lavin and Groarke, 2005; Rayant and Sheiham,1980). Almost all studies (except for Defrance et al. (2008)) explore the relationship between SCMs, frequency and /or effectiveness of oral hygiene procedures and some explore the relationship between SCMs and clinical status (Buunk-Werkhoven et al., 2009; Defranc et al., 2008; Lavin and Groarke, 2005; Barker, 1994; Kuhner and Raetzke, 1989; Rayant and Sheiham, 1980). Most of the studies were intervention studies that added an additional SCM construct to the actual model (e.g. adding self-efficacy to the HBM) known to predict oral health behaviour change. For example some authors added self- efficacy to the selected SCM to underpin the design of the intervention to change oral health behaviour (Anagnostopoulos et al., 2011; Buglar et al., 2010; Clarkson et al., 2009). Four studies applied a psychological model in addition to action planning (implementation intention) to predict the oral health behaviours (Pakpour and Sniehotta, 2012; Clarkson et al., 2009; Lavin and Groarke, 2005; Schüz et al., 2006). The latter four studies assessed the role of motivational and volitional stages in improving adherence to oral health behaviours. Renz and Newton (2009) highlight the importance of distinguishing between a motivational stage, which is a stage of intention to act (Glanz et al., 2008), and a volitional stage, the stage where concrete plans are made and detailed action is initiated (Glanz et al., 2008). The motivation-intention gap has been identified by Orbell and Sheeran (1998) as an area that warrants further study. Renz and Newton (2009) suggested that different approaches at different stages would enhance the likelihood of behaviour change. Therefore, a motivational intervention might

emphasise the benefits and self-efficacy beliefs about oral hygiene behaviour, whereas a volitional intervention might emphasise planning, which they describe as the 'when, where and how' of behaviour change (Renz and Newton, 2009).

Renz et al. (2007) conducted a systematic review of the efficacy of using psychological models to underpin intervention to predict oral health behaviour. They found that most interventions were low quality and that designs of the interventions were weak. The paucity and low quality of studies using psychological interventions to promote adherence to oral hygiene, caused Renz et al. (2007) to conclude that there was only tentative evidence that such interventions were effective in promoting adherence to oral hygiene measures. No model appeared to be superior to any other. Therefore, Renz et al (2007) conducted a cross-sectional study that was based on selected constructs (found to be significant in the review) from different psychological theories to assess oral hygiene behaviour (tooth brushing and flossing) amongst patients with periodontal disease. They found that knowledge, risk perception, barriers, outcome expectation, intention and implementation intention correlated with adherence to tooth brushing and dental flossing.

The lack of agreement over when and how constructs should be used, amongst other reasons, has led authors to develop a taxonomy of constructs commonly appearing as part of SCMs (Michie et al., 2005). The framework was designed to simplify and integrate various psychological theories and constructs thus supporting health care researchers in implementing evidence-based practice. The framework spans 12 theoretical domains, which enhance the understanding of the behaviour change process. The framework was developed to aid the comparison and evaluation of interventions. The variety of ways in

which models have been used in the dental literature demonstrates that there is no preeminent psychological model used in studies of oral health behaviour. As can be seen from Table 2.3, a whole range of different constructs were associated with or predicted oral health behaviour; however, no constructs were common to all interventions.

Newton and Asimakopoulou (2015) also thought that it is better for oral health researchers to design their research based on taxonomies of behaviour change such as Michie et al. (2005). This suggestion occurred after conducting a systematic review of dental studies using psychological measures (n=15). Newton and Asimakopoulou (2015) explored the psychological constructs that affect the oral health behaviour amongst adults with periodontitis. The authors found that most of the included studies applied psychological models inadequately; sometimes the models overlapped. Additionally, the methodology of the studies was unclear. Two constructs, self-efficacy and perceived benefit, were found to be enhancing of oral health behaviour.

An additional challenge with these SCM constructs are that most of the dental studies have been undertaken in developed Westernised countries with well-organised and available oral health care. Only Pakpour and Sniehotta (2012) and Suresh et al. (2011) were conducted outside the USA and Europe. It cannot be assumed that these SCM constructs might be relevant and pertinent to pregnant women in Kuwait who have to live within a very different social and cultural context. Indeed, Table 2.3 illustrates that not all of the hypothesised constructs in the established health behaviour models in the dental literature were associated with or predicted oral behaviours or adherence. It would therefore be important to undertake some preliminary work prior to a DHE intervention in order to understand the social and cultural context in Kuwait and

to determine the constructs which might be important and relevant in determining pregnant women's oral health behaviour.

In previous oral health research, longitudinal studies appeared to be more efficient than cross-sectional studies (single-measure studies) measuring the differences and improvements in oral health behaviours. Researchers highlighted the importance of time as an important factor in determining how sustained and embedded new health behaviour becomes. Morrison and Bennett (2006) insist on the importance of longitudinal research to study the association between health behaviour and an individual's health status.

In previous oral health research, several constructs such as self-efficacy, attitude, intention and action planning appeared to play some role in predicting oral health behaviours. However, the studies do not yield conclusive results and no one model can be identified as the best. It might be more appropriate, therefore, to design a behaviour change intervention that is inspired by constructs known to be associated with oral health adherence amongst the target group, rather than being dictated by the existing SCM.

It would be important to have a sense of the SCM constructs that influence oral health behaviours in pregnant women in Kuwait in order to plan a DHE intervention that is relevant, appropriate and theoretically sound. As there is no previous work upon which to draw, a preliminary qualitative study exploring the women's knowledge, attitudes, reported behaviours (and social and cultural context in which oral health behaviours occur) would be necessary to inform the planning of a DHE intervention. This approach has been used previously by Gilinsky et al. (2012). Gilinsky et al. (2012) adopted an approach in the use of SCM constructs, which was different from the approach used in previous oral

health studies which have employed or partially employed psychological models of health behaviour. In this 2012 study, the authors investigated the efficacy of using a theory-based intervention to change oral health knowledge, attitudes, and behaviours of nursery staff, parents and children. The study consisted of two phases: a qualitative study and a quantitative intervention. The qualitative study was undertaken to investigate barriers and facilitators of oral health behaviour by assessing knowledge, attitudes and beliefs amongst the parents and staff. The second phase was the intervention study, which was designed based on SCM constructs chosen by using techniques from the taxonomy of behaviour change developed by Abraham and Michie (2008). The authors found that only knowledge improved amongst the staff. There were no improvements in the attitudes, beliefs and intentions of participants. The authors reported that the findings suggested that the oral health behaviour (tooth brushing for their children) only improved amongst parents who found tooth brushing easier at the baseline, being able to complete the intervention. Thus, the oral health behaviour prediction was based on their past oral health behaviour.

Table 2.3: Summary of research studies with applied psychological models to assess oral heath behaviour

Psycho logical model	Reference	Sample Size	Study Design	Oral Health and Behaviour Measures	Psychological Variables that Correlated with oral Health Outcome/Behaviour
HBM	Rayant and Sheiham (1980)	161 participants attending a dental hygiene clinic	Cross-sectional survey (Single measure study)	Gingival Index Plaque Index Questionnaire (HBM constructs and self-reported oral health behaviours)	No significant association
	Kuhner and Raetzke (1989)	96 participants attending a periodontal clinic	Longitudinal study survey (repeated measure study depending on participants visiting pattern, no more than four visits)	Bleeding on probing Periodontal pockets Oral hygiene education Questionnaire (HBM constructs and self-reported oral health behaviours). Intervention: feedback on oral hygiene effectiveness via plaque score; supragingival scaling and elimination of plaque retentive factors (overhang restoration and caries lesion) and OHI on two, three or four occasions.	Motivation Seriousness Benefits
	Barker (1994)	43 participants in dental clinic (hospital setting)	Longitudinal Intervention (one month)	Plaque score Bleeding score Questionnaire (HBM constructs and self-efficacy) Intervention: modified Bass technique and feedback on plaque score	Benefits Susceptibility

	Buglar et al. (2010a)	92 participants drawn from private and dental hospital clinic in Australia	Cross-sectional survey (single measure study)	Questionnaire (HBM constructs, self-efficacy and self-reported oral hygiene behaviour: tooth brushing and flossing)	Partial support (barriers) Predicting self-reported oral health behaviour Self-efficacy an additional predictor of oral self-care
	Anagnostopoulos et al. (2011)	125 dental patients. from hospital, practice	Cross-sectional survey (single measure study)	Self-reported questionnaire (HBM constructs and self-efficacy) about frequency of tooth brushing.	Self-efficacy Severity
	Kasmaei et al., (2014)	265 female Iranian students attending school in Iran	Cross-sectional survey (single measure study)	Self-reported questionnaire (HBM constructs and self-efficacy) about tooth brushing behaviour.	Severity Barriers
PMT	Beck and Lund (1981)	81 dental patients attending university dental clinic	Longitudinal study (contacted participants four weeks after the first visit by telephone to ask about the recommended dental hygiene adherence)	Questionnaire (feeling about their dental health and current oral hygiene behaviour) communication (related periodontal disease and prevention) Questionnaire (emotional stimulation, beliefs regarding periodontal disease, beliefs concerning prevention of the periodontal disease, and intentions to carry on with the recommended actions)	Severity Self- efficacy Intention
TPB	Lavin and Groarke (2005)	161 participants attending a dental hygiene clinic	Cross-sectional survey (single measure study)	Gingival Index Plaque Index Questionnaire (HBM constructs and self-reported oral health behaviours)	No significant association

	Defrance et al. (2008)	96 participants attending a periodontal clinic	Longitudinal study survey(repeated measure study depending on participants case no more four visits)	Bleeding on probing Periodontal pockets Oral hygiene education Questionnaire (HBM constructs and self-reported oral health behaviours) Intervention: feedback on oral hygiene effectiveness via plaque score; supragingival scaling and elimination of plaque retentive factors(overhang restoration and caries lesion) and OHI on two, three, or four occasions	Motivation Seriousness Benefits
	Buunk-Werkhoven et al. (2009)	43 participants in dental clinic	Longitudinal Intervention (one month)	Plaque score Bleeding score Questionnaire (HBM constructs and self-efficacy) Intervention: modified Bass technique and feedback on plaque score	Benefits Susceptibility
	Pakpour and Sniehotta, (2012)	987 high school students attending school in Iran	Longitudinal study Repeated measure study (4 weeks)	Tooth brushing behaviour Questionnaire (assessed perceived behavioural control and intention and action planning)	Perceived behavioural control Intention Action planning
SCT	Schüz et al. (2006)	175 (healthy volunteers) attending a course at the university	Longitudinal study (repeated measure study design: 3 points measurement over 6 weeks)	Self-reported oral hygiene: flossing and measure of floss use Intervention, leaflet on flossing technique and floss calendar	Risk perceptions Outcome expectations Self-efficacy Intention Planning

	Clarkson et al. (2009)	778 patients and 87 dentists (RCT N = 37 dentists and 300 patien cluster RCT N= 50 dentists and N=478 patients).	Longitudinal study (RCT and cluster RCT) (repeated measure study design: 8 weeks)	Questionnaire (oral health behaviour including tooth brushing time, duration and method); self-efficacy and planning (patients were asked to plan tooth brushing duration, timing and method). Clinical assessment (Plaque Index and gingival bleeding on probing) Intervention group had information and were trained to use a power toothbrush.	Self-efficacy Planning
	Buglar et al. (2010)	92 participants drawn from private and dental hospital clinics in Australia	Cross-sectional survey (single measure study)	Questionnaire (HBM constructs, self-efficacy and self-reported oral hygiene behaviour: tooth brushing and flossing)	Partial support barriers Self-efficacy an additional predictor of oral self-care
Implementation Intention	Schüz et al. (2006)	175 healthy volunteers attending a course at the university	Longitudinal study (repeated measure study design: 3 points measurement over 6 weeks)	Self-reported oral hygiene: flossing and measure of floss use Intervention, leaflet on flossing technique and floss calendar	Risk perceptions Outcome expectations Self-efficacy Intention Planning
	Lavin and Groarke (2005)	119 participants of university population (RCT N = 37 dentists and 300 patients; cluster RCT N= 50 dentists and N=478 patients).	Longitudinal Intervention study (3 weeks)	Questionnaire (TPB constructs and self-reported flossing behaviour) Intervention (participants received a packet of dental floss and diary card to tick the days they flossed for the next 3 weeks. Participants had been randomized to experimental and control; groups) Intervention group were asked to make implementation intentions specifying where and when they floss for the next 3 weeks	Attitude Perceived behavioural control Intention

	Clarkson et al. (2009)	778 patients and 87 dentists (RCT N = 37 dentists and 300 patien cluster RCT N= 50 dentists and N=478 patients).	Longitudinal study (RCT and cluster RCT) (Repeated measure study design: 8 weeks)	Questionnaire (oral health behaviour including tooth brushing time, duration and method); self-efficacy and planning (patients were asked to plan tooth brushing duration, timing and method). Clinical assessment (Plaque Index and gingival bleeding on probing) Intervention group had information and trained to use a power toothbrush.	Self-efficacy Planning
	Pakpour and Sniehotta (2012)	987 high school students attending school in Iran	Longitudinal study repeated measure study(4 weeks)	Tooth brushing behaviour Questionnaire (assessed perceived behavioural control and intention and action planning)	Perceived behavioural control Intention Action planning
	Suresh et al. (2011)	73 patients with periodontal disease in public clinic in Kuwait	Longitudinal study repeated measure study(4 weeks)	Flossing frequency Plaque score Bleeding	Planning
SCM	Renz 2007	101 participants attending a periodontal clinic	Cross-sectional survey (single measure study)	Pocketing depth, plaque score and/ or bleeding score Questionnaire (SCM constructs and self-reported oral hygiene behaviour: tooth brushing and flossing).	Knowledge, Risk perception, Barriers Outcome expectancy Intention Implementation intention

2.7 Summary of key findings from the literature review and rationale for the studies

The literature review has highlighted the following:

1. There is a clear need for DHE amongst pregnant women in Kuwait and the wider health literature suggests that the antenatal period is an opportune time for an intervention as women may be particularly receptive to oral health information.

2. There is confusion amongst dental health professionals and pregnant women about the relationship between oral health and pregnancy and about the safety and efficacy of dental treatment during pregnancy. Any DHE intervention undertaken with pregnant women must be based on a sound and up-to-date evidence base. In order to better inform pregnant a need to systematically review the literature in relation to the relationship between periodontal disease and pregnancy, and the safety and efficacy of non-surgical periodontal treatment (NSPT) during pregnancy.

3. Evidence from DHE interventions in other settings and countries with pregnant women suggests that it is important to have a clear understanding of the social and cultural context in which oral health behaviours take place and that this context should be incorporated into interventions.

4. There is a wide range of psychological models of behaviour change which have been used in dental settings; however, there is no preeminent model as not all social cognition constructs are associated with or predict behaviour change, and few of these models have been used outside Westernised health care settings.

5. It would be important that a DHE intervention proposed with women in Kuwait would:

   a. Reflect the social and cultural context in which oral health behaviours take place.

   b. Be based on social cognition constructs known to be relevant to oral health behaviour in pregnant women in Kuwait

The thesis consists of three studies. Due to the conflicts between published studies concerning the association between adverse pregnancy outcomes and periodontal disease and non-surgical periodontal therapy, the first study proposed was a systematic review and meta-analysis of the literature. This was undertaken to assess the association between periodontal disease and adverse pregnancy outcomes and the efficacy and safety of non-surgical periodontal therapy in preventing adverse birth outcomes.

The second study proposed was a qualitative study undertaken to understand the social and cultural context of oral health behaviours amongst Kuwaiti pregnant women, and the psychological constructs relevant to oral health behaviours amongst pregnant women in Kuwait.

The last study was a single- blinded randomised controlled trial (intervention study) that was designed to promote oral health adherence based on the findings of the first and second studies.

2.8   Aims

The aim of the thesis was to design, implement and evaluate a dental health education (DHE) intervention for Kuwaiti pregnant women. In order to achieve this aim of the thesis, three studies were undertaken:

1. Systematic review and meta-analysis to assess: a) the association between periodontal disease and adverse pregnancy outcomes, b) the efficacy of providing non-surgical periodontal treatment during pregnancy to prevent adverse birth outcomes, and c) the safety of periodontal treatment during pregnancy.

2. A qualitative study to explore perceptions, beliefs, attitudes and expectations about oral health amongst Kuwaiti pregnant women, and to explore beliefs and attitudes about maintaining and improving oral health amongst Kuwaiti women during pregnancy.

3. An RCT to assess the efficacy of dental health education (DHE) with or without a planning intervention on adherence to dental health related behaviours amongst Kuwaiti pregnant women.

Chapter 3

The relationship between periodontal disease and adverse birth outcomes (ABOs), and the relationship between non-surgical periodontal treatment (NSPT) and adverse birth outcomes: A systematic review of the literature

3.1 Introduction

This chapter will present a systematic review with regard to the relationship between periodontal disease (PD) and adverse birth outcomes (ABOs) and the relationship between nonsurgical periodontal treatment (NSPT) and ABOs.

The accumulating evidence for a relationship between PD and ABOs and the efficacy of treatment of PD to prevent ABOs is conflicted and marred by the poor methodological quality of the primary studies.

Several systematic reviews suggested that there might be an association between PD and ABOs (Chambrone et al., 2011a; Vergnes and Sixou, 2007; Xiong et al., 2007). Xiong et al. (2007) suggested that two thirds of the observational studies included in their review (29 out of N=44) (conducted between 1996 and 2006) found some evidence of an association between PD and ABOs (specifically Preterm Birth (PTB), Low Birth Weight (LBW), miscarriage and stillbirth) reporting odds ratios ranging from 1.10 to 20. Two more recent systematic reviews of observational studies evaluated the association between PD and ABOs (Ide and Papapanou, 2013; Chambrone et al., 2011a) also found evidence for an association between PD and ABOs. However, Vettore et al. (2006) noted in their systematic review that the poor methodological quality of studies up to 2005 meant that they could not reliably draw conclusions on the association between PD and ABOs. Indeed in one review based on studies drawn from this earlier period (Vergnes and Sixou, 2007) the results were pooled from case control and cohort studies. Case control studies are prone to bias because it is not possible to know whether PD was present prior to delivery (Chambrone et al. 2011a). The case definition of

PD was also noted to be highly problematic (Ide and Pappanou 2014; Chambrone et al., 2011a; Manau et al., 2008).

Following on from suggestions in the literature that PD might be associated with ABOs, a number of primary studies sought to explore whether provision of NSPT was efficacious in reducing ABOs. Early primary studies suggested that NSPT could prevent PD (Offenbacher et al., 2006a; Lopez et al., 2005; Jeffcoat et al., 2003; Lopez et al., 2002), whereas some later primary studies (Newnham et al., 2009; Michalowicz et al., 2006) suggested that NSPT did not have an effect on ABOs. Polyzoz et al. (2010) attributed this conflict in the literature to the poor methodological quality of studies and the case definitions of PD used. Systematic reviews of these intervention studies have also produced conflicting findings. Some reviews have suggested that NSPT might reduce the incidence of ABOs (George et al., 2011; Polyzos et al., 2009). Other systematic reviews with meta-analyses showed that periodontal treatment during pregnancy did not reduce the incidence of ABOs (Kim et al., 2012; Chambrone et al., 2011b; Polyzos et al., 2010).

In addition to methodological quality, as was the issue with the observational studies, many of these primary intervention studies used insecure definitions of PD. The case definition of PD in many of these primary intervention studies must be regarded as inadequate and they weaken the case where such criteria have been used (Chambrone et al., 2011a; Chambrone et al., 2011b; Manau et al., 2008).

It would be important to have a clear understanding of the relationship between pregnancy, ABOs and PD and the efficacy and safety of NSPT during pregnancy in preventing ABOs which are based on high quality studies and a

secure definition of PD. Few studies have investigated the safety of NSPT during pregnancy, yet safety of dental treatment has been identified as a key concern of pregnant women in both Eastern and Western settings (Detman et al., 2010; Acharya and Bhat, 2009).

In order for the researcher to use evidence to underpin the proposed DHE intervention, it was necessary to know whether there was evidence that PD was a risk factor for ABOs. And if so should a DHE intervention recommend that women attend the dentist for screening for PD and treatment for NSPT during pregnancy?

3.2   Objectives

The aims of this review were to assess the association between PD and ABOs and the efficacy and safety of providing NSPT during pregnancy to prevent ABOs.

3.3   Methods

The review was conducted and completed in accordance with PRISMA guidelines for reporting systematic reviews (Moher et al., 2009). This review consisted of two parts. The first part (Part 1) was a systematic review of observational (prospective cohort) studies to assess the association between PD and PTB (Preterm), LBW (Low Birth Weight) PLBW (Preterm and low birth) and stillbirth; with meta- analysis should data be available and suitable. Chambrone et al. (2011a) and Jeffcoat et al. (2001) have argued that a cohort study is the best type of design to assess the relationship between PD and ABOs. This is because the presence of PD is identified as being present at the beginning of the study, which avoids the bias inherent in a case control and cross sectional studies. These study designs assess periodontal health status

of participants after giving birth, and cannot confirm the threat of the gingivitis or periodontitis during pregnancy because it is not clear when women had active PD. Indeed Guyatt et al. (2006) have suggested that a longitudinal cohort is the study design of a choice when assessing causal/association relationships. Finally Ide and Pappanou (2014) have argued that a longitudinal observational blinded cohort study is the gold standard for assessing the relationship between PD and ABOs because it allows for the 'assessment of the impact of and interactions between a range of exposures including periodontal disease' (Ide and Pappanou, 2014, p. S182). Therefore it was decided to only include cohort studies in Part 1 of the review.

The second part (Part 2) was a systematic review and meta-analysis of RCTs assessing NSPT of PD to determine the efficacy and safety of treatment during pregnancy to prevent ABOs. Only RCTs were included as a randomised controlled trial is the study design of choice when assessing the efficacy of an intervention.

3.3.1 Types of studies

3.3.1.1 Observational studies

For Part 1 of the review of observational studies, only cohort studies were included that assessed the relationship between PD and PTB (<37 weeks), LBW (<2,500 gram), PLBW (<37 weeks and <2500 gram) and stillbirth.

3.3.1.2 RCTs

Only RCTs were considered for inclusion in Part 2 of the review which investigated the efficacy and safety of NSPT and PTB (<37 weeks), LBW (<2,500 gram) PLBW (<37 weeks and <2500 gram) and stillbirth. In Part 2 of the review the non-surgical interventions examined were supra and sub gingival

calculus removal, root debridement and use /no use of chlorhexidine antiseptic mouthwashes and rinses.

3.3.2 Type of participants and inclusion criteria

For both Parts 1 and 2, women over the age of 16 who were pregnant and who may have had more than one previous pregnancy and a previous PTB were included. Women with a single birth only were also included. Studies which included participants who were smokers or who had known risk factors for ABOs were also included.

3.3.3 Exclusion Criteria

In Part 1 microbiological studies, cross-sectional, case control and retrospective cohort studies were excluded.

In Part 2, trials, which were defined as single arm studies, non-randomised and pseudo randomised or trials published as abstracts at scientific meetings were excluded.

3.3.4 Definition of ABOs

All studies included in both parts 1 and 2 of this review were required to use explicit and validated criteria for the identification of PTB, LBW, PLBW and/or stillbirth. These ABOs follow the accepted definitions used by the WHO (2012). It is recognised that PTB may have a relationship with LBW, but gestational age can only be reliably ascertained in 15% of cases (Wimmer and Pihlstrom, 2008) and so LBW is often used as a proxy for PTB, but LBW is a distinct entity as a baby may be born at term though underweight (Wimmer and Pihlstrom, 2008). It was decided not to include pre-eclampsia and preterm premature rupture of the membranes (PPROM) because of their close association with PTB (Goldenberg et al., 2008).

3.3.5 Definition of periodontal disease

For Parts 1 and 2 of the review, studies were considered eligible if a validated diagnosis of gingivitis or periodontitis was recorded and studies were included regardless of the severity of PD or gingivitis. Studies were included if participants had any permanent teeth with a diagnosis of PD or gingivitis against validated diagnostic criteria.

Due to the inconsistent case definition of the PD, the author decided to adopt the PD 'secure' case definition from Nibali et al. (2013) to categorise the 'security' of the case definition of PD. These case definitions are based on international consensus definitions (Tonelli, 2009; Biesbrock et al., 2007; Page and Eke, 2007; Sillness and Loe, 1964). Using these sources, Nibali and his colleagues (2013) divided periodontal diagnosis into secure and insecure gingivitis and periodontitis (see Figure 3.1 for a summary of the criteria). It has been suggested that clinical attachment level (CAL) gives an indication of past PD and periodontal pocket depth (PPD) may give better indication of current disease status (Leroy et al., 2010). Where possible, case definitions of mild, moderate and severe gingivitis were planned to be presented (Page and Eke, 2007), together with an indication of the security of the definition.

Figure 3.1: PD case definition adapted from Nibali et al. (2013)

In Part 1, studies were included when they provided a definition of periodontitis diagnosis by PPD and CAL (Eickholz et al., 2004), a clear definition of the ABOs was provided and the study reported the number or the percentages of women with PD and ABOs in cohort studies.

It was planned to assess studies, which used categorical or continuous data to present presence and severity of PD.

For Part 2 of the review, trials were included if they compared NSPT which included scale and polish, root debridement, extraction of hopeless teeth, oral hygiene instruction and/or use of antiseptic rinses and mouthwashes. Studies with any type of local intervention used for the NSPT of PD or gingivitis compared to a different local intervention, placebo or no treatment were included. Studies reporting on systemic use of antibiotics for the treatment of Bacterial Vaginosis (BV) were not excluded provided this intervention was available to all participants in all arms of the study. Studies were included when they provided a definition of periodontitis diagnosis by PPD and CAL (Eickholz et al., 2004). Trials were required to specify the case definition for PD using either continuous or categorical data. Trials reporting gingivitis only were not excluded.

3.3.6 Types of outcome measures

For Part 1 and Part 2, the primary outcomes were 'PTB' which was defined as a baby born before 37 weeks' gestation (World Health Organization, 2012; Martin and Reeb, 1982); 'LBW' which was defined as a baby weighing less than 2500 grams,(World Health Organization, 2012), 'PLBW' which was defined as a baby born before 37 weeks and with weight less than 2500 gram (Gomes-Filho et al., 2007); 'stillbirth' was defined as 'foetal death after 20 weeks' (March of Dimes, 2010). The mean birth weight in the experimental and control group was recorded if reported in the study.

In Part 2, the secondary outcomes were change in periodontal outcomes if reported relating to measures of PD and gingivitis: bleeding on probing (BOP),

CAL, and presence of PPD. The PD diagnosis would be allocated to categorized or continuous, and then it would be assessed whether the definition was secure or insecure according to the criteria outlined by Nibali et al. (2013). Safety was also reported as a secondary outcome if reported as an adverse event, or an untoward event.

3.3.6.1   Reporting of outcomes

Although not necessary, data obtained from visual analogue scales and any categorical outcomes would have been converted into dichotomous data if appropriate prior to analysis. For continuous outcomes, the mean differences and 95% confidence intervals would be used to summarise the data for each group where the mean difference and standard deviations were calculable from the data presented.

For dichotomous data, the risk ratio (relative risk) was computed, which is the ratio of the risk of an event occurring in the experimental and control group, together with the 95% confidence interval.

3.3.7 Search methods

Prior to conducting the search the researcher consulted an information specialist to inform the choice of search terms and the search strategy.

The Medline (1966 to present 2014), EMBASE (1980 to present 2014), Cochrane library and Cinahl were used. There was no restriction on languages. In addition a manual search of the Journal of Clinical Periodontology, Journal of Periodontology, and Periodontology 2000 was conducted.

Gingivitis, periodontitis, periodontal disease, dental scaling, dental polishing, PTB and LBW were the main keywords utilized in this search. Each keyword

was mapped to a subject headings tree that included subheadings as well. The subject headings tree and all subheadings for each item were combined by "OR". The search results for the main keywords were combined by "AND" [(PD, gingivitis, periodontitis, dental scaling or dental polishing) and (PTB or LBW)]. In addition, on advice from the information specialist, terms were added to the search to identify cohort studies and trials. The search strategy is provided in Appendix B.

3.3.8 Data collection and analysis

3.3.8.1 Selection of studies

For parts 1 and 2 of the review, two review authors assessed the abstracts of retrieved studies on an independent basis. The full copies of studies considered relevant and potentially relevant i.e. those appearing to meet the inclusion criteria, but where there was insufficient information in the title and abstract to make a decision were then obtained. The full text papers assessed independently by two review authors and any disagreements on the eligibility of included studies were resolved through discussion and consensus. A third review author was consulted in the case of disagreement on inclusion criteria.

Any studies that did not match the inclusion criteria were excluded (Appendix C presents the xcluded studies for Part 1 and Appendix D presents the excluded studies for Part 2 of the review).

3.3.9 Data extraction, management and synthesis

3.3.9.1 Part 1 of the review (Cohort studies)

The study details and outcome data were collected independently and in duplicate by both review authors using a form designed for the purpose. These data were entered into a table detailing the characteristics of the studies

'Characteristics of included studies' (Table 3.1, for cohort studies) and the outcome data were entered into additional tables or if appropriate, as forest plots in RevMan (Higgins and Green, 2011). Any disagreements were discussed. Data were included if there was an independently reached consensus. If necessary, a third review author was consulted to resolve inconsistencies. The following details were extracted:

- Participants: (a) country of origin; (b) inclusion criteria and characteristics of population.

- PD definition.

- Outcomes: primary outcomes: PTB, LBW and PLBW

Data were summarized into a descriptive table to determine the studies' similarities and differences concerning participants, study methods, outcomes and conclusion. Pooling of data was based on outcomes of interest. The pooled data for dichotomous data were expressed as risk ratio (RR) when available (sometimes data were reported as odd ratio (OR)) and associated 95% confidence intervals. Meta-analysis was planned to be undertaken separately for cohort studies when sufficient suitable data were available.

3.3.9.2 Part 2 of the review (RCTs)

The study details and outcomes data were collected independently and in duplicate by both review authors using a form designed for the purpose. The data for included studies were entered into three tables detailing the characteristics of included studies' (Table 3.6, 3.7 and 3.8) and the outcome data were entered into additional tables or as forest plots in RevMan (Higgins and Green, 2011). Any disagreements were discussed. Data were included if there was an independently reached consensus. If necessary, a third review author was consulted to resolve inconsistencies.

The following details were extracted based on PICO format (participants, intervention, comparator and outcome):

- Trial methods: (a) method of allocation; (b) masking of participants and outcomes; (c) exclusion of participants after randomisation and proportion of losses at follow up.
- Participants: (a) country of origin; (b) sample size; (c) age; (d) gender; (e) inclusion and exclusion criteria (symptoms and duration, information on diagnosis verification).
- Intervention and procedural information.
- Outcomes: primary and secondary outcomes outlined in the types outcome measures section of this review.

This information was used to help assess the clinical diversity and generalisability of any included trials.

The sources of funding of any of the included studies reported in the study were recorded.

3.3.10   Quality assessment

3.3.10.1 Quality of cohort studies in Part 1

The quality of the cohort studies was assessed using the Newcastle-Ottawa Quality Assessment Scale. Appendix E presents the assessment of each study included in the review of cohort studies according to the Newcastle-Ottawa Quality Assessment Scale (Lo et al., 2014).

The Newcastle-Ottawa Scale was developed to assess the quality of non-randomized studies (including case control and cohort studies). The main aim of the scale is to develop a convenient scale to evaluate the quality of non-randomized studies that might be used in a systematic review. The scale

includes three main elements to assess: selection, comparability, and outcome (Lo et al., 2014). Selection can achieve a 'one' star maximum score based on criteria which include representativeness of the exposed cohort, selection of the non-exposed cohort, ascertainment of the exposure or demonstration that the outcome of interest is not present at the start of the study. The category of comparability may be awarded up to two stars based on what factors the study controlled for. The category of outcome may be awarded one star based on the assessment of the outcome, length of follow-up, and adequacy of follow up of cohort (Lo et al., 2014). The scale is useful for interpreting the results of meta-analyses (Lo et al., 2014).

3.3.10.2 Quality of RCTs in Part 2

3.3.10.2.1 Assessment of risk of bias in included studies

Studies identified for inclusion in this study were assessed independently by two review authors who graded them according to a contingency form following a domain-based evaluation described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins and Green, 2011). The assessments were made independently and discussed if there was any disagreement on comparison. The authors assessed the following domains as: 'low risk of bias', 'uncertain risk of bias or 'high risk of bias' according to criteria of Higgins and Green (2011). The domains were:

- Sequence generation
- Allocation concealment
- Blinding of a) participants and personnel; b) outcomes assessors
- Selective outcome reporting
- Free of other bias

The assessment for each included study was reported in the corresponding section of the risk of bias tables which were produced using Revman 5 (The Cochrane Library, 2011). An assessment was also made of the overall risk of bias and consideration given to the contribution of each domain, and individual studies were assessed as low, unclear and high risk of bias. The following category explanations were used:

- Low risk of bias (plausible bias unlikely to seriously alter results) if all criteria met.

- Unclear risk of bias (plausible bias raising doubt about results) when one or more domains were assessed as 'unclear risk of bias'

- High risk of bias (plausible bias) likely to seriously affect confidence in results, if one or more criteria were not met.

Trials scoring 7/7 on the ROB were designated as high quality trials. Trials scoring below 7/7 were designated as low quality.

3.3.11 Dealing with missing data

For Parts 1 and 2, it was intended to contact authors of included studies to obtain missing trial details and data from the reports, however all data were present.

3.3.12 Assessment of heterogeneity

Studies brought together in a systematic review will vary inevitably. All variability may be called by the umbrella term heterogeneity, but its causes can be attributed to three main factors (Higgins and Green, 2011).

- Clinical diversity, variation attributable to the characteristics of the participants, interventions and outcomes. The term clinical heterogeneity is also used (Higgins and Green, 2011).

- Methodological diversity attributed to study design, quality and risk of bias. The term methodological heterogeneity is sometimes used (Higgins et al., 2011).

- Statistical diversity related to variability in intervention effects and which may be attributable to either clinical or methodological diversity or both. The term statistical heterogeneity is sometimes used (Higgins and Green, 2011).

In parts 1 and 2, clinical heterogeneity was assessed by examining the characteristics of the participants, the similarity between the types of participants, the interventions and the outcomes as specified in the criteria for included studies. Possible methodological heterogeneity was explored by investigating the design of the study, quality and risk of bias, through sensitivity analysis. Statistical heterogeneity was assessed using a Chi^2 test, and the I^2 statistic was used to assess inconsistency across studies due to heterogeneity rather than chance where I^2 values between 50% to 90% represent substantial heterogeneity (Higgins and Green, 2011). In the case of homogeneity a fixed effects model was used and a pooled RR and 95% Confidence Intervals (CI) calculated. In the case of heterogeneity a random effects model was used and a pooled RR and 95% Confidence Intervals (CI) calculated.

In parts 1 and 2, it was planned to undertake subgroup analyses and consider data according to the clinical definitions and 'security' of diagnosis of PD (see section 3.3.5). Subgroup analyses were also planned, if data were sufficient to

explore the impact of race, smoking, previous history of ABOs, income and education as previous studies indicated these were risk factors for ABOs, and previous studies indicated higher prevalence of these variables in different populations. Findings in relation to non- Caucasian women, and women who have experienced a previous ABOs, are of particular relevance to Kuwait. In Kuwait, women tend to have more than one pregnancy and the estimated proportion of new-born deaths caused by PTB in 2000 was 22% (World Health Organization, 2006).

For the subgroup analysis studies with respect to race, it was planned to identify studies where the proportion of non-Caucasian women (sometimes reported as 'Black and ethnic minorities') were reported, and categorise these into high, moderate and low representation, depending on the proportions presented in the studies available. The same approach was planned to be adopted for 'previous history of PTB', proportion smoking, income and education. Cut-off points were based on cut-offs which were observed through scrutinising individual studies.

In the event that there were insufficient clinically homogeneous outcome data for any specific intervention or insufficient study data that could be pooled, a narrative synthesis was presented.

3.3.13   Assessment of reporting biases

For Part 1 and 2, publication bias and small study effects was planned to be assessed according to the recommendations on testing for funnel plot asymmetry (Egger et al., 1997) as described in section 10.4.3.1 of the *Cochrane Handbook for Systematic Reviews of Interventions*(Higgins and

Green, 2011), and if asymmetry was identified, other possible causes would be considered.

3.3.14 Sensitivity analysis

Sensitivity analyses were conducted for the two parts of the review to assess the robustness of the review results by repeating the analysis with high quality studies based on Newcastle-Ottawa Quality Assessment Scale for cohort studies (i.e. those scoring the minimum 9) and the following adjustments for RCTs: exclusion of studies with unclear or inadequate allocation concealment, unclear or inadequate blinding of outcomes assessment and unclear or inadequate completeness of follow up.

3.4 Results

The electronic searches retrieved 1380 studies in the preliminary search of databases that included: 606 studies in EMBASE, 421 studies in MEDLINE, 200 studies in CINAHL and 153 studies in the Cochrane Library (See 3.2 for the flow diagram and appendix B for the search strategies). The authors eliminated the duplicates studies (n=567). After examination of the titles and abstracts of the references all of those which did not match the inclusion criteria and were clearly ineligible were eliminated (n=634). Full text copies of the remaining 179 studies were obtained and these were then subjected to further evaluation. The bibliographical references of all potentially eligible studies were also examined and no more studies found. Sixteen cohort studies and 13 RCTs studies were considered to be eligible to be included in this review.

Our search also retrieved 14 systematic reviews: Ide and Papapanou (2014), Shah et al. (2013), Kim et al. (2012), Rosa et al. (2012), Chambrone et al. (2011a), Chambrone et al. (2011b), Fogacci et al. (2011), George et al. (2011),

Oliveira et al. (2011), Polyzos et al. (2010), Uppal et al. (2010), Polyzos et al. (2009), Vergnes and Sixou (2007), Xiong et al. (2007), which were also examined for potentially eligible studies however, no additional studies were identified.
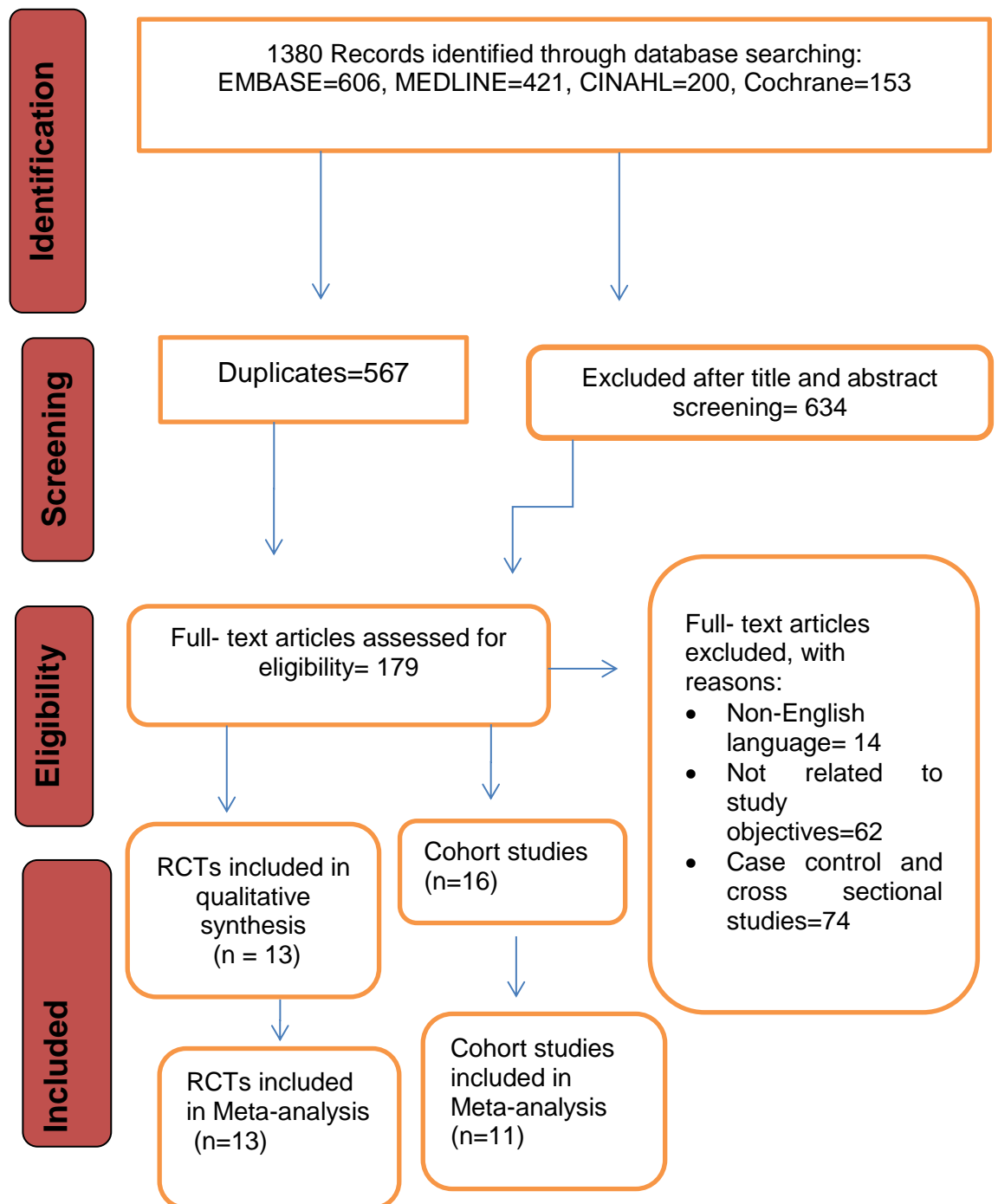
Figure 3.2: Flow chart of the systematic review

3.4.1 Included studies

3.4.1.1   Cohort studies

A total of 14232 pregnant women were included in 16 cohort studies with a mean age of 31.3. Eleven studies allocated the participants into two groups according to the existence of diagnosed PD; studies included 1458 pregnant women with PD and 4384 pregnant women without PD (Ali and Abidin, 2012; Rakoto-Alson et al., 2010; Vogt et al., 2010; Srinivas et al., 2009; Agueda et al., 2008; Pitiphat et al., 2008; Saddki et al., 2008; Sharma et al., 2007; Marin et al., 2005; Rajapakse et al., 2005;Jeffcoat et al., 2001). Three studies allocated groups based on birth outcomes including a term and PTB group (number of women with PD=4807 and without PD =763) (Offenbacher et al., 2006a; Moore et al., 2004; Offenbacher et al., 2001) and one study allocated the groups based on the birth outcomes including PTB, LBW and PLBW (Al Habashneh et al., 2013). One study reported stillbirth only as an outcome (Mobeen et al., 2008).

Seven studies were multicentre studies (Al Habashneh et al., 2013; Ali and Abidin, 2012; Rakoto-Alson et al., 2010; Srinivas et al., 2009; Mobeen et al., 2008; Pitiphat et al., 2008; Sharma et al., 2007).

The studies were conducted in nine different countries: USA (Srinivas et al., 2009; Pitiphat et al., 2008; Offenbacher et al., 2006a; Jeffcoat et al., 2001; Offenbacher et al., 2001), Malaysia (Ali and Abidin, 2012; Saddki et al., 2008), UK (Marin et al., 2005; Moore et al., 2004), Sri Lanka (Rajapakse et al., 2005), Spain (Agueda et al., 2008), Madagascar (Rakoto-Alson et al., 2010), Fiji Island (Sharma et al., 2007), Pakistan (Mobeen et al., 2008), Jordan (Al Habashneh et al., 2013) and Brazil (Vogt et al., 2010).

PTB, LBW and PLBW were the main ABO outcomes of the included studies in this Part 1 of the review except Mobeen et al. (2008) who reported stillbirth as the main outcome of his study.

The providers of care included dentists in nine studies (Rakoto-Alson et al., 2010; Agueda et al., 2008; Mobeen et al., 2008; Pitiphat et al., 2008; Saddki et al., 2008; Offenbacher et al., 2006a; Marin et al., 2005; Rajapakse et al., 2005; Moore et al., 2004), two studies included periodontists (Ali and Abidin, 2012; Vogt et al., 2010), two studies included nurses (Srinivas et al., 2009; Offenbacher et al., 2001) and one study included dental hygienists (Jeffcoat et al., 2001). Al Habashneh et al. (2013) included dental examiners but it was not stated whether they were dentists, nurses or dental hygienists and Sharma et al. (2007) did not report who performed the research assessments.

Three studies (Rakoto-Alson et al., 2010; Vogt et al., 2010; Offenbacher et al., 2001) supported the association between PD and PTB (PTB OR 1.89-10.9) and PD and LBW (LBW OR 1.64-13). Al Habashneh et al. (2013) supported the association between PD and PTB, LBW and PLBW. Four studies supported a relationship between PD and PTB only (Agueda et al., 2008; Pitiphat et al., 2008; Offenbacher et al., 2006a; Jeffcoat et al., 2001) (OR 1.2 -1.77). Two studies supported the relationship between PD and LBW only (Saddki et al., 2008; Marin et al., 2005) (OR 4.81), two studies supported the relationship between PD and PLBW (Sharma el at., 2007; Rajapakse et al., 2005), and one study supported a relationship between PD with stillbirth (Mobeen et al., 2008) (OR 1.26). In contrast Ali and Abidin (2012) and Moore et al. (2004) did not support a relationship between PD and ABOs (PTB and LBW). Srinivas et al. (2009) did not support a relationship between PD and PTB, while Agueda et al.

(2008) found no evidence to support a relationship between PD and LBW.

Table 3.1 reports the main characteristic of the included cohort studies.

3.4.1.1.1 Quality of cohort studies

The Newcastle-Ottawa quality assessment scale for cohort studies was used to evaluate the quality of the cohort studies in part 1 of the review (Appendix E). This assessment tool included three main criteria: selection, comparability and outcomes. Most studies scored 4/4 stars for the selection criteria, except Jeffcoat et al. (2001) and Offenbacher et al. (2001) who did not have complete details on how original sample was derived, though the non-exposed cohort had been selected in a similar way in both studies.

Three studies did not account for the comparability of cohorts on the basis of the study design or subsequent analysis (Al Habashneh et al., 2013; Ali and Abidin et al., 2012; Mobeen et al., 2008). Five studies were awarded two stars, (Rakota Alson et al., 2010; Srinivas et al., 2009; Agueda et al., 2008; Moore et al., 2004; Offenbacher et al., 2006). Most studies reporting that they adjusted for confounders using regression analysis. Typically these factors were smoking, maternal age, history of ABO, race, education, income, obesity, genitourinary tract infection, socioeconomic position and systemic conditions. The remaining studies scoring one star either did not report their analysis in detail, with Sharma et al. (2007) reporting they conducted a logistic regression on 42 women (a partial sample) who did not display the known risk factors (smoking etc.). Five studies were awarded the maximum of three stars for the assessment of outcomes (Agueda et al., 2008; Mobeen et al., 2008; Saddki et al., 2008; Moore et al., 2004; Offenbacher et al., 2006a) and the other remaining (n=11) studies received two stars out of three stars because there

was no descriptive statement concerning the follow-up (see appendix E). Only four studies reported that a power calculation was conducted on the basis of PD and ABO prevalence (Srinivas et al., 2009; Agueda et al., 2008; Saddiki et al., 2008; Sharma et al 2007). All studies reported the ABO outcomes adequately.

3.4.1.1.2 Periodontal case definition

Another quality issue is the case definition of 'periodontitis' used. Two studies did not report a clear definition of periodontal disease (Al Habashneh et al., 2013; Mobeen et al., 2008).

Only one study (Marin et al., 2005) reported a secure definition of PD according to Nibali et al. (2013) criteria (see Table 3.1), although Marin et al (2005) recorded PD status over a range of times over the pregnancy. The remaining studies (n=13) used an 'insecure periodontal definition' to categorise the case definition (see Table 3.1). The remaining two studies of the 16, (Rakoto-Alson et al., 2010; Srinivas et al., 2009) reported partial secure definition of PD according to Nibali et al. (2013) criteria. Both studies defined PD by measuring three or more teeth with CAL equal to three millimetres or more, however the studies did not reported whether the PD assessment included measuring nonadjacent teeth and proximal CAL (Nibali et al., 2013). Page et al. (2007) stresses the importance of assessing CAL on at least two different sites on different teeth and one or more PPD on interproximal sites because the inflammation usually startes and is most severe in interproximal sites.

Most of the studies (n=12) used categorical data to report periodontal outcomes and only two studies used continuous (Rajapakse et al., 2005; Moore et al., 2004) (see Table 3.1).

Table 3.1: Characteristics of included cohort studies

Author	Year, Location	Characteristics of population	PD Definition	Continuous/ categorical Secure/ Insecure PD	Methods	Outcomes	Results OR/RR	Conclusion	Quality score Notes
Jeffcoat et al. (2001)	2001 Perinatal Emphasis Research Centre, (PERC) at University of Alabama	1313 pregnant woman, at least one visit to the PERC study health clinics as an obstetric patient and to have reached 21 to 24 weeks' gestation.	a) PD ≥3 sites with CAL of ≥3 mm b) Gen. PD (90 or more sites with CAL of 3 mm or more) c) No disease (less than three sites with 3 mm of CAL	Categorical Insecure periodontitis (not mentioned whether the teeth are non-adjacent teeth or measurement of proximal CAL)	Demographic assessment, patient's behaviour and oral health history questionnaire, assessment pregnancy outcomes after pregnancy Dental and periodontal examination: Pocketing, recession and CAL	PTB <37, 35 and 32 weeks The risk of PTB in subjects with generalised periodontitis was from 4.45 to 7.07 times higher than that in periodontally healthy patients. Only OR reported No rates reported	Patients with severe or generalised PD had OR of 4.45 (2.16-9.18) for PTB < 37 weeks The OR increased with increasing prematurity to 5.28 (2.05-13.60) before 35 wks. and 7.07 (1.70-27.4) before 32 wks.	There was an association between the presence of periodontitis at 21 to 24 weeks gestation and subsequent PTB.	Selection *** Comparability * Outcome ** 6/9
Offenbacher et al. (2001)	2001 Prenatal Care Clinic University of North Carolina Hospitals, USA	812 Pregnant women Gestational age <26 weeks (no other inclusion criteria were reported)	a) Moderate to severe PD: > 4 sites with at least 5 mm PPD and 2 mm CAL at ≥ 4 sites b) Periodontal health: absence of any PPD >3 mm and no sites with CAL >2 mm, c) Mild: mothers had	Categorical Insecure periodontitis (not mentioned non-adjacent teeth or proximal CAL)	Interview and full-mouth periodontal examinations (PPD), CAL and BOP), at enrolment and within 48 hrs postpartum.	PTB <37weeks LBW<2500g Term: 624 Healthy: 163 Mild PD: 434 Moderate to severe PD: 27 PTB: 188 Healthy: 38 Mild: 132 Moderate to severe PD: 18 (Data only provided for BW<1000g not within study criteria)	Women with PD: PTB 150/611 Without PD: 38/201 Mild PD 132/566 Mod to Severe 18/45 RR and OR not reported	Maternal PD and incident progression are significant contributors to obstetric risk for PTB and LBW (but LBW definition outside present study definition, for Low birth).	Selection *** Comparability * Outcome ** 6/9

				less disease than a) and more disease than b).					
Moore et al.(2004)	2004 Guy's and St Thomas' Hospital Trust, London, UK between August 1998 and July	3823 enrolled but 3,738 pregnant women completed. Recruited from those attending ultrasounds scan at approximately 12 weeks of pregnancy. Mean age 29.9 years	PPD and/or CAL were used to identify the periodontal disease health and severity	Continuous Insecure (No details of the measures for CAL or PPD). a) PD defined as more than 10% of sites with PPD ≥3mm and 5% of sites with CAL≥2mm; b) Severe PD defined as >5 sites with PPD ≥5mm and >3 sites with CAL ≥3mm	Questionnaire assessing: demographic details, pregnancy and medical history, health behaviour, dental experience and smoking status a full mouth, two sites per tooth assessment was performed for: plaque and BOP (presence or Absence), PD and CAL recorded Data were recorded orally onto a cassette tape and then transcribed to a clinical examination sheet.	PTB < 37 weeks spontaneous PTB < 32 wks LBW < 2500g and late miscarriage (between 12 and 24 wks. gestation), Stillbirth was combined into the group termed 'Miscarriage'. (Non-PTB 3452 PTB: 268, stillbirth/late miscarriage: 49 Non-LBW 3492 LBW: 246	Women with PD: Non-PTB 3461 PTB: 268/ 3461 LBW: 246/3461 Stillbirth/miscarriage: 6/3461 Women without PD: PTB: 20/ 277 LBW: 22/277 Stillbirth/ miscarriage: 1/277 PTB With PD Mild 242/3192 Severe 24/269 LBW With PD Mild 246/3192 Sever 23/269	There was no association between either PTB birth or LBW and PD in this population	Selection **** Comparability ** Outcome *** 9/9
Rajapakse et al. (2005)	2005 Base Hospital in Matale for prenatal care, Matale, Sri Lanka.	277 pregnant women Age range 18- 34 years ; in late third trimester of pregnancy, free of maternal hypertension, diabetes, smoking, alcohol and drug abuse,	The 'exposure' was defined as having mean PPD, PI (plaque score), and BOP scores that are greater than the median	Continuous Insecure (the score of the PPD not given and radiographs not used)	Questionnaire to assess demographics, pregnancy and ABOs (PLBW) outcomes PD, BOP, PI	PLBW: BW less than 2500 g, and delivered before 37 wks. 17 (7.5%) PLBW with PD = 8/66 (12%) without PD= 9/161 (5.6%)	OR= 2.3 (0.9-6.3).	Suggests a tentative association between periodontal disease and PLBW	Selection **** Comparability* * Outcome

		no history of past periodontal treatment during pregnancy	value in the total cohort, either individually or in combination						** 8/9
Marin et al. (2005)	2005 Public health clinic of Bucarein (Joinville, state of Santa Catarina, Brazil).	152 Caucasian pregnant women aged 14–39 years, with singleton gestation, Any weeks gestation.	Healthy periodontal: < 5% BOP without CAL >than 6mm in 2 or more sites and without one or more sites with probing depth ≥ 5mm Gingivitis: Women showing >5% BOP, but without CAL higher than 6mm in 2 or more sites and without one or more sites with probing depth ≥5mm. periodontitis: women showing	Categorical Secure PD	Medical records obtained to assess demographic and pregnancy and pregnancy outcomes PPD, BOP, PI, CAL	Healthy: PTB: 2/38, LBW: 0/38 Gingivitis: PTB: 3/71, LBW: 4/71 Periodontitis PTB: 3/43, LBW: 3/43	Not reported	Periodontal disease Caucasian women, older than 25 years, associated with LBW.	Selection *** Comparability * Outcome ** 6/9

			more than 5% BOP, with CAL higher than 6mm in 2 or more sites and with one or more sites with PPD≥5mm.						
Offenbacher et al. (2006a)	2006 Oral Conditions and Pregnancy Study (beginning in December of 1997)	1020 pregnant women before 26 weeks of gestation.	PD definition: a) moderate to severe: ≥4 sites with at least 5 mm PPD and 2 mm CAL at ≥4 sites b) Periodontal health: absence of any PPD >3 mm and no sites with CAL >2 mm, Mild: mothers had less disease than the moderate to severe group and had more disease than the healthy group	Categorical Insecure periodontitis (not mentioned whether the teeth non-adjacent teeth or measuring the proximal CAL)	Comprehensive, full-mouth, periodontal examinations (including PI, GI, bleeding scores, PPD and CAL at 6 sites per tooth) before 26 wks. gestational age and within 72 hours postpartum (Kappa 0.9)	PTB < 37wks PTB= 186 (18.2%) Healthy: 32(11.2%)/ 285 Mild: 112/588 (19%) Moderate to severe: 42/147 (28.6%) Term: 834(81.7% Healthy: 283(88.8%) Mild: 476(81%) Moderate to severe: 105 (71.4%)	Mild PD RR: 1.2 (0.9–1.7). Moderate to severe PD RR: 1.6, (11–2.3). Women with PD PTB: 154/735 Women without PD PTB: 32/285	Maternal periodontal disease increases relative risk for PTB spontaneous births.	Selection **** Comparability ** Outcome *** 8/9

Study	Year/Setting	Sample	Periodontal measure	Exposure classification	Assessment method	Outcome data	Effect estimate	Conclusion	Quality
Sharma el at. (2007)	2007 A multi-centered Ante-natal clinics at the Colonial War Memorial and Lautoka Clinic, FIJI Island.	670 pregnant women Mean age was 25.8 13 had PTB history 48 women smoked during pregnancy 56 women consumed alcohol during pregnancy	Periodontal status determined using the CPITN	Categorical Insecure periodontitis (using CPITN)	Participants were interviewed, and oral examination was conducted by using CPITN Index	Women with PD= 95: 7 PLBW Women without PD= 575: 6 PLBW,	Not reported	There is a highly significant relationship between PLBW and moderate to severe PD.	Selection **** Comparability * Outcome ** 7/9
Agueda et al. (2008)	2008 Pregnant women seeking prenatal care at the University Hospital of Lleida (Spain)	1296 pregnant women, age between 18 and 40 years, pregnancy duration of 20–24 weeks and the presence of 18 teeth. The mean age 29.6 272 women used tobacco during pregnancy 73 women consumed alcohol during pregnancy 75 women had history of PTB 66 women had history of LBW	Periodontal disease was defined as the presence of ≥4 teeth with ≥1 site with PPD ≥4mm and CAL ≥3mm at the same site	Categorical Insecure periodontitis (not reported whether the selected teeth non-adjacent teeth and did not assess the proximal CAL)	Assessment of demographic data and medical and dental history, Periodontal assessment were recorded: PPD, CAL, PI & BOP	Women with PD= 338: 31 PTB, 28 LBW and 16 PLBW Women without PD= 958: 54 PTB, 50 LBW and 27 PLBW	PTB=OR 1.77(1.08-2.88) LBW=Not reported	There was an association between periodontitis and PTB. LBW was not associated with PD.	Selection **** Comparability *** Outcome *** 9/9
Mobeen et al. (2008)	2008 Four units of Latifabad,	1152 pregnant women: 20-26 weeks of gestation.	a) Moderate PD ≥3mm PPD for at least	Continuous Insecure periodontitis (not mentioned	A full-mouth periodontal examination including: PI, GI,	Not reported	Stillbirth=RR 1.26(0.84-1.89)	Pregnant Pakistani women have high levels of	Selection ****

	in the Hyderabad District of Pakistan	Mean age was 26.5 2,7% had at least 1 stillbirth history	three teeth; CAL≥3mm for 4 teeth b) Gingivitis GI of 3 for at least 4 teeth	whether the teeth non-adjacent teeth or measuring the proximal CAL)	CAL,PPD, recession and DMFT			moderate-to-severe dental disease. Stillbirth and neonatal and perinatal deaths increased with the severity of PD.	Comparability Outcome *** 7/9
Pitiphat el at. (2008)	2008 Prenatal visit at one of eight Harvard Vanguard Medical Associates centers USA	1635 participants in the 2nd trimester of gestation The mean age was 33.7 8.8% women had PTB history 3.9% women consumed alcohol during pregnancy	At least one site with CAL ≥3 mm	Categorical Insecure periodontitis (at least 2 nonadjacent teeth with proximal sites)	Pregnancy outcomes were obtained from medical records. Self-reported periodontitis was assessed during the second trimester of pregnancy, and validated against radiographs (bitewing radiographs)	Women with PD= 62: 8.1% PTB (approximately 5 PTB) Women without PD= 1573: 6.4% PTB (approximately 100 PTB)	OR PTB=1.74(95% CI: 0.65–4.66)	Periodontitis is an independent risk factor for poor pregnancy outcome (PTB) among middle-class women	Selection **** Comparability ** Outcome ** 8/9
Saddki et al. (2008)	2008 Antenatal care, which is delivered free of charge at maternal and child health Malaysia	500 participants (250 with periodontal disease and 250 without periodontal disease) Malay pregnant women in the second trimester of pregnancy (14–27 week gestation) The mean age was 29.11	The presence of four or more sites with PD 4 mm or higher, and CAL 3 mm or higher at the same site with presence of BOP	Categorical Insecure periodontitis (need to assess non-adjacent teeth and assess proximal CAL to be secure)	Randomly selected participants Periodontal examinations: CAL, PPD, BO Periodontal examinations were repeated at 2–4 weeks interval during the follow-up period	Women with PD= 232: 33 LBW, 16 PTB Women without PD= 240: 8 LBW, 3 PTB	OR LBW=4.81(95% CI: 2.17–10.65) PTB=Not reported	There is a relationship between PD and low birth weight	Selection **** Comparability * Outcome *** 8/9

		21 women had PTB history 68 women had LBW history							
Srinivas et al. (2009)	2009 Multicentre University based, USA	786 pregnant women who were 6-20 weeks' gestation The mean age was 23.1 97 women used tobacco during pregnancy 99 had history of PTB	CAL 3 mm on 3 or more teeth site	Categorical Insecure periodontitis (not mentioned whether the teeth non-adjacent teeth or measuring the Proximal CAL)	Interviewed at enrolment and ultrasound and periodontal examination	Women with PD= 311: 37 PTB Women without PD= 475: 72 PTB	OR PTB=0.77 (95% CI: 0.49–1.21)	No relationship between PD and pregnancy outcomes	Selection **** Comparability* * Outcome ** 8/9
Rakoto-Alson et al. (2010)	2010 Three public prenatal care health clinics in Madagascar	204 pregnant women aged 18 to 38 with a gestational age between 20 and 34 weeks The mean age was 25.6 9 women had history of PTB	At least 3 sites from different teeth with CAL ≥4 mm	Categorical Insecure periodontitis (not mentioned whether the teeth non-adjacent teeth or measuring the Proximal CAL)	Periodontal parameters, such as PPD and CAL, were recorded	47 with PD= 33 PTB, 17 LBW, 7 PLBW 157 without PD= 9 PTB, 5 LBW, 2 PLBW	LBW = 9.55 (95%CI Not reported), PLBW= 5.51 (95%CI Not reported). RR Women with light PD and women without PD: PTB =10.9(95%CI Not reported), LBW =13(95%CI Not reported), PLBW =41.9 (95%CI Not reported). Women with moderate to severe PD and women without PD: PTB=13.6 (95%CI Not reported),	There is a strong relationship between PD and PTB and LBW.	Selection **** Comparability* * Outcome ** 8/9
Vogt et al. (2010)	2010 University based,	327 pregnant women aged 18 to 42, gestational	Presence of 4 or more teeth	Categorical Insecure periodontitis	Pregnant women divided in groups with or without PD.	156 with PD= 19 PTB, 18 LBW 171 without	PTB= 1.89 (95% CI: 0.93–3.85) LBW=1.64 (95% CI:	There is a connection between PD	Selection

	Brazil	age ≤ 32 weeks and low risk. The mean age was 25 32 women used tobacco during pregnancy 23 women consumed alcohol during pregnancy	showing at least one site with 4 mm of PPD and CAL at the same site, with BOP	(not giving score for CAL)	Indexes of PI and BOP,PPD, CAL and gingival recession were performed	PD=11 PTB, 12 LBW	0.82–3.30)	and PTB and LBW	**** Comparability * Outcome ** 7/9
Ali and Abidin (2012)	2012 Ante-natal Clinics in Selangor (Kuala Lumpur General Hospital and National University of Malaysia Hospital) and three ante-natal Clinics in Perak (Malaysia)	73 healthy pregnant women between 28 to 36 gestation weeks attending 5 ante-natal centres The mean age was 29.1	Had ≥ 2 teeth with ≥ 5mm PPD depth and CAL ≥ 3mm.	Categorical Insecure periodontitis (not mentioned whether the teeth non-adjacent teeth or measuring the proximal CAL)	Interviewer-administered Questionnaire and Periodontal examination, which included PI, GI, Papillary Bleeding index, PPD and CAL were conducted.	37 with PD=4 PTB, 3 LBW 36 without PD= 10 PTB, 2 LBW	PTB=0.39 (95% CI: 0.13–1.13) LBW= 1.46(95% CI: 0.26–8.23)	No relationship between PD and ABOs	Selection **** Comparability Outcome ** 6/9
AlHabashneh et al. (2013)	2013 Four main prenatal clinics in the southern and Northern parts of	277 pregnant with a gestational age of 20 weeks or less and had at least 20 present teeth.	Not reported	NA	Socio-demographic assessment, PI, GI, PPD and CAL The means PI, GI, PPD, and CAL over all examined surfaces or sites and percentages of	PT, LBW and PLBW ranged from0.84 to 0.87 for average CAL, 0.78–0.86 for% of sites with CAL ≥ 5mm, 0.63–0.74 for% of sites with CAL≥6	PTB=OR 0.49 (0.37, 0.61) LBW=OR 0.52 (0.41, 0.62) PLBW=OR 0.52 (0.43, 0.61)	There is an increased risk in developing ABOs among women with increased average CAL or% of sites with	Selection **** Comparability Outcome ** 6/9

Jordan in the period between April 2009 and June 2010.	sites with CAL ≥ 3 mm, CAL ≥4mm, CAL ≥5 mm, CAL ≥ 6 mm, PPD ≥ 3 mm, PPD ≥ 4 mm, PPD ≥5 and PPD ≥6 were calculated for each participant	mm	CAL ≥ 5 mm or% of sites with CAL ≥ 6mm or number of missing teeth.

Categ: Categorical; Cont.: continuous; Sec: Secure; Insec: Insecure; Perio Def: periodontal definition; PD: Periodontal disease; PPD: periodontal pocket depth
CAL: Clinical attachment level; OH: oral health instruction; SRP: scaling and root planning; OR: odd ratio; SPTB: spontaneous preterm birth; GI: gingival index;
PI: Plaque index; BOP: bleeding on probing; RR: risk raio; I: intervention; C: control; P:P value

3.4.1.2 Meta-analysis of cohort studies

In terms of meta-analysis, thirteen studies could be included according to their findings whether it was PTB, LBW and/or PLBW. There was only one study reporting on stillbirth (Mobeen et al., 2008) so a meta-analysis was not undertaken. Two studies (Al Habashneh et al., 2013; Jeffcoat et al., 2001) did not provide the number of cases (in terms of PTB, LBW or PLBW) in the two study groups (with/without PD) so the studies could not be included in the meta-analysis.

a. PTB

The data were pooled from eleven cohort studies that assessed the presence of PTB in women with or without PD regardless of how 'securely' PD was defined (Ali and Abidin, 2012; Rakoto-Alson et al., 2010; Vogt et al., 2010; Srinivas et al., 2009; Agueda et al., 2008; Pitiphat et al., 2008; Saddki et al., 2008; Offenbacher et al., 2006; Marin et al., 2005; Moore et al., 2004; Offenbacher et al., 2001).

Of 6104 women diagnosed with PD, 723 (12%) of them had PTB. A total of 351 (8%) women had a PTB from 4411 women without PD. The meta-analysis indicated an overall statistically significant risk of PTB in women with PD, with a risk ratio (RR) of 1.63 (95% CI: 1.06, 2.50, P=0.03). Figure 3.3 shows the meta-analysis of data pooled from 11 cohort studies to assess PTB. There was evidence of substantial heterogeneity between the studies by using the random effects model (I^2=85%); heterogeneity was statistically significant (P< 0.00001).

Study or Subgroup	women with PD Events	women with PD Total	women without PD Events	women without PD Total	Weight	Risk Ratio M-H, Random, 95% CI
Ali and Abidin, 2012;	4	37	10	36	7.0%	0.39 [0.13, 1.13]
Augeeda 2008	31	338	54	958	10.9%	1.63 [1.06, 2.49]
Marin et al., 2005	6	114	2	38	4.7%	1.00 [0.21, 4.75]
Moore et al., 2004	268	3461	20	277	10.8%	1.07 [0.69, 1.66]
Offenbacher et al., 2001	150	611	38	201	11.4%	1.30 [0.94, 1.79]
Offenbacher et al., 2006a	154	735	32	285	11.2%	1.87 [1.31, 2.66]
Pitiphat et al., 2008	5	62	100	1573	8.2%	1.27 [0.54, 3.00]
Rakoto-Alson et al., 2010;	33	47	9	157	9.4%	12.25 [6.32, 23.72]
Saddki et al., 2008;	16	232	3	240	6.2%	5.52 [1.63, 18.68]
Srinivas et al., 2009	37	311	72	475	11.1%	0.78 [0.54, 1.14]
Vogt et al., 201o	19	156	11	171	9.1%	1.89 [0.93, 3.85]
Total (95% CI)		6104		4411	100.0%	1.63 [1.06, 2.50]
Total events	723		351			

Heterogeneity: Tau² = 0.40; Chi² = 66.52, df = 10 (P < 0.00001); I² = 85%

Test for overall effect: Z = 2.21 (P = 0.03)

Figure 3.3: Forest plot of PTB in cohort studies

b. LBW

The data were pooled from seven cohort studies, which assessed the presence of LBW in women with or without PD (Ali and Abidin, 2012; Rakoto-Alson et al., 2010; Vogt et al., 2010; Agueda et al., 2008; Saddki et al., 2008; Marin et al., 2005; Moore et al., 2004).

A total of 352 women (8%) with PD had a baby with LBW out of 4385 women in the group, and 99 (5%) women without PD in a group of 1877 had a baby of LBW. Figure 3.4 shows the meta-analysis of data pooled from the seven cohort studies. There was evidence of considerable heterogeneity between the studies (I^2=81%) using a random effects model; heterogeneity was statistically significant (P< 0.0001).

The RR for LBW was 2.35 (95% CI: 1.21-4.57, P=0.01) based on seven cohort studies. The meta-analysis suggested that women without PD experienced statistically fewer LBW, suggesting that there was evidence of an association between PD and LBW (see Figure 3.4).

Study or Subgroup	women without PD Events	Total	women with PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	28	338	50	958	19.2%	1.59 [1.02, 2.48]	
Ali and Abidin 2012	3	37	2	36	8.7%	1.46 [0.26, 8.23]	
Marine 2005	7	114	0	38	4.4%	5.09 [0.30, 87.03]	
Moore et al., 2004	246	3461	22	277	19.4%	0.89 [0.59, 1.36]	
Rakoto-Alson et al., 2010	17	47	5	157	14.8%	11.36 [4.43, 29.14]	
Saddki et al., 2008	33	232	8	240	16.6%	4.27 [2.01, 9.04]	
Vogt et al., (2010)	18	156	12	171	17.1%	1.64 [0.82, 3.30]	
Total (95% CI)		4385		1877	100.0%	2.35 [1.21, 4.57]	
Total events	352		99				

Heterogeneity: Tau² = 0.55; Chi² = 31.35, df = 6 (P < 0.0001); I² = 81%
Test for overall effect: Z = 2.52 (P = 0.01)

0.01 0.1 1 10 100
women without PD   women with PD

Figure 3.4: Forest plot of LBW in cohort studies

c. PLBW

The data were pooled from four cohort studies, which assessed the presence of PLBW in women with or without PD (Rakoto-Alson et al., 2010; Agueda et al., 2008; Sharma et al., 2007; Rajapakse et al., 2005).

A total of 38 women (7%) with PD had a PLBW out of 546 women, and 44 (2%) women without PD had a PLBW out of 1851 women. Figure 3.5 shows the meta-analysis of data pooled from four cohort studies. There was evidence of considerable heterogeneity between the studies (I^2=67%) and heterogeneity was statistically significant (P= 0.03) using a random effects model.

The RR for PD was 3.53 (95% CI: 1.51 -8.20, P=0.003) based on four studies. Women without PD had statistically fewer PLBW compared to women with PD. The overall effect of PLBW meta-analysis was statistically significant (P =0.003). There is some evidence for an association between PD and PLBW.

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Study or Subgroup	Favours women with PD Events	Total	Favours women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	16	338	27	958	32.3%	1.68 [0.92, 3.08]
Rajapakse et al.,2005	8	66	9	161	26.8%	2.17 [0.87, 5.38]
Rakoto-Alson et al., 2010	7	47	2	157	17.0%	11.69 [2.51, 54.39]
Sharma el at., 2007	7	95	6	575	23.9%	7.06 [2.43, 20.56]
Total (95% CI)		546		1851	100.0%	3.53 [1.51, 8.20]
Total events	38		44			

Heterogeneity: Tau² = 0.48; Chi² = 9.18, df = 3 (P = 0.03); I² = 67%
Test for overall effect: Z = 2.92 (P = 0.003)

Figure 3.5: Forest plot PLBW in of cohort studies

3.4.1.2.1 Sensitivity analysis of the cohort studies

a. PTB

A sensitivity analysis was undertaken comparing high quality studies that is those scoring the maximum score (9) on the Newcastle Ottawa scale versus low quality studies (a score <9). Only two studies out of 11 were rated as high quality scoring the maximum of nine (Agueda et al., 2008; Moore et al 2004). In these two studies 3799 women were diagnosed with PD 299 (8%) of them had PTB. A total of 74 (6%) women had a PTB from 1235 women without PD. There was moderate heterogeneity between the studies using the random effect model (I^2=45%); heterogeneity was not statistically significant (P=0.18). The RR was 1.33 (95% CI: 0.88-2.00, P=0.18) for the two studies. This meta-analysis of high quality cohort studies did not support an association between PD and PTB (see Figure 3.6).

The meta-analysis of the low quality studies reported an RR of 1.72 (95% CI: 0.98, 3.02, P=0.06) from 9 studies, and did not support an association between PD and PTB (see Figure 3.7).

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	31	338	54	958	50.9%	1.63 [1.06, 2.49]
Moore et al., 2004	268	3461	20	277	49.1%	1.07 [0.69, 1.66]
Total (95% CI)		3799		1235	100.0%	1.33 [0.88, 2.00]
Total events	299		74			

Heterogeneity: Tau² = 0.04; Chi² = 1.81, df = 1 (P = 0.18); I² = 45%
Test for overall effect: Z = 1.35 (P = 0.18)
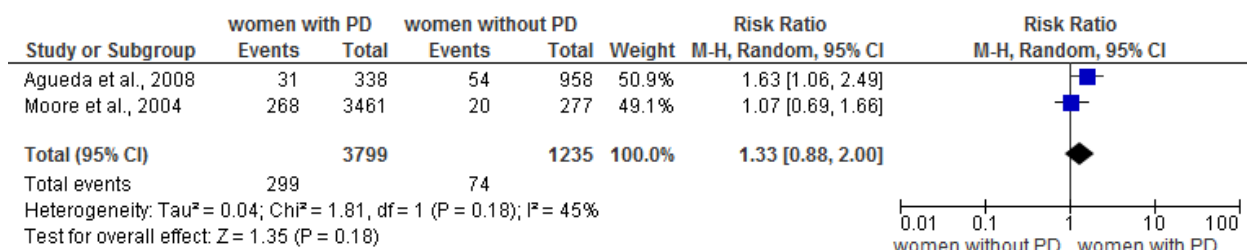
Figure 3.6: Forest plot of PTB in high quality cohort studies

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Ali and Abidin, 2012;	4	37	10	36	9.5%	0.39 [0.13, 1.13]
Marin et al., 2005	6	114	2	38	6.8%	1.00 [0.21, 4.75]
Offenbacher et al., 2001	150	611	38	201	13.7%	1.30 [0.94, 1.79]
Offenbacher et al., 2006a	154	735	32	285	13.6%	1.87 [1.31, 2.66]
Pitiphat et al., 2008	5	62	100	1573	10.7%	1.27 [0.54, 3.00]
Rakoto-Alson et al., 2010;	33	47	9	157	12.0%	12.25 [6.32, 23.72]
Saddki et al., 2008;	16	232	3	240	8.5%	5.52 [1.63, 18.68]
Srinivas et al., 2009	37	311	72	475	13.5%	0.78 [0.54, 1.14]
Vogt et al., 201o	19	156	11	171	11.7%	1.89 [0.93, 3.85]
Total (95% CI)		2305		3176	100.0%	1.72 [0.98, 3.02]
Total events	424		277			

Heterogeneity: Tau² = 0.57; Chi² = 64.27, df = 8 (P < 0.00001); I² = 88%
Test for overall effect: Z = 1.91 (P = 0.06)

Figure 3.7: Forest plot of PTB in low quality cohort studies

b. LBW

Sensitivity analysis comparing high quality studies (Agueda et al., 2008; Moore et al., 2004). There were considerable heterogeneity between the studies using the random effects model (I^2=70%); heterogeneity was not statistically significant (P=0.07). The RR was 1.19 (95% CI: 0.68-2.08, P=0.55) from two studies. This meta-analysis did not support an association between PD and LBW (see Figure 3.8). The meta-analysis of the low quality studies reported an RR was 3.61 (95% CI: 1.55, 8.37, P=0.003) from five studies, supporting PD and LBW (see Figure 3.9).

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	28	338	50	958	49.1%	1.59 [1.02, 2.48]	
Moore et al., 2004	246	3461	22	277	50.9%	0.89 [0.59, 1.36]	
Total (95% CI)		**3799**		**1235**	**100.0%**	**1.19 [0.68, 2.08]**	
Total events	274		72				

Heterogeneity: Tau² = 0.12; Chi² = 3.37, df = 1 (P = 0.07); I² = 70%
Test for overall effect: Z = 0.59 (P = 0.55)

0.01 0.1 1 10 100
women without PD   women with PD

Figure 3.8: Forest plot of LBW in high quality cohort studies

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Ali and Abidin, 2012;	3	37	2	36	14.0%	1.46 [0.26, 8.23]	
Marin et al., 2005	7	114	0	38	7.0%	5.09 [0.30, 87.03]	
Rakoto-Alson et al., 2010;	17	47	5	157	24.1%	11.36 [4.43, 29.14]	
Saddki et al., 2008;	33	232	8	240	27.0%	4.27 [2.01, 9.04]	
Vogt et al., 201o	18	156	12	171	27.9%	1.64 [0.82, 3.30]	
Total (95% CI)		**586**		**642**	**100.0%**	**3.61 [1.55, 8.37]**	
Total events	78		27				

Heterogeneity: Tau² = 0.54; Chi² = 11.82, df = 4 (P = 0.02); I² = 66%
Test for overall effect: Z = 2.98 (P = 0.003)

0.01 0.1 1 10 100
women without PD   women with PD

Figure 3.9: Forest plot of LBW in low quality cohort studies

c. PLBW

Only one study (Augeda et al., 2008) met the criteria for high quality studies, so sensitivity analysis was not undertaken here.

3.4.1.2.2 Subgroup analysis of PTB, LBW and PLBW based on secure PD case definition

The cohort studies in Part 1 of this review display considerable clinical variation; one possible issue is the insecurity of the case definition of PD. Only one study was assessed as using secure definitions of PD (Marin et al., 2005). So subgroup analyses based on secure PD definition were not undertaken. None of the studies reported assessing non-adjacent teeth and measuring proximal CAL as these criteria were important in assessing the PD case definition (Nibali et al., 2013).

3.4.1.2.3 Subgroup analysis of cohort studies: Black and ethnic minorities

It is recognised that Black and Asian populations experience higher rates of ABO compared to Caucasian women. This was a potential source of clinical heterogeneity warranting further investigation in subgroup analysis. Eleven studies explicitly report the race/ethnic origins of their participants (Rakota-Alson et al., 2010; Vogt et al., 2010; Saddki et al., 2009; Srinivas et al., 2009; Agueda et al., 2008; Pitiphat et al., 2008; Marine et al., 2006; Offenbacheret al., 2006a; Moore et al., 2004; Jeffcoat et al., 2001; Offenbacher et al., 2001). Ali and Abidin (2012) reported their sample as 'multi-ethnic' but no breakdown is given. Representation from non-Caucasian groups was set as: low 0-30%, moderate 31-60% and high 61-100%. The forest plot of the subgroup meta-analyses of cohort studies may be found in Appendix F.

a. PTB

The data were pooled from 10 cohort studies which reported the race/ethnicity of participants and assessed the presence of PTB with or without PD (Rakota-Alson et al., 2010; Vogt et al., 2010; Saddki et al., 2009; Srinivas et al., 2009; Agueda et al., 2008; Pitiphat et al., 2008; Marine et al., 2006; Offenbacher et al., 2006a; Moore et al., 2004; Offenbacher et al., 2001) .

Respectively the representation from non-Caucasian groups in these studies was: 21%, 100%, 28%, 50%, 60%, 24%, 100%, 100%, 90%, and 53%). Three studies had low representation from Black and Asian populations (Agueda et al., 2008; Pitiphat et al., 2008; Moore et al., 2004) while three had moderate representation (Vogt et al., 2010; Offenbacher et al., 2006a; Offenbacher et al., 2001) and extensive representation was noted in four studies (Rakota-Alson et

al., 2010; Saddki et al., 2009; Srinivas et al., 2009; Marine et al., 2006). The cut-offs were set as: low 0-30%, moderate 31-60% and high 61-100% (see Table 3.2).

The meta-analysis of all studies which included Black and Asian populations supported an association between PD and PTB. The meta-analyses of low and extensive representation did not support the association while the meta-analysis of moderate representation studies supported the association (see Table 3.2).

b. LBW

The data were pooled from six cohort studies, which reported the race/ethnicity of participants and assessed the presence of LBW in women with or without PD (Rakoto-Alson et al., 2010; Vogt et al., 2010; Agueda et al., 2008; Saddki et al., 2008; Marin et al., 2005; Moore et al., 2004).

Respectively the representation from non-Caucasian groups in these studies was: 21%, 100%, 28%, 100%, 100%, and 53%. Two studies have low representation form Black and Asian populations (Agueda et al., 2008; Moore et al., 2004) while one has moderate representation (Vogt et al., 2010); meta-analysis was not undertaken for moderate representation. Three studies have extensive representation (Rakota-Alson et al., 2010; Saddki et al., 2009; Marine et al., 2006) (see Table 3.2).

The meta-analysis of all studies including Black and Asian populations supported an association between PD and LBW. The meta-analysis of studies with low representation did not support the association while the meta-analysis of studies with extensive representation supported the association (see Table 3.2).

c. PLBW

The data were pooled from four cohort studies, which reported the race/ethnicity of participants and assessing the presence of PLBW in women with or without PD (Rakoto-Alson et al., 2010; Agueda et al., 2008; Sharma et al., 2007; Rajapakse et al., 2005).

Respectively the representation from non-Caucasian groups in these studies was: 21%, 100%, 100%, and 100%. One study have low representation from Black and Asian populations (Agueda et al., 2008) and three have extensive representation (Rakoto-Alson et al., 2010; Sharma et al., 2007; Rajapakse et al., 2005) (see Table 3.2). The meta-analysis of all studies including Black and Asian populations supported an association between PD and PLBW and the meta-analysis of studies with extensive representation supported the association as well (see Table 3.2).

Table 3.2: ABOs in cohort studies reporting the race/ethnicity of participants

ABO	Represent-ation	RR	I^2	Number of studies	Number of women
PTB	All	1.81 (95% CI: 1.17, 2.79 P=0.008)	85% (P <0.00001)	10	10442
	Low	1.31 (95% CI: 0.98, 1.74	0% (P=0.40)	3	6669
	Moderate	1.58 (95% CI: 1.21, 2.06 P=0.0008)	22% (P=0.28)	3	2159
	Extensive	2.74 (95%CI:0.51, 14.60 P=0.24)	95% (P<0.00001)	4	1614
LBW	All	2.47 (95%CI: 1.21, 5.0, P=0.01)	84% (P<0.00001)	6	6189
	Low	1.19 (95% CI: 0.68, 2.08 P=0.55)	70% (P=0.07)	2	5034
	Extensive	6.39(95% CI: 3.13, 13.05 P<0.00001)	23% (P=0.27)	3	828
PLBW	All	3.53 (95% CI: 1.51, 8.20 P=0.003)	67% (P =0.03)	4	2397
	Low	Meta-analysis was not undertaken because only one study was included (Augeda et al., 2008)			

Extensive	5.00 (95% CI:1.83,13.63 P=0.002)	57% (P=0.10)	3	1101

3.4.1.2.4   Subgroup analysis of cohort studies including women who have experienced ABOs previously

a.   PTB

The data were pooled from nine cohort studies reporting on participants who have experienced ABOs previously and assessed the presence of PTB with or without PD (Rakoto-Alson et al., 2010; Srinivas et al., 2009; Agueda et al., 2008; Pitiphat et al., 2008; Saddki et al., 2008; Offenbacher et al., 2006a; Marin et al., 2005; Moore et al., 2004; Offenbacher et al., 2001).

Respectively the representation of the history of ABOs in these studies was: 10.6%, 6.6%, 4.2%, 17.9%, 16.3%, 14.5, 4.4%, 25%, and 24.9%. Based on the percentages the cut-offs were set as: under and equal to 15% (low) and above 15% would be high representation. Four studies had low representation from participants with an ABO history (Rakoto-Alson et al., 2010; Agueda et al., 2008; Marin et al., 2005; Moore et al., 2004) while five had high representation (Srinivas et al., 2009; Pitiphat et al., 2008; Saddki et al., 2008; Offenbacher et al., 2006a; Offenbacher et al., 2001). Table 3.3 Presents PTB in cohort studies reporting participants with an ABO history.

The meta-analysis of all studies included women with history of ABO supported an association between PD and PTB. The meta-analysis of studies with low and extensive representation did not support the association.

b.   LBW

The data were pooled from five cohort studies with participants who experienced ABOs previously and assessed the presence of LBW in women

with or without PD (Rakoto-Alson et al., 2010; Agueda et al., 2008; Saddki et al., 2008; Marin et al., 2005; Moore et al., 2004).

Four studies have low representation from participants with ABO history (10.6% Agueda et al., 2008; 6.6% Marin et al., 2005; 4.2% Moore et al., 2004; 4.4% Rakoto-Alson et al., 2010) and only one had extensive representation (25% Saddki et al., 2008) so the meta-analysis was not undertaken for LBW and extensive representation. Table 3.3 Presents LBW in cohort studies reporting participants with ABO history.

The meta-analysis of all studies including women with an ABO history supported an association between PD and LBW and the meta-analysis of low representation studies did not support the association.

c. PLBW

The data were pooled from two cohort studies including participants who had experienced ABO previously and assessed the presence of PLBW in women with or without PD (Rakoto-Alson et al., 2010; Agueda et al., 2008) .

The two studies had low representation from participants with an ABO history (10.6% Agueda et al., 2008, 4.4% Rakoto-Alson et al., 2010).

Table 3.3 presents PLBW in cohort studies reporting participants with ABOs history (see Table 3.3). The meta-analysis of all studies which included women with an ABO history did not support an association between PD and PLBW.

Table 3.3: ABOs in cohort studies reporting participants with ABOs history

ABO	Representation	RR	I^2	Number of studies	Number of women
PTB	All	1.80 (95% CI: 1.12, .89, P=0.01)	87% (P<0.00001)	9	10115
	Low	2.25 (95% CI: 0.76, 6.64, P=0.14)	92% (P<0.00001)	4	5390
	Extensive	1.43 (95% CI: 0.92, 2.24, P=0.12)	76% (P=0.002)	5	4725
LBW	All	2.79 (95% CI: 1.15, 6.77, P=0.02)	87% (P<0.00001)	5	5862
	Low	2.47 (95% CI: 0.89, 6.84, P=0.08)	88% (P<0.0001)	4	5390
	Extensive	Meta-analysis was not undertaken because only one study included.			
PLBW	All and low	3.88 (95% CI: 0.59, 25.65, P=0.16)	81% (P=0.02)	2	1500
	Extensive	Meta-analysis was not undertaken because no study included.			

3.4.1.2.5 Subgroup analysis of cohort studies reporting smoking prevalence

Smoking prevalence varied across the studies and is a known important risk factor for both ABO and PD (Kim et al., 2012; Polyzos et al., 2009). Cohort studies reported smoking as a characteristic of recruited participants differently. Five studies reported the percentage of the number of smoking partcipants (19.8% Vogt et al., 2010; 26.2% Srinivas et al., 2009; 15.8% Offenbacher et al., 2006a; 14.5% Moore et al., 2004; 16.8% Offenbacher et al., 2001). Two studies reported smoking based on the number of cigarette per day (21% Agueda et al., 2008; 9.8% Marin et al.,2005). Agueda et al. (2008) reported the percentage of Ex-smoker in addition to the percentage of smoking participants. Only one study reported the percentage of passive smokers (60.8% Saddki et al., 2008) and three studies reported the percentage of non-smokers in addition to smokers (Ali and Abidin, 2012; Agueda et al., 2008; Offenbacher et al., 2006a). Pitiphat et al. (2008) reported the percentage of partcipants smoking in the three months before pregnancy (22.6%). Based on the percentage provided by the

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studies that range between 9.8% and 26.2%, the cut-offs set were less than and equal to 15% (low representation) and higher than 15% would be considered extensive representation.

Meta-analysis for PLBW was not undertaken because only one study included (Agueda et al., 2008).

a. PTB

The data were pooled from seven cohort studies including smoking participants and assessed the presence of PTB in women with or without PD (Vogt et al., 2010; Srinivas et al., 2009; Agueda et al., 2008; Offenbacher et al., 2006a; Marin et al., 2005; Moore et al., 2004; Offenbacher et al., 2001).

Three cohort studies have low representation from smoking participants (15.8% Offenbacher et al., 2006a; 9.8% Marin et al.,2005;14.5% Moore et al., 2004) and four studies have extensive representation (19.8% Vogt et al., 2010; 26.2% Srinivas et al., 2009; 21% Agueda et al., 2008; 16.8% Offenbacher et al., 2001). Table 3.4 Presents PTB in cohort studies reporting smoking participants.

The meta-analysis of all studies included smoking participants supported an association between PD and PTB. The meta-analysis of low and extensive representation studies did not support the association.

b. LBW

The data were pooled from four cohort studies including smoking participants and assessed the presence of LBW in women with or without periodontal disease (Vogt et al., 2010; Agueda et al., 2008; Marin et al., 2005; Moore et al., 2004).

Two cohort studies have low representation from smoking participants (9.8% Marin et al.,2005; 14.5% Moore et al., 2004) and two studies have extensive

representation (19.8% Vogt et al., 2010; 21% Agueda et al., 2008). Table 3.4
Presents LBW in cohort studies reporting smoking participants.

The meta-analysis of all studies included smoking population did not support an
association between PD and LBW. The meta-analysis of low representation
studies did not support the association while the meta-analysis of extensive
representation studies supported the association.

Table 3.4: ABOs in cohort studies reporting participants using tobacco

ABO	Representation	RR	I^2	Number of studies	Number of women
PTB	All	1.31 (95% CI: 1.00,1.72 P=0.05)	58% (P=0.03)	7	8131
	Low	1.40 (95% CI: 0.89, 2.21 P=0.14)	50% (P=0.14)	3	4910
	Extensive	1.27(95% CI: 0.88,1.83 P=0.20)	66% (P=0.03)	4	3221
LBW	All	1.31 (95% CI: 0.87, 1.98 P=0.19)	41% (P=0.17)	4	5513
	Low	1.20 (95% CI: 0.33, 4.41 P=0.78)	31% (P=0.23)	2	3890
	Extensive	1.60 (95% CI: 1.10, 2.34 P=0.01)	0% (P=0.93)	2	1623

3.4.1.2.5.1   Subgroup analysis of cohort studies regarding income and education

Subgroup meta-analyses were planned for income and education as these
factors were known as risk factors for ABOs. They were not undertaken
because the data were inconsistently reported.

3.4.1.3.   Publication bias for cohort studies

Other bias including publication bias was investigated for Part 1 assessing the
relationship between PD and PTB in 11 cohort studies (Figure 3.10). This meta-
analysis included more than 10 studies. As a rule, thumb funnel plots should be

used only when there are at least 10 studies included in the meta- analysis (Higgins and Green, 2011).

Figure 3.10 presents the funnel plot for studies reporting the association between PD and PTB. The funnel plot appears to approximate an asymmetrical funnel, which suggests the presence of publication bias over the time period. It suggested the presence of relevant bias, which might be explained by the large number of small studies assessing and supporting the association between PD and PTB, studies reporting on women at high risk to PTB or who have severe levels of PD, and it might also be explained by lack of reporting of studies with negative findings.
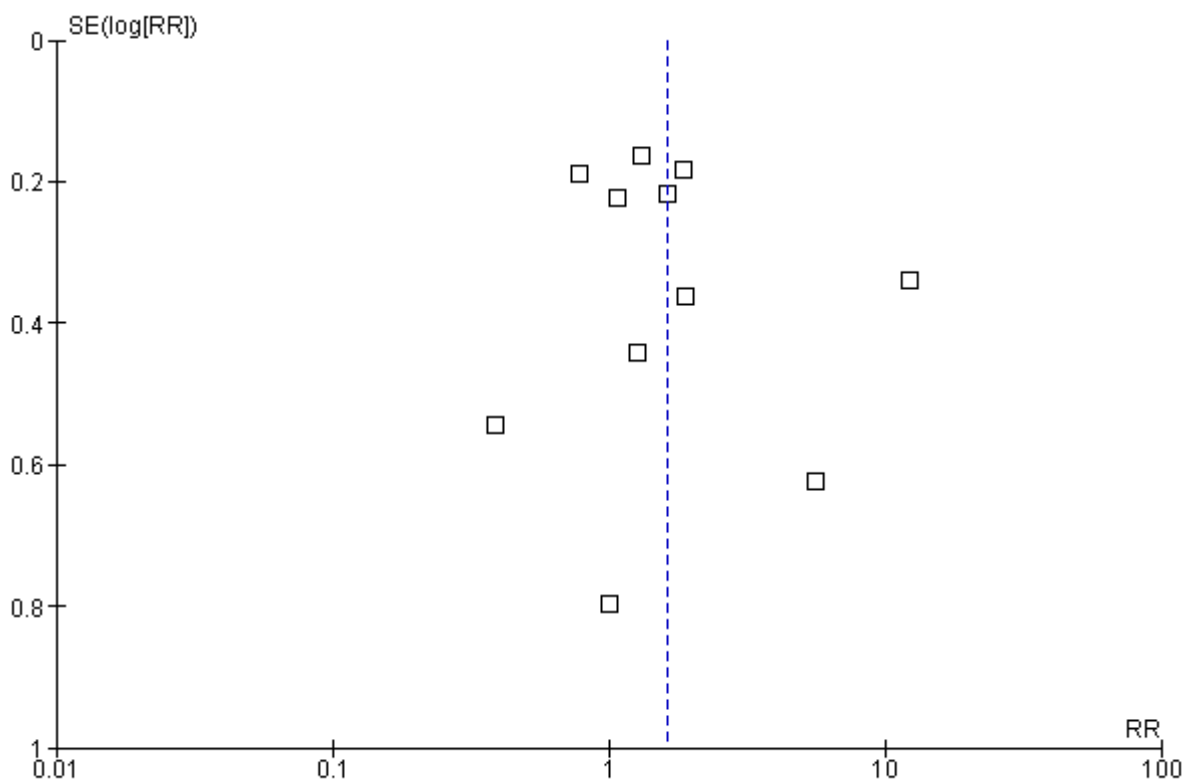
Figure 3.10: Funnel plot for studies reporting PTB in cohort studies

3.4.1.4 RCTs

Thirteen studies were included in this review. All (N= 13) evaluated the relationship between NSPT and incidence of PTB (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Newnham et al., 2009; Offenbacher et al., 2009; Radnai et al., 2009; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; Offenbacher et al., 2006b; Sadatmansouri et al., 2006; López et al., 2005; Jeffcoat et al., 2003; Lopez et al., 2002). Eleven studies evaluated the relationship between periodontal treatment and incidence of LBW (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Offenbacher et al., 2009; Radnai et al., 2009; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; Offenbacher et al., 2006b; Sadatmansouri et al., 2006; López et al., 2005; Lopez et al., 2002). Seven studies evaluated the relationship between periodontal treatment and incidence of PLBW (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Radnai et al., 2009; Sadatmansouri et al., 2006; López et al., 2005; Lopez et al., 2002) and four assessed stillbirth (Weidlich et al., 2012; Macones et al., 2010; Newnham et al., 2009; Michalowicz et al., 2006). See Table 3.6, 3.7 and 3.9 which report individual study details, sample size and periodontal disease entry criteria.

Most (n=11) studies comprehensively addressed PTB and LBW as a primary outcome though PLBW and stillbirth were reported less often (n=7 and n=4 respectively).

None of the studies reported using a secure case definition of PD. Six studies reported partial use (Oliveira et al., 2011; Macones et al., 2010; Offenbacher et al., 2009; Sadatmansouri et al., 2006; Jeffcoat et al., 2003; Lopez et al., 2002) however none of these studies reported CAL in non-adjacent sites and PD in

interproximal sites (Nibali et al., 2013). Not all studies reported periodontal outcomes fully, though some (n=8) reported baseline and post intervention change in periodontal status (Weidlich et al., 2012; Oliveira et al., 2011; Newnham et al., 2009; Michalowicz et al., 2006; Offenbacher et al., 2006b, Sadatmansouri et al., 2006; López et al., 2005; Lopez et al., 2002).

3.4.1.4.1 Characteristics of the trial setting and investigators

Thirteen studies were included in the systematic review of the efficacy of NSPT to prevent ABOs. Four of the studies were conducted in College/University prenatal departments (Offenbacher et al., 2009; Radnai et al., 2009; Michalowicz et al., 2006; Jeffcoat et al., 2003). Prenatal clinics or hospitals were the settings for nine of the studies (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Newnham et al., 2009; Tarannum and Faizuddin, 2007; Offenbacher et al., 2006b; Sadatmansouri et al., 2006; López et al., 2005; Lopez et al., 2002). Three studies were multi-centre studies conducted in universities and medical centers in USA (Macones et al., 2010; Michalowicz et al., 2006; Offenbacher et al., 2006b).

Five studies were conducted in the USA (Macones et al., 2010; Offenbacher et al., 2009; Michalowicz et al., 2006; Offenbacher et al., 2006b; Jeffcoat et al., 2003), two studies in Chile (López et al., 2005; Lopez et al., 2002), two studies in Brazil (Weidlich et al., 2012; Oliveira et al., 2011), one study in India (Tarannum and Faizuddin, 2007), one study in Hungary (Radnai et al., 2009), one study in Iran (Sadatmansouri et al., 2006) and one study in Australia (Newnham et al., 2009).

The providers of care for six studies included periodontists only (Weidlich et al., 2012; Oliveira et al., 2011; Radnai et al., 2009; Michalowicz et al., 2006; López

et al., 2005; Lopez et al., 2002); five studies included dental hygienists, dentists or/ and periodontists (Macones et al., 2010; Newnham et al., 2009; Offenbacher et al., 2009; Offenbacher et al., 2006b; Jeffcoat et al., 2003); four studies also included nurses, obstetricians or /and interviewer (Weidlich et al., 2012; Macones et al., 2010; Newnham et al., 2009; Radnai et al., 2009) and two studies did not state the examiners who performed the research intervention (Tarannum and Faizuddin, 2007; Sadatmansouri et al., 2006). Ten trials trained and calibrated examiners on periodontal diagnostic criteria (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Offenbacher et al., 2009; Radnai et al., 2009; Offenbacher et al., 2006b; Mialowicz et al., 2006; López et al., 2005; Jeffcoat et al., 2003; Lopez et al., 2002). Three centres provided four of the studies included in this review (Offenbacher et al., 2009; Offenbacher et al., 2006b; López et al., 2005; Lopez et al., 2002).

None of the RCTs used a secure case definition of PD according to Nibali et al. (2013) (see Figure 3.1). Six studies reported partially using a secure case definition of PD (Oliveira et al., 2011; Macones et al., 2010; Offenbacher et al., 2009; Sadatmansouri et al., 2006; Jeffcoat et al., 2003; Lopez et al., 2002) . These six studies defined PD by measuring three or more teeth with CAL equal to three millimetres or more, however the studies did not report whether the PD assessment included measuring non-adjacent teeth and proximal CAL (Nibali et al., 2013). All studies used categorical data to define PD, except Weldich et al. (2012). Only eight studies reported periodontal outcomes fully at baseline and post intervention change in periodontal status (see Table 3.6 and 3.7).

A total of 7136 (I: 3595, C: 3541) pregnant women participated in the 13 studies including White, African black, Hispanic, Asian and women from other ethnic

groups. Eight hundred and twenty nine (n=829) pregnant women reported smoking during pregnancy and 257 pregnant women reported drinking alcohol during pregnancy.

3.4.1.4.2 Characteristics of the interventions

All studies included scale and polish (S&P), supra and sub gingival calculus removal including root debridement (S&P and RD) and oral hygiene instruction as part of the active intervention (N=13) (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Newnham et al., 2009; Offenbacher et al., 2009; Radnai et al., 2009; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; Offenbacher et al., 2006b; Sadatmansouri et al., 2006; López et al., 2005; Jeffcoat et al., 2003; Lopez et al., 2002). Some studies in addition reported the use of 0.12% chlorhexidine mouthwash (n= 5) (Newnham et al., 2009; Tarannum and Faizuddin, 2007; Sadatmansouri et al., 2006; López et al., 2005; Lopez et al., 2002).

Regimes for chlorhexidine usage: in three studies women were advised to rinse once a day as part of their daily oral hygiene (Newnham et al., 2009; López et al., 2005; Lopez et al., 2002) and Tarannum and Faizuddin (2007) advised women to rinse with 0.2% chlorhexidine twice a day, while Sadatmansouri et al. (2006) advised the participants to rinse by using 0.2% chlorhexidine once a day for one week only. One study included metronidazole in one of the treatment arms (Jeffcoat et al., 2003), though this arm has not been included in the meta-analyses in the present study.

Six studies reported PTB, LBW and PLBW (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Radnai et al., 2009; Sadatmansouri et al., 2006; Lopez et al., 2002). PTB and LBW reported in four studies (Offenbacher et al.,

2009; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; López et al., 2005), and four studies also reported stillbirth (Weidlich et al., 2012; Macones et al., 2010; Newnham et al., 2009; Michalowicz et al., 2006). PTB as the only ABO was reported in two studies (Offenbacher et al., 2006b; Jeffcoat et al., 2003). See Table 3.6, 3.7 and 3.8 for full details. PTB, LBW, PLBW and Stillbirth events and periodontal outcomes were reported in the studies.

The inclusion criteria for the RCT studies were: healthy pregnant women who were aged between 18 to 35 years old, one study included women as young as 16 years old (Newnham et al., 2009) with a single gestation of 9 to 25 weeks, a minimum of 20 natural teeth, and had PD.

3.4.1.4.3 Excluded studies

One hundred and thirty six studies were excluded from this review and the reasons for their exclusion were because most did not answer the research questions or were studies about bacteria and/ or inflammatory meditators. Some studies reported PTB defined as before 35 weeks of gestation so the criteria were not within the definition used for this review. Further information about the reasons for exclusion of these studies is available in the table 'Exclusion studies of Part 2 (RCTs)' (see Appendix D).

3.4.1.4.4 Risk of bias in included studies

For the RCTs, the Cochrane Risk of Bias tool was used to assess quality and potential bias (Cochrane 2012). The risk of bias assessment was undertaken for the primary outcome (whether or not the patient had an adverse birth outcome). See Figure 3.11 and Table 3.5.

- **Allocation (selection bias)**

Random sequence generation was considered to be at low risk of bias in 10 studies and unclear risk for three studies (Oliveira et al., 2011; Offenbacher et al., 2006b; Sadatmansouri et al., 2006). 77% of studies were at low risk of bias for selection bias.

Allocation concealment was considered to be low risk of bias in eight trials (62%) and for the remainder of the studies it was deemed as either unclear in two trials (15%) (Tarannum and Faizuddin, 2007; Lopez et al., 2002) or at high risk of bias in three trials (23%) (Offenbacher et al., 2006b; Sadatmansouri et al., 2006; López et al., 2005).

- **Blinding of participants and personnel (performance bias)**

Blinding of participants and personnel (performance bias) was considered to be at low risk of bias in nine trials (69%). It was judged as being unclear in two trials (15%) (Michalowicz et al., 2006; Lopez et al., 2002), and at high risk of bias for two trials (15%) (Sadatmansouri et al., 2006; López et al., 2005).

- **Blinding of outcome assessment (detection bias)**

Blinding of outcome assessment (detection bias) was considered be low risk of bias in eight studies (62%), unclear bias in two trials (15%) (Weidlich et al., 2012; Tarannum and Faizuddin, 2007) and as a high risk of bias in three trials (23%) (Macones et al., 2010; Sadatmansouri et al., 2006; Jeffcoat et al., 2003).

- **Incomplete outcome data (attrition bias)**

It was assumed that dropouts in the prevention of adverse pregnancy outcome studies probably did not have adverse outcomes as in most cases they would have needed to return for treatment. Twelve of the trials (92%) were considered to be at low risk of bias with respect to dropouts. One of these studies had no

dropouts (Jeffcoat et al., 2003). One trial was considered to be at high risk of bias with respect to attrition, which did not fully report drop outs in the study (Sadatmansouri et al., 2006).

- **Selective reporting (reporting bias)**

Only the reporting of PTB, LBW was considered for this item for the trials. The majority of trials reported this well either as a dichotomous outcome or as a mean and/or standard deviation and were considered at low risk of bias.

- **Overall risk of bias**

Three studies were at overall low risk of bias (Newnham et al., 2009; Offenbacher et al., 2009; Radnai et al., 2009). Six studies were at unclear risk of bias having at least one domain categorised as unclear risk of bias (Weidlich et al., 2012; Oliveira et al., 2011; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; Offenbacher et al., 2006b; Lopez et al., 2002).

The remaining four studies were considered to be at high risk having at least one domain categorised as being at high risk of bias (Macones et al., 2010; Sadatmansouri et al., 2006; López et al., 2005; Jeffcoat et al., 2003) (see Figure 3.11 and Table 3.5).
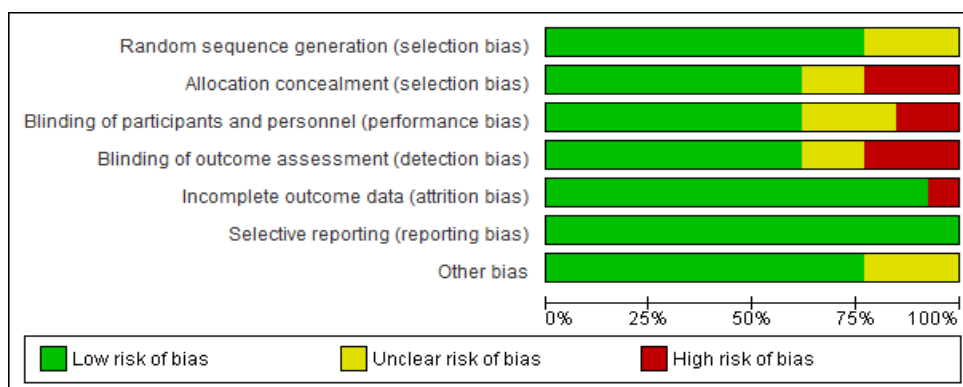
Figure 3.11: Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all studies

Table 3.5: Quality of evidence in included studies: individual domains and overall risk of bias

Author name (date)	Sequence generation (assessed % studies at low risk)	Allocation concealment assessed (% studies at low risk)	Blinding of participants, personnel and outcome assessors assessed (% studies low risk)	Blinding of outcome assessment (detection bias)	Incomplete outcome data assessed (% studies low risk)	Selective outcome reporting assessed (% studies low risk)	Other potential threats it validity assessed (% studies low risk)	Overall Risk of bias Score* (7)
Lopez et al. (2002)	Low risk Toss of coin	Unclear risk Toss of coin, but no report of allocation concealment in paper	Unclear risk Participants not blinded, care givers not blinded	Low risk Primary outcomes provided by obstetricians without knowing allocation	Low risk Women who developed complications for other reasons were included in the analysis , regardless of compliance	Low risk Reported	Low risk None	5/7 Unclear risk of bias
Jeffcoat et al. (2003)	Low risk Independent pharmacy researcher drew up randomisation table	Low risk Codes held in sealed packets	Low risk Participants and personnel blinded	High risk Primary outcomes assessed by abstractors who reviewed women's medical records blinded to group allocation. Statistician however knew groups for data entry	Low risk Fully reported	Low risk Fully reported	Low risk	6/7 High risk of bias
López et al. (2005)	Low risk Randomised using block	High risk No report of allocation concealment	High risk No report of how participants and	Low risk Individual blind to periodontal status and group	Low risk Attrition reported	Low risk Reported	Unclear risk Control group had more women with	4/7 High risk of bias

			personnel were blinded as to treatment	allocation abstracted data from participants' records			previous experience of PTB or LWB	
Michalowicz et al. (2006)	Low risk Using Block randomization	Low risk Telephone call to centre but not clear how allocation concealment was ensured	Unclear risk Personnel were not blinded to care, but patients could have been as returned for checks at same level as intervention group	Low risk Examiners and nurses were not aware of study group assignments	Low risk Intention to treat analysis performed	Low risk	Low risk	6/7 Unclear risk of bias
Offenbacher et al. (2006b)	Unclear risk Not described	Unclear risk Not reported	Low risk Examiner were blinded	Low risk Fully reported	Low risk Fully reported	Low risk Fully reported	Low risk None	5/7 Unclear risk of bias
Sadatmansouri et al. (2006)	Unclear risk Said it was randomised but not clear how	High risk No mention of allocation concealment	High risk Not reported	High risk Not reported who or how obstetric data were abstracted	High risk No details provided on attrition or response rates to participate	Low risk Reported	Unclear risk Conditions under which this study was completed is unclear	1/7 High risk of bias
Tarannum and Faizuddin (2007)	Low risk A total of 100 subjects were assigned randomly, by the flip of a coin, to the treatment group.	Unclear risk Not reported	Low risk reported masking	Unclear risk Not clear whether person abstracting data was masked	Low risk All reported	Low risk All reputed	Low risk None	5/7 Unclear risk of bias
Newnham et al. (2009)	Low risk Randomization was conducted by a research midwife or hygienist using	Low risk Details of all medical, obstetric, and neonatal	Low risk All medical, nursing, and perinatal pathology staff	Low risk Fully reported	Low risk Fully reported	Low risk Fully reported	Low risk None	7/7 Low risk of bias

	computer randomization software specifically designed to allocate each case at random with stratification for nulliparity, history of preterm birth, and current smoking.	outcomes were extracted from the medical records by research midwives who were also blinded to the treatment allocation.	members were unaware of the treatment allocation of each woman in the study,					
Offenbacher et al. (2009)	Low risk randomisation on permuted blocks described	Low risk allocation concealment not described	Low risk Efforts to blind participants and personnel to intervention and control groups	Low risk Independent researcher blind to group allocation abstracted the data	Low risk Fully described	Low risk All data comprehensively reported	Low risk None	7/7 Low risk of bias
Radnai et al. (2009)	Low risk We generated a random sequence of 1's and 2's, and the treatment was allocated accordingly to the 1st or 2nd person in the blocks	Low risk For the allocation of the participants for periodontal treatment, we used a block randomization with blocks of two. We generated a random sequence of 1's and 2's, and the treatment was allocated accordingly to the 1st or 2nd person in the blocks, leaving the other for the control group.	Low risk The dentist who examined and treated the women was blind to the pregnancy outcome	Low risk Fully reported	Low risk Fully reported	Low risk Fully reported	Low risk None	7/7 Low risk of bias

Study								Score*
Macones et al. (2010)	Low risk Using Block randomization	Low risk Reported	Low risk Each subject received an assigned treatment by the trained dental hygienist	High risk Not reported	Low risk Reported	Low risk Reported	none	6/7 High risk of bias
Oliveira et al. (2011)	Unclear risk Not reported	Low risk The periodontist examiner was blinded to the location of each subject within the groups.	Low risk Reported	Low risk Reported	Low risk Reported	Low risk Fully reported	Low risk Fully reported	6/7 Unclear risk of bias
Weidlich et al. (2012)	Low risk Using a block-stratified strategy	Low risk Randomization table was computer generated and allocation to treatment was concealed in an opaque, sealed, and serially numbered envelope opened by the examiner	Low risk	Unclear risk Not clear whether person abstracting data was masked	Low risk All reported	Low risk All reported	Low risk All reported	6/7 Unclear risk of bias

* Score refers to the number of domains recorded as being at low risk of bias

3.4.1.4.5 Effects of interventions

Thirteen RCT studies assessed the efficacy of periodontal therapy on reducing the incidence of ABOs. Two studies found that performing NSPT in pregnant women with periodontitis may reduce the incidence of PTB (Tarannum and Faizuddin, 2007; Jeffcoat et al., 2003), six RCT studies reported that periodontal therapy during pregnancy may reduce the risk of PTB and LBW (Offenbacher et al., 2009; Radnai et al., 2009; Offenbacher et al., 2006b; Sadatmoansouri et al., 2006; Lopez et al., 2005; Lopez et al., 2002) and five studies did not support this finding (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Newnham et al., 2009; Michalowicz et al., 2006).

None of the RCTs explored the safety of the NSPT, so there was no evidence for the safety of the NSPT. However four studies reported that NSPT was safe and successful during pregnancy; it had no hazardous effect on women during pregnancy (Wedlich et al., 2012; Newnham et al., 2009; Michalowicz et al., 2006; Offenbacher et al., 2006b). Also All RCT studies included in this review did not report any side effect or harm from receiving NSPT during pregnancy. No data were available to allow any further judgement beyond a statement from individual authors about the safety of treatment.

Table 3.6: Characteristics of included RCTS

Author	Year, Location	Characteristics of population	Sample size	Periodontitis Definition	Categ. /cont. Sec. /Insec. perio def	Intervention	Outcomes	Results /OR	Conclusion
Lopez et al. (2002)	2002 Consultori Carol Urzúa of Peñalolén,a district of Santiago, Chile.	Healthy pregnant women, aged 18 to 35, with a singleton gestation, between 9 and 21 weeks of gestation, with periodontal disease and with fewer than 18 natural teeth	400 women (I: 200 and C:200) 13 excluded from analysis of IG and 8 from CG)	presence of 4 or more teeth with 1 or more sites with PD ≥4 mm and with CAL ≥3 mm at the same site	Categorical Insecure (non adjacent and proximal CAL not reported)	OHI, SRP, rinse once a day with 0.12% chlorhexidine. .	PTB <37 weeks LBW <2500 g PLBW	PTB 2/163(1.22%) C: 12/188(6.38%)OR 5.48 (1.17-27.71)P=.014 LBW 1/163(0.61%) and C: 7/188 (3.72%) OR 6.26(0.73-53.78)P=.052 PLBW 1.84% (3/163) and C: 10.11% (19/188) OR :5.49, (1.65 -18.22) P = 0.001. Multivariate logistic regression analysis showed that periodontal disease was the strongest factor related to : PLBW (OR 4.70, 95% CI 1.29 to 17.13). Other factors significantly associated were: previous PLBW (OR 3.98(1.11 -14.21) less than 6 prenatal visits OR 3.70(1.46- 9.38) Maternal low weights gain OR 3.42 (1.16- 10.03).	Periodontal disease appears to be an independent risk factor for PLBW. Periodontal therapy significantly reduces the rates of PLBW in this population of women with periodontal disease.
Jeffcoat et al. (2003)	2003 University of Alabama at Birmingham (UAB) School of Dentistry	Pregnant women between 21and 25 weeks' gestation. Screened for at least three sites with CAL ≥3 mm.	IG:366 CG:723 three treatment groups were included	At least three sites with CAL ≥3 mm.	Categorical Insecure (non adjacent and proximal CAL not reported)	3 treatment groups were included with stratification on the following two factors1) previous SPTB	PTB<37 weeks, and spontaneous PTB <35 weeks	PTB at <35 weeks was 4.9% in the prophylaxis group, 3.3% in the SRP plus metronidazole group and 0.8% in the SRP plus placebo group (P = 0.75 and 0.12, respectively). The rate of PTB	SRP in pregnant women with periodontitis may reduce PTB in this population.

(USA)		with stratification on the following two factors1) previous SPTB at <35weeks and 2) body mass index <19.8 or bacterial vaginosis as assessed by gram stain. G1=123 G2=123 G3=120				at <35weeks and 2) body mass index <19.8 or bacterial vaginosis as assessed by gram stain. The IG: 1) dental prophylaxis (tooth cleaning and polish) plus placebo capsule 3 times a day; 2) SRP plus placebo capsule three times a day; and 3) SRP plus metronidazole 250 mg three times a day for 1 week.		at <35 weeks was 6.3%in the reference group. PTB (<37weeks) SRP + Placebo (N = 123) RR:0.5 (CI 0.2, 1.3) P = 0.12 PTB (<35weeks) 0.2 (CI 0.02,1.4)P= 0.12 SRP + Metronidazole (N = 120) PTB (<37weeks) 1.4 (CI 0.7, 2.9) PTB >35 weeks 0.7 (CI 0.2, 2.4).	Adjunctive metronidazole therapy did not improve pregnancy outcome
López et al. (2005)	2005 public health clinic in Santiago, Chile	Healthy pregnant women over age 18, with a single gestation, 22 weeks or less of gestation, gingival inflammation with ≥25%of sites with BOP, and no sites with CAL loss >2 mm.	870 women I:580 C:290	gingival inflammation with ≥25%of sites with BOP, and no sites with CAL loss >2 mm.	Categorical Insecure gingivitis	OHI, supra and subgingival scaling, and crown polishing. woman was provided with toothbrushes and chlorhexidine and instructed to rinse once a day with 0.12% chlorhexidine	PTB <37 weeks LBW <2500g. PLBW <37 weeks and <2500g.	PTB I; 8/560(1.42%) C: 16/283(5.65%) OR 4.11(1.73 - 9.73)P=.0005 LBW I: 4/560 (0.71%) C: 3/283(0.79%) OR1.47(0.32 - 6.54)P=0.61 PLBW I: 12/560(2.14%) C:19/283 (6.71%) OR3.26(1.56 - 6.83)P=.0009	Periodontal treatment significantly reduced the PLBW rate in this population of women with pregnancy-associated gingivitis.

| Michalowicz et al. (2006) | 2006 Hennepin County Medical Center (MN), the University of Kentucky, the University of Mississippi Medical Center, and Harlem Hospital (NY) USA | 13 and 17 weeks of gestation women Had at least 20 natural teeth and the presence of periodontal disease | 812 I:407 C:405 | 4 or more teeth with PD of at least 4 mm and CAL of at least 2 mm. BOP at 35% or more of tooth sites | Categorical Insecure (CAL less than 3mm and not stated the number of sites) | OHI, SRP, Tooth polishing | PTB<37weeks LBW<2500g | PTB <37weeks I: 49/407(12%) C: 52/405 (12.8%)

 <35 weeks I: 22/407 (5.4%) C: 26/405 (6.4%)

 <32weeks I: 10/407 (2.5%) C: 18/405 (4.4%)

 LBW <2500 I: 40/406 (9.9%) C: 43/403 (10.7%)

 <1500 g I: 8/406 (2.0%) C: 15/403 (3.7%)

 Preeclampsia I: 31/407 (7.6%) C: 20/405 (4.9%) | Treatment of periodontitis in pregnant women improves periodontal disease and is safe but does not significantly alter rates of preterm birth, low birth weight, or foetal growth restriction. |
| Offenbacher et al. (2006) | 2006 From January 2001 to November 2003 The Wake County Human Services dental clinic. USA | 18 years and older pregnant women at <22 weeks gestation Had two or more sites measuring ≥5 mm PD plus CAL of 1 to 2 mm at one or more sites with PDs ≥5 mm Had ≥20 teeth Had a history of preterm/low birth weight delivery | N=74 I=40 C=34 | Not specified but PD defined as two or more sites with ≥5m plus CAL of 1-2 mm at one or more sites with 5mm Used PI, GI, PPD, Recession, and BOP | Categorical Insecure | OHI, SRP, & sonic toothbrush | PTB<37 weeks | PTB Intervention: OR 0.26 (0.08 - 0.85)P= 0.026 Baseline extent of PD ≥5 mm: OR 0 1.22 (1.02 to 1.46) P= 0.026 | Periodontal treatment reduced PTB and LBW, Treatment is safe during pregnancy |

Sadatma nsouri et al.(2006)	2004-2005 Javaheri hospital, Iran	18 to 35 year age group with moderate or advanced periodontal disease who were in the 13th to 20th week	30 I=15 C=15	≥4 teeth, with at least one site with PPD ≥4 mm) and CAL≥3mm	Categorical Insecure (non adjacent and proximal CAL not reported)	OHI, SRP and 0.2% chlorhexidine mouth rinse once a night for one week	PTB<37 weeks LBW<2500g	Not reported	Periodontal therapy, phase I, results in a reduction in PLBW incidence rate. Therefore, the application of such a simple method among periodontally diseased pregnant women is recommended
Tarann um and Faizud din (2007)	August 2004 to August 2005. Department of Obstetrics and Gynecology, Dr. B.R. Ambedkar Medical College and Hospital, Bangalore, Karnataka, India	Healthy pregnant women aged 18 to 35 years; single gestation between 9 and 21 weeks; subjects with ≥20 completely erupted teeth, subjects with ≥2mm CAL≥ 50% of examined sites.	200 I=100 C=100	≥2mm CAL≥ 50% of examined sites	Categorical Insecure	OHI, rinsing twice daily with 0.2% chlorhexidine SRP	PTB<37 weeks LBW<2500g	Not reported OR or RR	Non-surgical periodontal therapy can reduce the risk for preterm births in mothers who are affected by periodontitis.

Study	Year/Location	Inclusion criteria	Sample	Periodontal disease definition	Measurement	Intervention	Outcomes	Results	Conclusion
Newnham et al. (2009)	2009 six obstetric sites in metropolitan Perth, Western Australia	more than 16 years of age; did not have maternal cardiac disease that would warrant the need for antibiotics for periodontal examination or treatment; had not already received periodontal treatment during the current pregnancy; had no fewer than 20 natural teeth; had a single pregnancy of more than 12 and less than 20 weeks of gestational age; did not have any known foetal anomalies or other risk factors, such as hydramnios, that would place the pregnancy at imminent risk of complications	1078 I:538 C:540	Presence of PD≥ 4mm or at 12 or more probing sites in fully erupted teeth	Categorical insecure	OHI, S&P,RD and during treatment 0.12% CHX rinse. More tx if not successful	PTB Preeclampsia Stillbirth Is death of the unborn foetus after 20 completed weeks of gestation or more than 400 g birth weight.	PTB I=52/ 538 C=50/540 9.3% com-pared with 9.7%, odds ratio [OR] 1.05, 95% confidence interval [CI 0.7–1.58], P=.81), birth weight I=53/ 99 C=68/89 (3,450 com-pared with 3,410 g, P=.12), Stillbirth I=0/ 538 C=4/540 preeclampsia I; 18/538 (3.4%) C: 22/540 (4.1%) compared with 3.4%, OR 0.82, 95% CI 0.44–1.56, P=.55),	Present study does not support the hypothesis that treatment of periodontal disease during pregnancy in this population prevents preterm birth, foetal growth restriction, or pre-eclampsia. Periodontal treatment was not hazardous to the women or their pregnancies.
Offenb acher et al. (2009)	December 2003 to October 2007 University of Alabama and 2 sites in San Antonio, multi centred, US	at least 20 teeth and at least 3 periodontal sites with at least 3 mm of CAL	1806 I:903 C:903	CAL at ≥3mm at least ≥3 sites	Categorical Insecure (non adjacent and proximal CAL not reported)	OHI, SRP C= Full protocol of care delivered postpartum	PTB<37 Secondary outcomes PTB<35 weeks	PTB<37 OR:1.219 (0.0893–1.664) PTB<35 OR: 0.998 (0.640–1.554) PTB<32 OR: 1.138(0.637–2.033) intrauterine growth restriction OR 0.801 (0.604–1.062) LBW<2500 OR:1.008 (0.716–1.419)	Periodontal therapy did not reduce the incidence of preterm delivery.

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Study	Year/Setting	Population	Sample	Periodontal disease definition	Measurement	Intervention	Outcomes	Results	Conclusion
								LBW< 1,500 1.148 (0.543–2.428).	
Radnai et al.(2009)	2005 and 2006. University of Szeged, Department of Obstetrics & Gynaecology	Caucasian women who were hospitalized due to threatened preterm delivery	83 I=41 C=42	≥ 4 mm PD at least at one site, and BOP for ≥ 50% of teeth.	Categorical Insecure	OHI, supra &sub SC, dental polishing	PTB<37 weeks LBW<2500g	PTB OR:3.4(1.3-8.6)P= 0.013 LBW OR:4.3(1.5-12.6)P= 0.007 PLBW OR4.6(1.3-15.5)P= 0.015	Periodontal treatment completed before the 35th week appeared to have a beneficial effect on birth weight and time of delivery.
Macones et al. (2010)	2010 Three prenatal care clinics in the metropolitan Philadelphia area USA	6 and 20 weeks gestation CAL≥ 3mm on ≥3 teeth	757 I:378 C:379	CAL≥ 3mm on ≥3 teeth. Moderate-severe periodontal disease was defined as CAL ≥5mm on≥3 teeth.	Categorical Insecure (non adjacent and proximal CAL not reported)	Scaling and Root planning Polishing for control	spontaneous PTB <35 weeks Subgroup analysis: PTB<37weeks LBW<2500g LBW<1500g stillbirth	RR 1.56(0.91-2.68)P=0.11 RR1.24(0.87-1.77)P=0.24 RR1.38(0.92-2.08)P=.22 RR1.84(0.69-4.93)P=0.82 RR0.90(0.35-2.30)P=0.82	Treating periodontal disease does not reduce the incidence of SPTD.
Oliveira et al. (2011)	2011 Two public hospitals in Belo Horizonte, Brazil	Healthy pregnant women aged 18–35 years, gestational period between 12 and 20 weeks, current single gestation, a minimum of 20 natural teeth, and the presence of periodontitis.	246 I:122 C:124	4 or more teeth with one or more sites with PPD≥4 mm and CAL≥3m	Categorical Insecure (non adjacent and proximal CAL not reported)	OHI, SRP	PTB<37 weeks LBW<2500g PLBW <37 weeks and <2500g.	PTB RR:0.915 (0.561–1.493) LBW RR: 0.735 (0.459–1.179) PLBW RR: 0.927 (0.601–1.431)	NSPT during the second semester of gestation did not reduce the risk for preterm birth, low birth weight and preterm low birth weight.
Weidlich et al. (2012)	April 2007 to June 2009 Presidente Vargas Maternal	18 to 35 years old and had a gestational age of 20 weeks or less. all eligible women who fulfilled the	I=147 C=156	Not reported But the examiners assessed PPD, CAL,BOP	Continuous Insecure	OHI, supragingival calculus removal, and SRP	PT<37 weeks LBW<2500g	PTB 11.7%vs 9.1%,p=00.57) LBW (5.6%vs 4.1%, p=00.59), and PLBW (4.15%vs 2.60%, p=00.53).	Do not support a potential beneficial effect of periodontal treatment on

Hospital	inclusion criteria were included in the study irrespective of periodontal status.		PLBW.

Categ: Categorical; Cont.: continuous; Sec: Secure; Insec: Insecure; Perio Def: periodontal definition; PD: Periodontal disease; PPD: periodontal pocket depth
CAL: Clinical attachment level; OH: oral health instruction; SRP: scaling and root planning; OR: odd ratio; SPTB: spontaneous preterm birth; GI: gingival index;
PI: Plaque index; BOP: bleeding on probing; RR: risk raio; I: intervention; C: control; P:P value

Table 3.7: Study details, sample size, periodontal disease entry criteria

Study and sample size	Intervention and Control group size	Loss to follow-up and attrition	Entry periodontal criteria	Country of Analysis and number of centres	Week of gestation intervention applied	Intervention	Mean Age of women (yrs.)	Conclusion
Lopez et al. (2002) N=400	I=200 C=200	All=49 I=37 C=12	No fewer than 18 teeth and at least 4 teeth with at least one site with CAL≥3mm and PPD ≥4mm	Santiago, Chile. Women attending routine prenatal care. Low S/E Single centre	Before 28 weeks	I=OHI, SRP, at beginning of treatment 0.12% CHX rinse. C= care delivered postpartum	27.6 I=28 C=27	NSPT reduced the rate of PLBW
Jeffcoat et al. (2003) N=366	IGrp 1=120, (comparison) IGrp 2=123 IGrp 3=123 (metroniadozole not include in analysis)	I= 0 C=0 No loss to follow-up	At least 3 sites of CAL ≥3mm	University of Alabama, Birmingham US Single centre, predominantly African American	21 to 25 weeks	IGrp 1=Scaling &Polish IGrp 2=SC, RD plus placebo pill 3 times a day IGrp 3= SC, RD plus metroniadozole Pill	I=22.5 C= 723	NSPT reduced PTB
Lopez et al. (2005) N=870	I=580, C=290	I=27 C= 9	Single gestation, No fewer than 18 teeth with ≥25% BOP with no sites with CAL≥2mm 'gingivitis'	Santiago, Chile. Women attending routine prenatal public health clinic	From 22 weeks and before 28 weeks	I=OHI, SRP, RD, at beginning of treatment 0.12% CHX rinse until delivery C= care delivered post parum	I=25.54 C=24.98	NSPT reduced PLBW
Michalowicz et al.(2006) N=823	I=413, C=410	I=24 C=5	At least 20 teeth with 4 or more teeth with CAL ≥2mm, and PD of at least 4mm on ≥ 4 teeth. BOP at 35% of sites	OPT study recruited from Hennepin County Medical Center (MN), the University of Kentucky, the University of Mississippi Medical Center, and Harlem Hospital (NY)	At least 21 weeks	I=OHI, S&P, RD, at beginning of treatment C= care delivered postpartum SRP	I=26.1 C=25.9	NSPT reduced PTB, but PR treatment is safe during pregnancy

Multi centre, US

Offenbacher et al. (2006b)	I=40 C=34	I=5 C=2	Not specified but PD defined as ≥5m. 13% pocketing >4 mm and 5.9% > 5mm	Wake County, North Carolina, USA	Not reported	OHI, S&P,RD & sonic toothbrush C= superficial debridement &SP & manual toothbrush, Full protocol of care delivered postpartum	I= 26.8 C=25.7	NSPT reduced PTB and LBW, TR is safe during pregnancy
Sadatmansouri et al. (2006) N=30	I= 15 C=15	I= 0 C=0	At least ≥1 3mm CAL and 4 or more teeth with PD ≥4mm	Not stated , Presume Iran Single site	Less than 28 weeks	I=OHI, S&P,RD, at beginning of treatment 0.12% CHX rinse for one week C= care delivered postpartum	I=29.1 C=28.4	NSPT reduced PTB and LBW
Tarannum and Faizuddin, (2007) N=200	I=100, C=100	I=9 C=11	At least 50% of sites bleeding and CAL ≥2mm	OPD Dept of Obs & Gynae, Karnataka, India	Less than 29 weeks 4-5 visits on a weekly basis	I=OHI, S&P,RD and during treatment 0.12% CHX rinse C= OHI at baseline but full protocol of care delivered Postpartum	I= 25 C=27	NSPT reduced the rate of PTB
Newnham et al. (2009)) N=1087	I=546 C=541	I=41 C=1	PD ≥4mm at ≥12 sites	Perth, Western Australia Single site	From 20-23 weeks, if condition not resolved in I group , repeated at 28-31 weeks	OHI, S&P,RD and during treatment 0.12% CHX rinse. More tx if not successful C= Full protocol of care delivered postpartum	I=30.5 C=30.5	NSPT reduced the rate of PTB and LBW, PR treatment not risky to women or their foetus
Offenbacher et al. (2009) N=1806	I=903 C=903	I=29 C=32	20 teeth, CAL at ≥3mm at least ≥3 sites	University of Alabama and 2 sites in San Antonio, multi centred, US	Less than 23 weeks	OHI, S&P,RD C= Full protocol of care delivered postpartum	I=25.5 C=25.4	NSPT did not reduce the rate of PTB
Radnai et al. (2009)	I=43,	I=2 C=4	PD≥4mm at least	Hungary ,	At around 32	OHI, S&P,RD	I=29.1	NSPT reduced the

N=87	C=46		at 1 site, BOP for ≥50% of teeth	University of Szeged	weeks	C= Full protocol of care delivered postpartum	C=28.9	rate of PTB and LBW
Macones et al (2010) N=756	1=376 C=380	1=23 C=20	CAL ≥3mm on ≥ 3sites, and PD of at least 3mm on ≥3 teeth. Random allocation of quadrants therefore a part score	Philadelphia, 3 sites in Philadelphia	Enrolled between 6 to 20 weeks of gestation	I=OHI, S&P, RD, at beginning of treatment C=received a polish, but calculus removal delivered postpartum SRP	I=24.1 C=24.4	NSPT did not reduce the rate of Spontaneous PTB, PTB and LBW
Oliveira et al. (2011) N=246	I=122 C=124	I=9 C=12	PD ≥ 4mm and CAL≥ 3mm for at least one site	Minos Gerais, Brazil, single site	Monthly between 20-30 weeks	OHI, S&P,RD C= Full protocol of care delivered Postpartum	I=29.96 C=26.58	NSPT did not reduce the rate of PTB LBW and PLBW
Weidlich et al. (2012) N=303	I=147 C=156	I=2 C=2	Stratified into >5 and<5 cigs Single gestation	Presidente Vargar Maternity Hospital Brazil	<24 weeks	I=OHI, S&P,RD C= OHI and supra gingival calculus removal at baseline but full protocol of care delivered postpartum	I = <20= 13 ≥20and <25=46 ≥25and <30=51 ≥30 =35 C= <20= 13 ≥20and <25=51 ≥25and <30=48 ≥30 =42	NSPT did not reduce PTB and LBW, PR treatment was successful during pregnancy

N= number; I: intervention; C: control; PPD: periodontal pocket depth; CAL: clinical attachment level; OHI: oral health instruction; SRP: scaling and root planning; NSPT: non-surgical periodontal treatment; SC: scaling; S&P: scaling and polishing; RD: root debridement

Table 3.8 PTB, LBW and Stillbirth events and periodontal outcome reported in the studies

Study	Events: PTB	Events :LBW	Events: Stillbirth	Events: PLBW	Rate of events in study	What was the periodontal outcome, from text of article?
Lopez et al. (2002)	I =2/163 C=12/188	CI=1/163 C=7/188	Not reported	I=3/163 C=19/188	PTB I=1.22.99% C=6.33% LBW I=I:0.61% C=3.72 PLBW I=1.84% C=10.11%	Women in the treatment group were 'periodontally healthy' by the end of trial p922 Periodontal therapy significantly reduces the rates of PLBW in this population of women with periodontal disease.
Jeffcoat et al. (2003)	>37weeks IGrp 1=11/123, (Comparison) IGrp 2= 5/123 IGrp 3= 15/120 (not used in analysis) C=92/723 >35weeks IGrp 1=6/123, (Comparison) IGrp 2= 1/123 IGrp 3= 4/120 (not used in analysis) C=0.5/723	Not reported	Not reported	Not reported	>37 PTB IGrp 11= 8.9% PTB IGrp 5= 4.1% PTB IGrp 15=12.5% PTB C= 12.7% (reported in the data) >35 PTB IGrp 6= 4.9% PTB IGrp 1= 0.8% PTB IGrp 4=3.3% PTB C = 6.3% (reported in the data)	Not reported No evidence that use of metroniadozole can have an impact
Lopez et al. (2005)	I =8/560 C=16/283	I=4/560 C=3/283		I=12/560 C=19/283 and spontaneous abortion 3/565	PTB I=1.42% ;C= 5.56% LBW I=0.71% C=1.15% PLBW I=I:2.14 C=6.71%	Women in treatment group all had better BOP, PD and CAL scores compared to control, but still some disease constituting *gingivitis* and some periodontal pocketing. Note 10 PTB in I group were attributed to other causes and excluded from analysis and 1 from C. They have been reinstated in this review as part of overall outcomes thus analysed total is greater than reported in Table 5 in the article

Study					Outcomes	Comments
Michalowicz et al. (2006)	I= 52/402, C=38/391 <35weeks I= 18/402, C=12/391 <32weeks I= 6/402, C=5/391 From table 2 p1891, used Live birth data	I=40/406 C= 43/403 <1500 I=8/406 C=15/403	I= 5/407 C=14/405		PTB I=12.0% C=12.58 % LBW I=12.7% C=12.3% Stillbirth not reported	Our treatment response, in terms of mean reductions in the probing depth and attachment loss, is consistent with improvements after scaling and root planing reported in persons who are not pregnant. It is possible that we delivered periodontal care too late in pregnancy to affect birth outcomes p 1893.
Offenbacher et al. (2006b)	I=9/35 C=14/32	Not reported	Not reported	Not reported	PTB I=25.7% C=43.8% Stillbirth & LBW not reported	Treatment safe and restored periodontal health and prevented periodontal progression
Sadatmansouri et al. (2006)	I=0/15 C=3/15	I=0/15 C=1/15	Not reported	I=0/15 C=4/15	PTB I=0.0% C= 6.7 % LBW I=0.0% C=20.0% Stillbirth not reported PLBW I=0.0% C=26.7%	Periodontal characteristics in monitored examinations demonstrate that periodontal problems were resolved in the treat group and significant differences in periodontal characteristics existed between groups (p <0.05) p 27
Tarannum and Faizuddin, (2007)	I=45/ 91 C=68/89	I=19/91 C=48/89	Not reported	Not reported	PTB I=12.0% C=12.58 % LBW I=12.7% C=12.3% Stillbirth not reported	Not reported
Newnham et al. (2009)	I=52/ 538 C=50/540	I=53/ 99 C=68/89	I=0/ 538 C=4/540		PTB I=9.7% C=9.3 % Stillbirth I=0% C=0.7% LBW not reported	Four hundred seventy-six women (88.3%) in the treatment group completed their treatment. Among the 63 women who did not complete their treatment, 35 did not attend any of their scheduled visits. The success of treatment was measured around 28 weeks of gestation. There were significant improvements in all clinical measures of disease after treatment p1245
Offenbacher et al. (2009)	I=97/882 C=81/880	I=72/872 C=71/866	Not reported		PTB I=11.0% C= 9.2% LBW I= 8.3% C=8.2% Stillbirth not reported	Restoration of periodontal health may not have been achieved
Radnai et al. (2009)	I=10/41 C=22/42	I=6/41 C=18/41	Not reported	I=4/41 C=14/41	PTB I= 24.3% C=52.4 % LBW I= 14.6% C=42.9% Stillbirth not reported PLBW=I= 9.8% C=33.3%	Not reported

Macones et al(2010)	I=58/359; C=47/361 (calculated from data in Table 2 p147 e5	I=49/359; C=35/361 (calculated from data in Table 2 p147 e5	I:7/359 C:8/361 calculated from data in Table 2 p147 e5	I:11/357 C:8/357 Calculated from data in Table 2 p147 e5	PTB I =16.2% C=13.0% LBW I=13.5% C= 9.8%	No evidence that active treatment improved PTB and LBW outcomes. Performed sub analysis which suggested that women with history of PTB in the treatment are more likely to have PTB compared to control, also an increased trend for women <35 weeks with moderate and severe PD to have PTB (defined as probing depth 5mm on ≥3 teeth)
Oliveira et al. (2011)	I=24/113 C=26/112	I=23/113 C=31/112	Not reported	I=29/113 C=31/112	PTB I=21.24% C= 23.21% LBW I= 20.35% C=27.68% PLBW I= 25.66% C= 27.68% Stillbirth not reported	Improvement in periodontal outcomes p 9
Wedlich et al. (2012)	I=17/145 C=14/154	I=8/145 C=6/154	I=1/145 C=2/154	I=6/145 C=4/154	PTB I=11.76% C=9.09 % LBW I=5.63%; C=4.05% Stillbirth I=0.69% C=1.36% PLBW I= 4.15% C= 2.60%	Prevented periodontal inflammation

N= number; I: intervention; C: control; PPD: periodontal pocket depth; CAL: Clinical attachment level; OHI: oral health instruction; SRP: scaling and root planning; PR: periodont

3.4.1.5   Meta-analysis of RCT studies

a.   PTB

The data were pooled from 13 RCTs studies which assessed the presence of PTB in women who received (experimental group) and did not receive (control group) NSPT (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Newnham et al., 2009; Offenbacher et al., 2009; Radnai et al., 2009; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; Offenbacher et al., 2006b; Sadatmansouri et al., 2006; López et al., 2005; Jeffcoat et al., 2003; Lopez et al., 2002).

A total of 390 out of 3590 women who received NSPT (11%) had a PTB. A total of 483 out of 3810 women (13%) who did not receive NSPT had PTB. Figure 3.12 shows the meta-analysis of data pooled from 13 RCTs studies.

There was evidence of substantial heterogeneity between the studies (I^2=73%); heterogeneity was statistically significant (p<0.0001). The RR was 0.78 (95% CI: 0.60-1.01, P=0.06). The relationship of NSPT and incidence of PTB was not statistically significant. Based on 7400 women in 13 studies of which three were at low risk of bias, and 10 were at unclear (6) and high risk of bias (4), there appears to be no benefit to women in receiving NSPT during pregnancy to prevent incidence of PTB.

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	2	163	12	188	2.5%	0.19 [0.04, 0.85]	
(López et al., 2005)	8	560	16	283	5.6%	0.25 [0.11, 0.58]	
(Macones et al., 2010)	58	359	47	361	10.2%	1.24 [0.87, 1.77]	
(Oliveira et al., 2011)	24	113	26	112	8.8%	0.91 [0.56, 1.49]	
Jeffcoat et al., 2003)	16	246	92	723	8.5%	0.51 [0.31, 0.85]	
Michalowicz et al., 2006)	52	402	38	391	9.8%	1.33 [0.90, 1.97]	
Newnham 2009	52	538	50	540	10.1%	1.04 [0.72, 1.51]	
Offenbacher 2009	97	882	81	880	11.0%	1.19 [0.90, 1.58]	
Offenbacher et al., 2006)	9	35	14	32	6.8%	0.59 [0.30, 1.17]	
Radnai 2009	10	41	22	42	7.5%	0.47 [0.25, 0.86]	
Sadatmansouri 2006	0	15	3	15	0.8%	0.14 [0.01, 2.55]	
Tarannnum 2007	45	91	68	89	11.4%	0.65 [0.51, 0.82]	
Weidlich et al., 2012	17	145	14	154	7.0%	1.29 [0.66, 2.52]	
Total (95% CI)		**3590**		**3810**	**100.0%**	**0.78 [0.60, 1.01]**	
Total events	390		483				

Heterogeneity: Tau² = 0.15; Chi² = 45.01, df = 12 (P < 0.0001); I² = 73%
Test for overall effect: Z = 1.86 (P = 0.06)

0.01 0.1 1 10 100
Favours experimental Favours control

Figure 3.12: Forest plot of comparison: NSPT outcome: PTB

b. LBW

The data were pooled from 11 RCTs studies that assessed the presence of LBW in women who received (experimental group) and did not receive (control group) NSPT (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Newnham et al., 2009; Offenbacher et al., 2009; Radnai et al., 2009; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; Sadatmansouri et al., 2006; López et al., 2005; Lopez et al., 2002).

A total of 275 out of 2864 women (10%) who received NSPT had LBW babies. A total of 331 out of 2601 women (13%) who did not receive NSPT had LBW babies. Figure 3.13 shows the meta-analysis of data pooled from 11 RCTs studies.

There was evidence of considerable heterogeneity ($I^2 = 67\%$) amongst the studies; heterogeneity was statistically significant (P= 0.0009). The risk ratio (RR) as 0.75 (95% CI: 0.56-0.99, P=0.05). The association between receipt of NSPT and reduced risk for LBW was statistically significant. This suggested there was advantage in receiving NSPT during pregnancy to prevent LBW.

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Lopez et al. (2002)	1	163	7	188	1.7%	0.16 [0.02, 1.33]	
López et al. (2005)	4	560	3	283	3.0%	0.67 [0.15, 2.99]	
Macones 2010	49	359	35	361	13.1%	1.41 [0.94, 2.12]	
Michalowicz 2006	40	406	43	403	13.1%	0.92 [0.61, 1.39]	
Newnham 2009	53	99	68	89	16.3%	0.70 [0.56, 0.87]	
Offenbacher 2009	72	872	71	866	14.8%	1.01 [0.74, 1.38]	
Oliveira 2011	23	113	31	112	12.0%	0.74 [0.46, 1.18]	
Radnai 2009	6	41	18	41	7.3%	0.33 [0.15, 0.75]	
Sadatmansouri et al. (2006)	0	15	1	15	0.8%	0.33 [0.01, 7.58]	
Tarannum and Faizuddin (2007	19	91	48	89	12.5%	0.39 [0.25, 0.60]	
Weidlich 2012	8	145	6	154	5.3%	1.42 [0.50, 3.98]	
Total (95% CI)		2864		2601	100.0%	0.75 [0.56, 0.99]	
Total events	275		331				

Heterogeneity: Tau^2 = 0.12; Chi^2 = 29.99, df = 10 (P = 0.0009); I^2 = 67%
Test for overall effect: Z = 2.00 (P = 0.05)

0.01 0.1 1 10 100
Favours [experimental] Favours [control]

Figure 3.13: Forest plot of comparison: NSPT outcome: LBW

d. PLBW

The data were pooled from seven RCTs studies that assessed the presence of PLBW in women who received (experimental group) and did not receive (control group) NSPT (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Radnai et al., 2009; Sadatmansouri et al., 2006; López et al., 2005; Lopez et al., 2002).

A total of 65 out of 1394 women (5%), who received NSPT, had a PLBW compared to 99 out of 1150 women who did not (8%). Figure 3.14 shows the meta-analysis of data pooled from seven RCTs studies.

There was evidence of considerable heterogeneity (I$^{2=}$=70%) amongst the studies; heterogeneity was statistically significant (P= 0.003). The risk ratio (RR) was 0.54 (95% CI: 0.28-1.03, P=0.06). The association between receipt of NSPT and reduced risk for PLBW was not statistically significant. This suggested there was no advantage in receiving periodontal treatment during pregnancy to prevent PLBW.
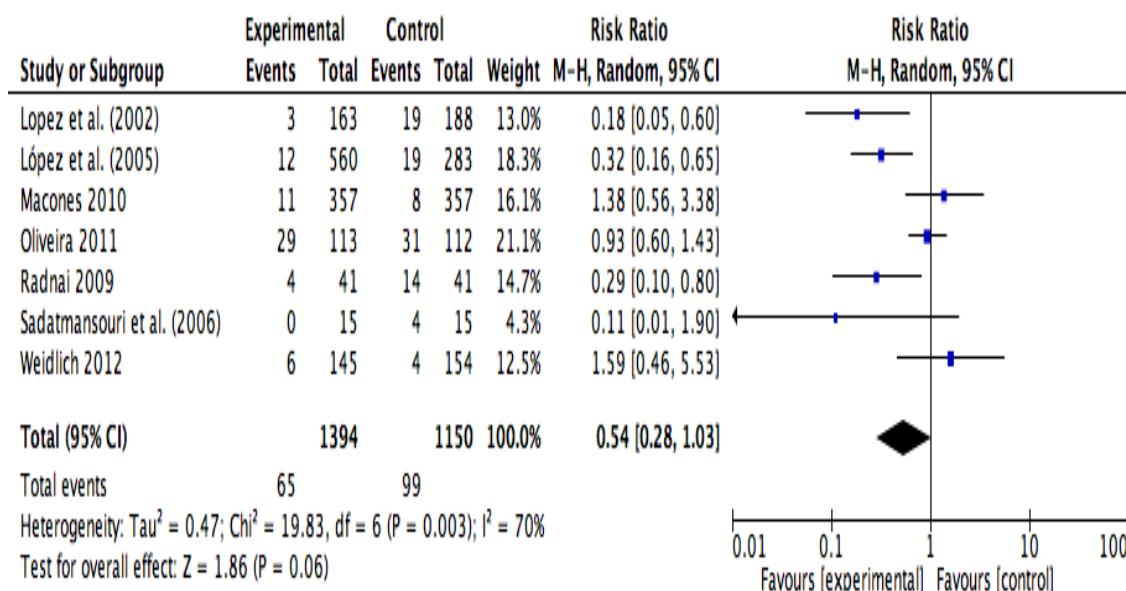
Figure 3.14: Forest plot of comparison: NSPT outcome: PLBW

d. Stillbirth

The data were pooled from four RCTs studies that assessed the presence of stillbirth in women who received (experimental group) and did not receive (control group) NSPT (Weidlich et al., 2012; Macones et al., 2010; Newnham et al., 2009; Michalowicz et al., 2006).

A total of 13 out of 1449 women, who received NSPT, had a stillbirth compared to 28 out of 1460 women who did not. Figure 3.15 shows the meta-analysis of data pooled from four RCTs studies.

There was no evidence of heterogeneity between the studies; heterogeneity analysis (I^2=0%) was not statistically significant (P= 0.44). The RR was 0.48 (95% CI: 0.25-0.90, P=0.02). The relationship of NSPT and stillbirth was statistically significant, suggesting that there was an advantage in receiving periodontal treatment during pregnancy to prevent stillbirth.

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
(Macones et al., 2010)	7	359	8	361	28.0%	0.88 [0.32, 2.40]
Michalowicz et al., 2006)	5	407	14	405	49.3%	0.36 [0.13, 0.98]
Newnham 2009	0	538	4	540	15.8%	0.11 [0.01, 2.07]
Weidlich et al., 2012	1	145	2	154	6.8%	0.53 [0.05, 5.79]
Total (95% CI)		1449		1460	100.0%	0.48 [0.25, 0.90]
Total events	13		28			

Heterogeneity: Chi² = 2.72, df = 3 (P = 0.44); I² = 0%
Test for overall effect: Z = 2.27 (P = 0.02)

Figure 3.15: Forest plot of comparison of NSPT outcome: Stillbirth

3.4.1.5.1 Sensitivity analysis of RCTs

The meta-analyses were planned to be repeated for PTB, LBW, PLBW and stillbirth but this time only studies rated as high quality RCTs were included i.e. trials that received 7/7 based on the Cochrane Risk of Bias tool.

Three RCTs (Newnham et al., 2009, Offenbacher et al., 2009, Radnai et al., 2009) received the maximum score (7/7) and were considered to be at low risk of bias.

The sensitivity analysis for PLBW and stillbirth were not undertaken because the meta-analysis would include only one study at low risk of bias for PLBW (Radnai et al., 2009) and stillbirth (Newnham et al., 2009).

a. PTB

The data were pooled from three high quality RCTs which assessed the presence of PTB in women who received (experimental group) and who did not receive (control group) NSPT(Newnham et al., 2009; Offenbacher et al., 2009; Radnai et al., 2009).

A total of 159 out of 1461 women who received NSPT (11%) had a PTB. A total of 153 out of 1462 women (10%) who did not receive NSPT had PTB.

There was evidence of substantial heterogeneity between the studies (I^2=74%); heterogeneity was statistically significant (P= 0.02). The RR was 0.90 (95% CI:

0.57-1.41, P=0.64). The relationship of NSPT and incidence of PTB was not statistically significant (see Figure 3.16). The relationship between NSPT and incidence of PTB in the 10 low quality RCTs was not statistically significant (Figure 3.17) with an RR 0.73 (0.52-1.02, P=0.06). Neither the high quality nor low quality studies supported the use of NSPT to prevent PTB.

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Newnham 2009	52	538	50	540	35.5%	1.04 [0.72, 1.51]
Offenbacher 2009	97	882	81	880	39.5%	1.19 [0.90, 1.58]
Radnai 2009	10	41	22	42	25.0%	0.47 [0.25, 0.86]
Total (95% CI)		1461		1462	100.0%	0.90 [0.57, 1.41]
Total events	159		153			

Heterogeneity: Tau² = 0.11; Chi² = 7.59, df = 2 (P = 0.02); I² = 74%
Test for overall effect: Z = 0.46 (P = 0.64)

0.01 0.1 1 10 100
Favours experimental   Favours control

Figure 3.16: Forest plot of comparison of NSPT outcome in high quality RCTs: PTB

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	2	163	12	188	3.9%	0.19 [0.04, 0.85]
(López et al., 2005)	8	560	16	283	8.1%	0.25 [0.11, 0.58]
(Macones et al., 2010)	58	359	47	361	14.0%	1.24 [0.87, 1.77]
(Oliveira et al., 2011)	24	113	26	112	12.2%	0.91 [0.56, 1.49]
Jeffcoat et al., 2003)	16	246	92	723	12.0%	0.51 [0.31, 0.85]
Michalowicz et al., 2006)	52	402	38	391	13.5%	1.33 [0.90, 1.97]
Offenbacher et al., 2006)	9	35	14	32	9.8%	0.59 [0.30, 1.17]
Sadatmansouri 2006	0	15	3	15	1.2%	0.14 [0.01, 2.55]
Tarannnum 2007	45	91	68	89	15.3%	0.65 [0.51, 0.82]
Weidlich et al., 2012	17	145	14	154	10.0%	1.29 [0.66, 2.52]
Total (95% CI)		2129		2348	100.0%	0.73 [0.52, 1.02]
Total events	231		330			

Heterogeneity: Tau² = 0.18; Chi² = 33.54, df = 9 (P = 0.0001); I² = 73%
Test for overall effect: Z = 1.85 (P = 0.06)

0.01 0.1 1 10 100
Favours experimental   Favours control

Figure 3.17: Forest plot of comparison of NSPT outcome in low quality RCTs: PTB (unclear and high risk of bias)

b. LBW

The data were pooled from three high quality RCTs which assessed the presence of LBW in women who received (experimental group) and did not receive (control group) NSPT (Newnham et al., 2009; Offenbacher et al., 2009; Radnai et al., 2009).

A total of 131 out of 1012 women who received NSPT (13%) had a LBW. A total of 157 out of 996 women (16%) who did not receive NSPT had LBW. There was evidence of substantial heterogeneity between the studies (I^2=74%); heterogeneity was statistically significant (P= 0.02). The RR was 0.71 (95% CI: 0.46-1.08, P=0.11). The relationship of NSPT and incidence of LBW was not statistically significant (see Figure 3.18). The meta-analysis of the low quality RCTs and incidence of LBW was not statistically significant (see Figure 3.19). Neither high nor low quality studies in the meta-analysis supported the use of NSPT to prevent LBW.

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Newnham 2009	53	99	68	89	43.7%	0.70 [0.56, 0.87]
Offenbacher 2009	72	872	71	866	38.8%	1.01 [0.74, 1.38]
Radnai 2009	6	41	18	41	17.5%	0.33 [0.15, 0.75]
Total (95% CI)		1012		996	100.0%	0.71 [0.46, 1.08]
Total events	131		157			

Heterogeneity: Tau² = 0.10; Chi² = 7.84, df = 2 (P = 0.02); I² = 74%
Test for overall effect: Z = 1.59 (P = 0.11)

Figure 3.18: Forest plot of comparison of NSPT outcome in high quality RCTs: LBW

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	1	163	7	188	3.8%	0.16 [0.02, 1.33]
(López et al., 2005)	4	560	3	283	6.4%	0.67 [0.15, 2.99]
(Macones et al., 2010)	49	359	35	361	19.8%	1.41 [0.94, 2.12]
(Oliveira et al., 2011)	23	113	31	112	18.7%	0.74 [0.46, 1.18]
Michalowicz et al., 2006)	40	406	43	403	19.8%	0.92 [0.61, 1.39]
Sadatmansouri 2006	0	15	1	15	1.9%	0.33 [0.01, 7.58]
Tarannnum 2007	19	91	48	89	19.2%	0.39 [0.25, 0.60]
Weidlich et al., 2012	8	145	6	154	10.4%	1.42 [0.50, 3.98]
Total (95% CI)		1852		1605	100.0%	0.77 [0.49, 1.19]
Total events	144		174			

Heterogeneity: Tau² = 0.21; Chi² = 21.97, df = 7 (P = 0.003); I² = 68%
Test for overall effect: Z = 1.18 (P = 0.24)

Figure 3.19: Forest plot of comparison of NSPT outcome in low quality RCTs: LBW (unclear and high risk of bias)

3.4.1.5.2 Subgroup analysis of PTB, LBW, PLBW and stillbirth based on secure periodontal disease case definition

As in Part 1, the RCTs in Part 2 of this review display considerable clinical variation; one possible issue is the insecurity of the case definition of periodontal disease. None of the studies were assessed as using a secure definitions of periodontal disease based on Nibali et al. (2013). So meta-analysis was not conducted to look at data based on a secure definition of periodontal disease.

3.4.1.5.3 Subgroup analysis of RCTS including non-Caucasian women

Nine studies clearly report the race/ethnic origins of their participants (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Newnham et al., 2009; Offenbacher et al., 2009; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; Offenbacher et al., 2006b; Jeffcoat et al., 2003), three studies did not provide the partcipants ethnicity/race (Sadatmansouri et al., 2006; López et al., 2005; Lopez et al., 2002) and one study recruited 100% white women (Radnai et al., 2009). The cut-offs as in the first part of the review were: low 0-30%, moderate 31-60% and high 61-100%.

The forest plot of the subgroup meta-analyses of the RCTs may be found in Appendix G.

a. PTB

The data were pooled from nine RCTs which reported the race/ethnicity of participants and assessed the effect of NSPT on presence of PTB (Weidlich et al., 2012; Oliveira et al., 2011; Macones et al., 2010; Newnham et al., 2009; Offenbacher et al., 2009; Tarannum and Faizuddin, 2007; Michalowicz et al., 2006; Offenbacher et al., 2006b; Jeffcoat et al., 2003).

Respectively the representation from non-Caucasian groups in these studies was: 85%, 87%, 46%, 87.2%, 28.4%, 67.5 %, 67.37%, 100% and 32.41%).

Three RCTs had low representation from Black and Asian populations (Weidlich et al., 2012; Offenbacher et al., 2009; Michalowicz et al., 2006), two had moderate representation (Oliveira et al., 2011; Offenbacher et al., 2006b) and four have extensive representation (Macones et al., 2010; Newnham et al., 2009; Tarannum and Faizuddin, 2007; Jeffcoat et al., 2003) (see Table 3.9). The relationship between NSPT and prevention PTB was statistically significant only in studies with low representation RCTs (see Table 3.9).

b. LBW

The data were pooled from seven RCTs which reported the race/ethnicity of participants and assessed the effect of NSPT on the presence of LBW (32.41 % Weidlich et al., 2012; 67.37% Oliveira et al., 2011; 87% Macones et al., 2010; 87.2 % Newnham et al., 2009; 28.4% Offenbacher et al., 2009; 100% Tarannum and Faizuddin, 2007; 46% Michalowicz et al., 2006).

Three studies had low representation from Black and Asian populations (Weidlich et al., 2012; Offenbacher et al., 2009; Michalowicz et al., 2006); only one study has moderate representation (Oliveira et al., 2011) so meta-analysis was not undertaken. Three RCTs had extensive representation (Macones et al., 2010; Newnham et al., 2009; Tarannum and Faizuddin, 2007).

The relationships of NSPT and LBW were not statistically significant in studies with low representation and high representation (see Table 3.9).

c. PLBW

The data were pooled from three RCTs, which reported the race/ethnicity of participants and assessed the presence of PLBW in women with or without

periodontal disease (32.41 % Weidlich et al., 2012; 67.37% Oliveira et al., 2011; 87% Macones et al., 2010).

One RCT had low representation from Black and Asian populations (Weidlich et al., 2012); one RCT had moderate representation (Oliveira et al., 2011) and one had extensive representation (n=1) (Macones et al., 2010), so meta-analysis was not undertaken for these.

The relationship of NSPT and PLBW was not statistically significant (see Table 3.9).

d. Stillbirth

The data were pooled from four RCTs, which reported the race/ethnicity of participants and assessed the impact of NSPT on presence of stillbirth (32.41% Weidlich et al., 2012; 87% Macones et al., 2010; 87.2% Newnham et al., 2009; 46% Michalowicz et al., 2006). Two RCTs had low representation from Black and Asian populations (Weidlich et al., 2012; Michalowicz et al., 2006) while two RCTs had extensive representation (Macones et al., 2010; Newnham et al., 2009). The relationship between NSPT and stillbirth was statistically significant with all RCTs and in studies with low representation RCTs (see Table 3.9).

Table 3.9: ABOs in RCTs reporting the race/ethnicity of participants

ABO	Representation	RR	I^2	Number of studies	Number of women
PTB	All	0.93 (95% CI: 0.73, 1.19, P=0.59)	70% (P=0.0008)	9	6093
	Low	1.24 (95% CI: 1.00, 1.54, P=0.05)	0% (P=0.90)	3	2854
	Moderate	0.78 (95% CI: 0.52, 1.19, P=0.25)	6% (P=0.30)	2	292
	Extensive	0.82(95% CI: 0.56, 1.20, P=0.31)	79% (P =0.003)	4	2947
LBW	All	0.83 (95% CI: 0.62, 1.12, P=0.23)	75% (P=0.0006)	7	4159

	Low	1.00 (95% CI: 0.76, 1.30, P=0.98)	0% (P=0.75)	3	2846
	Extensive	0.73 (95% CI: 0.40, 1.34, P=0.31)	89% (P =0.0001)	3	1177
PLBW	All	1.07 (95% CI: 0.74, 1.56, P=0.72)	0% (P =0.57)	3	1238
	Extensive	1.02 (95% CI: 0.69,1.51, P=0.93)	0% (P=0.44)	2	939
Stillbirth	All	0.48 (95% CI: 0. 25,0.90 P=0.02)	0% (P=0.44)	4	2909
	Low	0.38 (95% CI: 0.15, 0.95, P=0.04)	0% (P=0.76)	2	1111
	Extensive	0.49 (95% CI: 0.07, 3.21, P=0.46)	45 % (P=0.18)	2	1798

3.4.1.5.4 Subgroup analysis of RCTS including women with history of ABOs

Low rates of a previous PTB was defined as less than or equal to 15% of participants, while high rates were defined as greater than 15% of participants.

a. PTB

The data were pooled from 10 RCTs reporting on studies where participants experienced ABOs previously and assessed the effect of NSPT on the presence of PTB (14.48% Weidlich et al., 2012; 24,6% Macones et al., 2010; 13.2% Newnham et al., 2009; 27.4% Offenbacher et al., 2009; 10.5% Michalowicz et al., 2006; 30% Offenbacher et al., 2006b; 13.3% Sadatmansouri et al., 2006; 10.91% López et al., 2005; 4.9% Jeffcoat et al., 2003; 21% Lopez et al., 2002).

Six studies have low representation from participants with ABO history (Weidlich et al., 2012; Newnham et al., 2009; Michalowicz et al., 2006; Sadatmansouri et al., 2006; López et al., 2005; Jeffcoat et al., 2003) while four have extensive representation (Macones et al., 2010; Offenbacher et al., 2009; Offenbacher et al., 2006b; Lopez et al., 2002) (see Table 3.10). The

relationships of NSPT and PTB were not statistically significant with all RCTs, and for those with low and extensive representation (see Table 3.10).

b. LBW

The data were pooled from eight RCTs reporting on participants who experienced ABO previously assessing the effect of NSPT on the presence of LBW (14.48% Weidlich et al., 2012; 24,6% Macones et al., 2010; 13.2% Newnham et al., 2009; 27.4%Offenbacher et al., 2009; 10.5% Michalowicz et al., 2006; 13.3% Sadatmansouri et al., 2006; 10.91% López et al., 2005; 21%Lopez et al., 2002).

Five studies had low representation from participants with an ABO history (Weidlich et al., 2012; Newnham et al., 2009; Michalowicz et al., 2006; Sadatmansouri et al., 2006; López et al., 2005) while three have high representation (Macones et al., 2010; Offenbacher et al., 2009; Lopez et al., 2002) (see Table 3.10).

The relationship of NSPT and impact on LBW was only statistically significant in studies with low representation (see Table 3.10).

c. PLBW

The data were pooled from five RCTs reporting on participants who experienced ABOs previously and assessed the effect of NSPT on the presence of PLBW (14.48% Weidlich et al., 2012; 24.6% Macones et al., 2010; 13.3% Sadatmansouri et al., 2006; 10.91% López et al., 2005; 21% Lopez et al., 2002).

Three studies have low representation from participants with ABOs history (Weidlich et al., 2012; Sadatmansouri et al., 2006; López et al., 2005) and two

have high representation (Macones et al., 2010;Lopez et al., 2002). (see Table 3.10).

The relationships of NSPT and PLBW was not statistically significant for all representations (see Table 3.10).

d. Stillbirth

The data were pooled from four RCTs reporting on participants who experienced ABO previously and assessed the effect of NSPT on the presence of stillbirth (14.48%Weidlich et al., 2012; 24.6% Macones et al., 2010; 13.2% Newnham et al., 2009; 10.5% Michalowicz et al., 2006).

Three studies hadlow representation from participants with ABOs history (Weidlich et al., 2012; Newnham et al., 2009; Michalowicz et al., 2006) and only one had extensive representation (Macones et al., 2010) (see Table 3.10) .

The relationships of NSPT and stillbirth were statistically significant for all and low representations (see Table 3.10).

Table 3.10: ABOs in RCTs reporting participants with ABOs history

ABO	Representation	RR	I^2	Number of studies	Number of women
PTB	All	0.82 (95% CI: 0.60, 1.13, P=0.23)	72% (P=0.0002)	10	6912
	Low	0.76 (95% CI: 0.46, 1.25, P=0.28)	76% (P=0.0009)	6	4012
	Extensive	0.87 (95% CI: 0.50, 1.49, P=0.60)	68% (P=0.02)	4	2900
LBW	All	0.93 (95% CI: 0.70, 1.23, P=0.60)	53% (P=0.004)	8	4978
	Low	0.80 (95% CI: 0.66, 0.99, P=0.04)	0% (P=0.48)	5	2203
	Extensive	1.07 (95% CI: 0.65, 1.74, P=0.80)	59% (P=0.09)	3	2809
PLBW	All	0.51(95% CI: 0.20, 1.33, P=0.17)	71% (P=0.009)	5	2237
	Low	0.49 (95% CI: 0.13, 1.86, P=0.29)	66% (P=0.06)	3	1172

	Extensive	0.52 (95% CI: 0.07, 3.90, P=0.53)	86% (P=0.007)	2	1065
Still-birth	All	0.48 (95% CI: 0.25, 0.90, P=0.02)	0% (P=0.44)	4	2909
	Low	0.32 (95% CI: 0.13, 0.76, P=0.01)	0% (P=0.70)	3	2189
	Extensive	Meta-analysis was not undertaken because only one study with high representation			

3.4.1.5.5 Subgroup analysis of RCTs including women who use tobacco

a. PTB

The data were pooled from seven RCTs including smoking participants and assessed the effect of NSPT on the incidence of PTB (18.62% Weidlich et al., 2012; 28% Newnham et al., 2009; 10.9% Offenbacher et al., 2009; 7.5% Offenbacher et al., 2006b; 15.46% López et al., 2005; 12.20% Jeffcoat et al., 2003; 24.50% Lopez et al., 2002). The cut-offs used as in the cohort studies was 15% and less would be considered low and above 15% would be considered extensive representation.

Three RCTs had low representation (Offenbacher et al., 2009; Offenbacher et al., 2006b; Jeffcoat et al., 2003) and four studies had extensive representation (Weidlich et al., 2012; Newnham et al., 2009; López et al., 2005; Lopez et al., 2002). Table 3.11 presents incidence of PTB in RCTs reporting on smoking participants.

 Regardless of smoking prevalence, there was no benefit in NSPT to reduce incidence of PTB.

b. LBW

The data were pooled from five RCTs where smoking was reported using the cut-offs for high and extensive described for PTB for RCTs (18.62% Weidlich et

al., 2012; 28% Newnham et al., 2009; 10.9% Offenbacher et al., 2009; 15.46% López et al., 2005; 24.50% Lopez et al., 2002).

Only one RCT reported a low prevalence of smoking (Offenbacher et al., 2009) and four studies reported extensive representation (Weidlich et al., 2012; Newnham et al., 2009; López et al., 2005; Lopez et al., 2002). Table 3.11 presents LBW in RCTs reporting smoking participants.

There was no benefit in NSPT to prevent LBW in all representation but there was a benefit in NSPT to prevent LBW in studies with low representations from smokers (see Table 3.11).

c. PLBW

The data were pooled from three RCTs which all have extensive representation from smokers (Weidlich et al., 2012; López et al., 2005; Lopez et al., 2002). Table 3.11 presents incidence of PLBW in RCTs reporting smoking prevalence. Regardless of prevalence of smoking, NSPT was not seen to prevent PLBW. (see Table 3.11)

d. Stillbirth

The data were pooled from two RCTs, which have extensive representation from smokers (Weidlich et al., 2012; Newnham et al., 2009).

The relationships of NSPT and stillbirth were not statistically significant (see Table 3.11).

Table 3.11: ABOs in RCTs reporting smoking participants

ABO	Representation	RR	I^2	Number of studies	Number of women
PTB	All	0.69 (95% CI: 0.45, 1.06, P=0.09)	76% (P=0.0003)	7	5369
	Low	0.74 (95% CI: 0.40, 1.38, P=0.34)	80% (P=0.006)	3	2798
	Extensive	0.59 (95% CI: 0.26, 1.33,	80%	4	2571

		P=0.21)	(P=0.002)		
LBW	All	0.82 (95% CI: 0.59, 1.16, P=0.27)	46% (P=0.12)	5	3419
	Low	Only one RCT included			
	Extensive	0.48 (95% CI: 0.30, 0.77 P=0.002)	51% (P=0.11)	4	1681
PLBW	All	0.43(95% CI:0.14, 1.31, P=0.14)	71% (P=0.03)	3	1493
Stillbirth	All &Extensive	0.24(95% CI:0.04, 1.39, P=0.11)	0% (P=0.41)	2	1377

3.4.1.5.6 Subgroup analysis of income and education

Subgroup meta-analyses were not undertaken based on income and education because data were inconsistently reported.

3.4.1.6 Publication bias of RCTs

Other bias including publication bias was investigated for Part 2, two meta-analyses that investigated the efficacy of NSPT on reducing the incidence of PTB (n=13) and LBW (n=11) (see Figure 3.27 and 3.28). As stated earlier funnel plots should be used only when there are at least 10 studies included in the meta-analysis (Higgins and Green, 2011).

Figures 3.20 and 3.21 present the funnel plot for studies reporting on NSPT for prevention of PTB and LBW respectively. The funnel plots for PTB and LBW are asymmetrical which suggests the presence of relevant bias, which might be explained by the large number of small studies treating women at high risk to PTB or who have severe levels of periodontal disease, it might also be explained by lack of reporting of studies with negative findings.
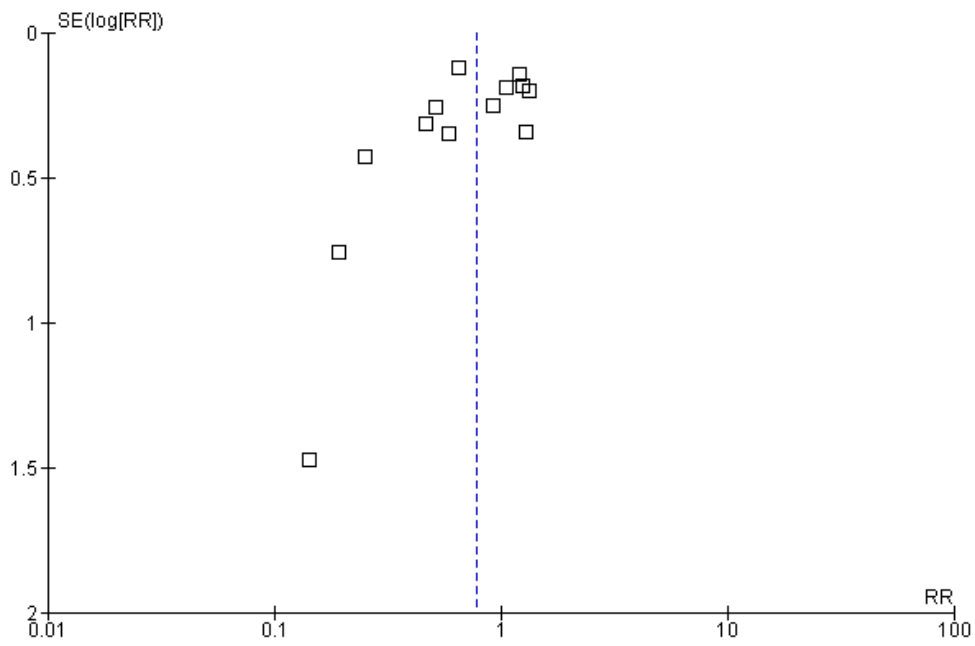
Figure 3.20: Funnel plot for studies reporting on NSPT for prevention PTB
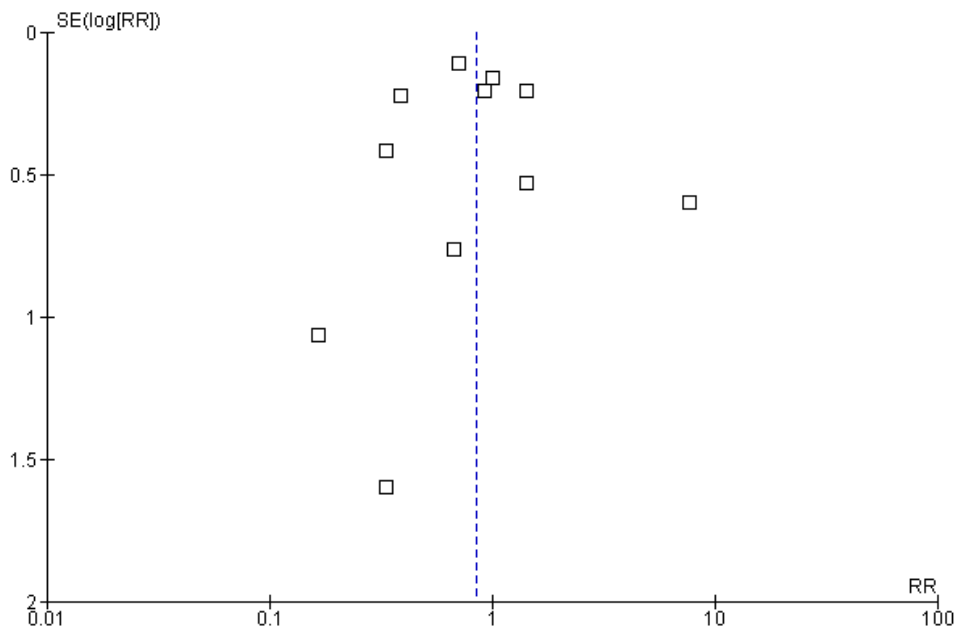
Figure 3.21: Funnel plot for studies reporting on NSPT for prevention LBW

3.5 Discussion

3.5.1 Summary of main results

Part 1: The association between PD and ABOs.

In Part 1 the specific questions addressed were: was there an association between PD and PTB, PD and LBW, PD and PLBW, and PD and stillbirth? A systematic review was conducted following the PRISMA guidelines and the analyses were planned in a protocol written a priori (Moher et al., 2010) based on the Cochrane Review template.

A systematic review and meta-analysis of cohort studies found that there was evidence from individual observational studies of an association between PD and ABOs including PTB (Al Habashneh et al.,2013; Rakoto-Alson et al., 2010; Vogt et al., 2010; Agueda et al., 2008; Pitiphat et al., 2008; Offenbacher et al., 2006a; Moore et al., 2004; Jeffcoat et al., 2001; Offenbacher et al., 2001), PD and LBW (Al Habashneh et al.,2013; Rakoto-Alson et al., 2010; Vogt et al., 2010; Saddki et al., 2008; Marin et al., 2005; Moore et al., 2004; Offenbacher et al., 2001) PD and PLBW (Al Habashneh et al.,2013; Rakoto-Alson et al., 2010; Agueda et al., 2008; Sharma et al., 2007; Rajapakse et al., 2005).

Only one cohort study investigated stillbirth (Mobeen et al., 2008) and found an association with PD.

Meta-analyses supported an association between PD and PTB (n=11) [RR1.63 (95% CI: 1.06-2.50, P=0.03)], PD and LBW (n=7) [RR 2.35 (95% CI: 1.21-4.57, P=0.01)], PD and PLBW (n=4) [RR 3.53 (95% CI: 1.51 -8.20, P=0.003)].

Based on the 16 cohort studies included in this systematic review, there is a body of evidence, which suggests an association between periodontal disease and adverse pregnancy outcomes.

The meta-analyses of the three outcomes were characterized by considerable levels of heterogeneity, which was not reduced by using a random effects model. Sensitivity analysis was used to explore heterogeneity which might be attributable to quality of the study design and the way in which the primary study was conducted. Only two studies (Agueda et al., 2008; Moore et al., 2004) scored a maximum high quality score on the Newcastle-Ottawa quality score which assigns a rating to the conduct of a cohort study on the basis of selection of participants, comparability and outcomes.

When subgroup analysis compared high quality (n=2) versus low quality studies (n=9) for PTB, the high quality studies did not support an association for PTB, [RR 1.33 (95% CI: 0.88-2.00, P=0.18)] while the low quality studies were also found not to support the association [RR 1.72 (95% CI: 0.98-3.02, P=0.06)]. The removal of Agueda et al. (2008) (N=300), a large primary study which had supported the relationship between PTB and PD, was sufficient to render the meta-analysis insignificant (P=0.06) though the heterogeneity remained high at I^2=45%. Similarly subgroup analysis of high quality studies (Agueda et al., 2008; Moore et al., 2004) versus low quality studies was conducted for LBW. The high quality studies did not support an association [RR 1.19 (95% CI: .68-2.08, P=0.55)] while the low quality studies did [RR 3.61 (95% CI: 1.55-8.37, P=0.003]. Both the PTB and LBW sensitivity analyses of the high quality of studies remained characterised by moderate (I^2= 45%) and high levels of heterogeneity respectively (I^2= 70%).

Further subgroup meta-analyses as outlined in the protocol were undertaken to identify possible sources of heterogeneity. The subgroup analyses were undertaken based on factors known to be risk factors for ABOs: women from black and ethnic minorities, past ABOs history, and proportion of women using tobacco. There remained evidence of associations in studies which specifically reported representation from Black/ Asian populations with PD and PTB (n=10), LBW (n=6) and PLBW (n=4). The association was also supported in studies reporting a past experience of ABO PTB (n=9) and LBW (n=5) respectively, but not supported for PLBW (n=2). In addition, there was an association found in studies reporting on tobacco use in women with PTB (n=7) but not for LBW (n=4). The heterogeneity level was reduced in some subgroup analyses when the extent of representation (including low and moderate representation from confounders) were analysed. The heterogeneity level was null in studies with low representation of women from Black and Asian populations in studies reporting on the association between PD and PTB.

In most of the subgroup analyses there were fewer than two or three studies, thus these subgroup analyses results should be treated with caution. The cause of these interactions and their impact on effect could have been explored further with meta-regression; however there were fewer than 10 studies which fully reported the variables of interest and therefore metaregression was not undertaken.

Overall the cohort studies found evidence of an association between PD and PTB, PD and LBW, PD and PLBW and PD and stillbirth (only one study).

Part 2: a. The efficacy of providing NSPT during pregnancy to reduce gingivitis and PD and to prevent ABOs

In the second part of the review, which assessed the efficacy of NSPT in the prevention of the incidence of ABOs, 13 RCT studies were included in the review. More than a half of the RCT studies (n=7) when assessed on an individual basis found that performing NSPT in pregnant women with periodontitis was associated with a reduction in the incidence of ABOs [Radnai et al., 2009 (LBW); Tarannum and Faizuddin, 2007 (PTB); Offenbacher et al., 2006b (PTB, LBW); Sadatmoansouri et al., 2006 (PLBW); Lopez et al., 2005 (PLBW); Jeffcoat et al., 2003 (PTB); Lopez et al., 2002 (PLBW)].

Four included studies assessed the relationship between NSPT and prevention of stillbirth in addition to PTB and LBW (Wedlich et al., 2012; Macones et al., 2010; Newnham et al., 2009; Michalowicz et al., 2006), none of these four RCT studies reported that scaling and root planning was associated with reduction in the incidence of stillbirth.

Eight studies reported that periodontal outcomes had improved after the intervention (Wedlich et al., 2012; Oliveira et al., 2011; Newnham et al., 2009; Michalowicz et al., 2006; Offenbacher et al., 2006b; Sadatmansouri et al., 2006; Lopez et al., 2005; Lopez et al., 2002). The single centre studies suggested a relationship between improved birth outcomes and treatment of PD; however the larger multi centre studies (Newnham et al., 2009; Offenbacher et al., 2009; Michalowicz et al., 2006) did not support the association.

Meta-analyses undertaken for the RCT studies to investigate the NSPT in reducing the incidence of PTB (n=13), LBW (n=11), PLBW (n=7) and stillbirth (n=4) produced some conflicting results. The meta-analyses did not support a

benefit in receiving NSPT during pregnancy to prevent PTB and PLBW but found a benefit in receiving NSPT to reduce the incidence of LBW and stillbirth. Analyses showed high levels of heterogeneity for PTB, LBW and PLBW outcomes, but null heterogeneity level for the stillbirth outcome.

Sensitivity analyses were undertaken including high quality RCT studies only (n=3) (Newnham et al., 2009; Offenbacher et al., 2009; Radnai et al., 2009), low risk of bias for all domains scoring 7/7. The meta-analyses which included only high quality studies did not support the efficacy of NSPT in reducing the incidences of PTB and LBW. The heterogeneity levels were not reduced for PTB and LBW. The sensitivity analysis was not conducted for assessing PLBW and stillbirth because only one study for each outcome was rated as high quality.

As in Part 1, subgroup analyses were undertaken to investigate possible sources of heterogeneity according to factors considered as risk factors for ABOs including proportion of women from Black and Asian groups, past history of ABOs and use of tobacco.

The division of subgroups based on representation of Black and Asian women (from low to high), only suggested some benefit of NSPT to reduce the rate of PTB in women from Caucasian groups amongst participants in studies with low representation. For stillbirth it was found to be of benefit for all including studies reporting low representation from Black and Asian groups. Heterogeneity only diminished in studies where there was low representation from Black and Asian groups.

Subgroup analyses of RCTs including women who had experienced ABOs previously did not show a benefit in receiving NSPT during pregnancy to reduce

the incidence of PTB, LBW and PLBW outcomes, but there was some evidence that rates of stillbirth were reduced. Heterogeneity was only decreased for LBW in studies where there was low representation of women who had experienced ABOs previously, and increased in studies where there was extensive representation of women who had experienced ABOs previously. The division of the subgroup analysis based on representation from low to high representation only suggested some benefit of NSPT to reduce the rate of LBW and stillbirth amongst studies with low representation from women who had experienced ABOs previously. Heterogeneity was null in low representation in studies for LBW and stillbirth, and reduced in studies for PTB with extensive representation. Most subgroup analyses again included only two or three studies.

It appeared that there was no benefit to women who used tobacco in receiving periodontal treatment during pregnancy to prevent PTB, LBW, PLBW and stillbirth. The heterogeneity was only slightly reduced amongst subgroup meta analyses. The division of the subgroup based on representation of smokers from low to high only suggested some benefit of NSPT to reduce the rate of LBW in studies where many women smoked. Heterogeneity was only reduced in the latter group.

There was evidence of publication bias for studies reporting on PTB. Smaller studies tended to produce outcomes in favour of the treatment arm and these tended to be from the earlier period between 2001-2006 when reports of the efficacy of NSPT began to emerge. However later studies, with higher numbers of participants tended to favour no effect.

b. Safety of NSPT during pregnancy

None of the studies robustly investigated the safety of the NSPT during pregnancy. Only four RCT studies reported that NSPT was safe and successful during pregnancy (Wedlich et al., 2012; Newnham et al., 2009; Michalowicz et al., 2006; Offenbacher et al., 2006b). It was not possible to undertake a detailed analysis because there was only a passing reference to the safety of treatment in any of the studies with only four making explicit reference. Only one study commented that scaling might be an unpleasant experience (Michalowicz et al 2006). All other studies did not actively collect safety data, though for all studies in the RCT part of the review, a reduction in risk of ABO favoured the treatment groups. The studies suggest that NSPT was not associated with adverse outcomes and those authors that did comment suggested NSPT was safe. Even so, there was not enough evidence to approve the safety of the NSPT during pregnancy since none of the RCT studies investigated the safety of the NSPT in a robust manner.

3.5.2 Interpretation of results

There were several significant concerns, which need to be considered in the appraisal of the reviewed results and the overall literature in relation to periodontal diseases and adverse birth outcomes.

3.5.2.1   Hetereogenity

Heterogeneity can be seen as a result of variability in participants, interventions and outcomes termed *clinical diversity*; it may also be as a result of variability in study design and bias termed '*methodological diversity*'; or it may be due to variability in intervention effects often as a consequence of clinical and methodological diversity (Higgins and Green, 2011). In the first section of the

review which explored the association between PD and ABOs, the decision was made to present outcomes for each study in order to minimise methodological diversity, yet it was not possible to identify studies of similar size with a consistent study design and there continued to be considerable heterogeneity within the analyses and sub group analyses. This heterogeneity could be partly explained by the diversity of participants in the studies who came from different locations and settings. The risk of ABOs differs in different populations; it is recognised as lower in North America and parts of Western Europe (Polyzoz et al., 2009; World Health Organization, 2006). In addition many of the known risk factors known to contribute to pregnancy birth outcomes were excluded in some studies but not in others. The pathogenesis of ABO is multifactorial, highly complex and variable (Stamilo et al., 2007) and the level of heterogeneity throughout the analyses suggests that many of the confounders and effect modifiers for ABOs were also not suitably planned for in the design of the studies included in the present review. In contrast to the poor quality of study design of observational studies reported by Vettore et al. (2006), Xiong et al. (2006) and Vergnes and Sixou (2007) in this present systematic review, the quality of papers in terms of reporting and conduct in Part 1 was in general good, based on the Newcastle and Ottawa scale. However most of the cohort studies did not adequately describe the population from which the exposed and control groups were derived. Not all relevant risk factors for ABOs were recorded in each study, and not all risk factors are fully understood. Clinical diversity therefore continues to be an important explanatory factor in the heterogeneity detected in the first part of the review.

There was also considerable diversity in how periodontal disease and gingivitis was assessed and measured in the cohort studies; only one study had a

'secure case definition of periodontitis' for the presence of periodontal disease (Nabili et al., 2013). The measurement of periodontal disease contributed to clinical diversity because most of the studies used measures which did not reliably detect the presence of periodontal disease. If the exposure of interest is inconsistently defined this could be an important explanation for some of the hetereogenity seen. Across all cohort studies using a random effects model did not decrease the level of heterogeneity seen. Only one subgroup analysis which involved two high quality cohort studies, assessing the association between LBW reported heterogeneity of 0%. The high quality cohort studies in the sensitivity analysis of the association between PTB and PD also reduced heterogentiy to 48% .

Higgins and Green (2011) recommend that high levels of hetereogenity should be explored through meta-regression or graphical tests such as funnel plots. This is an approach which is an extension of subgroup analysis. Meta-regression explores whether a linear relationship exists between variables and a comparative treatment, along with the direction (Baker et al 2009, p1426). It is recommended that these approaches should be used only when there are 10 or more studies, as below this figure is too low to allow an analysis (Higgins and Green, 2011). Fewer than 10 studies in the present study reliably recorded the proportion of women from Black and Asian groups, past history of ABOs and smoking prevalence, therefore meta regression was not undertaken.

In terms of the research question (the association of PD and ABO) a cohort design is the best method to answer this type of question (Ide and Papapanou, 2013; Chambrone et al 2011a; Greenhalgh, 2006; Jeffcoat et al. 2001). In a cohort study it is possible to define the experience and severity of disease at

baseline and to record also the possible confounders and effect modifers (Wimmer and Pihlstrom, 2008). Prospective cohort settings allow the researchers to record and quantify exposure a priori and events (Chambrone et al. 2011a). Thus future cohort studies should be undertaken in different settings and countries. The design of the study should be done using the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) (Sharp et al., 2014) and the meet quality criteria set out in the Newcastle-Ottawa quality scale. It is also recommended that future studies involve careful matching of confounders such as smoking, alcohol use, history of ABOs, deprivation and education level which are all known co-risk factors in ABOs (Wimmer and Pihlstrom, 2008; Vergnes and Sixou, 2007; Jeffcoat et al., 2003). Clear and robust criteria should be used to measure extent and severity of peridontal disease.

In Part 2 of the review, which explored the efficacy of treating periodontal disease and RCTs, the level of heterogeneity was high for the meta-analyses relating to PTB, LBW and PLBW but not for stillbirth. As with the observational studies, much of this heterogeneity was attributable to clinical diversity and methodological diversity of the studies relating to participants, country, setting, existing risk of ABOs in community and presence of other risk factors. While an RCT design was chosen, there were still differences in how studies were undertaken, how the presence of PD was measured, and how well authors adhered to guidelines on study design.

The publication bias for the meta-analysis of studies exploring effect of other biases suggest that for PTB the effect estimate as the measure of study size places the larger more powerful studies on the top, while smaller studies scatter

more widely on the bottom (Sterne et al., 2011) and indicates limited publication bias. The publication biases were asymmetrical for the meta- analyses in Part 2 that investigated the efficacy of NSPT on reducing the incidence of PTB (n=13) and LBW (n=11) (Figure 3.21 and 3.21). The explanation for the heterogeneity seen in the analyses may be explained by clinical and methodological diversity, but also may be explained by differences in the underlying risk of PTB and LBW between studies and the fact that some studies selected women who had high levels of PD. The funnel plot for the meta-analysis of studies exploring effect of other biases suggested that there is considerable asymmetry. Some of the heterogeneity might be explained by the clinical and methodological diversity in the studies. For example differences in underlying risks of PTB and LBW amongst the different studies, and the fact that some studies recruited women at high risk to LBW and with severe PD. Also not all studies reported LBW, so there may be some selective reporting bias operating as well. In any event, a large amount of heterogeneity in the RCTs remains largely unexplained. This would indicate a need for more targeted RCTs, where risk is established a priori (i.e. past experience of PTB, LBW and stillbirth), where prevalence of risk in community is known (so that the sampling can account for this), and where clear secure measures of PD are used and where other risk factors for ABO are accounted for.

3.5.2.2   Definition of periodontal disease

For both the cohort studies and the RCTs there were problems with how PD was recorded. In Part 1 of the review only one study used a secure definition of PD. In Part 2 there was no consistent definition of periodontal disease used across the studies. None of the RCT studies used a secure definition of PD according to Nabili et al. (2013). Several studies defined periodontal disease

according to probing depth or/and clinical attachment level (Sadatmansouri et al., 2006; Lopez et al., 2002). Other studies used dental indices e.g. bleeding on probing index, and /or CPITN (Ryalat et al., 2011). Chambrone et al. (2011b) suggests that the use of some indices may mean that some studies are not measuring periodontal disease at all. Nabili et al (2013) suggests that some approaches to measurement of periodontal disease are *'insecure'*. Thus, inconsistent definitions of periodontal disease lead to inconsistencies and disagreement in results. In addition, previous studies have highlighted the problem of differing definitions and measures of periodontal disease and how these might relate to measures of disease activity progression and the differing definitions and types of adverse outcomes (Gomes-Filho el at., 2007; Manau et al., 2008).

Ide and Pappanou (2013) found that the use of continuous or categorical measures impacted the results in their systematic review of cohort studies exploring the relationship between ABOs and PD. In that review the authors explicitly examined the use of continuous and categorical PD data in assessing the association between PD and ABOs. They found that when continuous variables were used the relationship between ABOs and PD was attenuated. They recommended that future studies use a combination of continuous and categorical data, and that partial recordings should be avoided particularly in young populations. Sanz and Korman (2013) reporting upon a consensus conference on PD and ABO suggest that additional measures should also be recorded because clinical measures do not adequately reflect the inflammatory burden present in pregnant women. These include assessment of the microbial composition of oral biofilm and measures of host inflammatory response. The

authors also recommend that more than one time point be used to reflect different exposures during gestation (Sanz and Korman, 2013).

All included cohort studies in the present review suggested a possible link between PD and adverse pregnancy outcomes but did not provide any underpinning explanations for how this association might operate. For example, these studies did not provide any scientific clarification for the characteristics of the pregnant women who were more likely to have adverse pregnancy outcomes. They also failed to specify the type of association whether it was causal or incidental. Risk factors for PD and ABOs are shared which further complicate study design and analysis (Wimmer and Pihlstrom, 2008).

Identifying the explicit effect of periodontal disease on adverse outcomes is difficult because of the multiple risk factors associated with these outcomes (Michalowicz et al., 2009). It is clear that the evidence is not conclusive, given the poor way in which PD has been recorded and more high quality studies from diverse settings and risk profiles should be included in future research. Women from Middle Eastern countries have a higher risk of PTB and LBW compared to women living in USA and Europe. There is a need for high quality prospective cohort studies to assess the association between PD and ABOs in Middle Eastern countries. The associations are unclear and more studies are needed to understand this general phenomenon. PTB and periodontitis share the risk factors of low socioeconomic status, smoking and black race (Michalowicz et al., 2009; Agueda et al., 2008). Future studies should control for these confounders and shared risk factors for periodontal disease to further understand the association between periodontal disease and PTB and/or LBW.

3.5.2.3   Safety findings

The safety findings were investigated in Part 2 of the review in relation to safety of receiving periodontal treatment during pregnancy. None of the RCT studies primarily investigated the safety of the NSPT during pregnancy. So there was no explicit evidence for the safety of the NSPT during pregnancy. The safety issues are sparsely reported in the studies included in Part 2 of the review. In the event that safety was mentioned (n=4), all studies reported no adverse events attributable to receiving NSPT. Future studies should explicitly state safety outcomes a priori.

3.5.3 Agreements and disagreements with other reviews

3.5.3.1   Cohort studies

Xiong et al. (2007) and Vergnes and Sixou (2007) review of cohort studies largely support the findings of our review of cohort studies, though they contain fewer studies of cohort studies. On the basis of individual studies, Chambrone et al. (2011a) supported the association between periodontal disease and adverse pregnancy outcomes (PTB, LBW, PLBW). This was consistent with the findings of our present review, which included two additional studies to Chambrone et al. 2011a (Ali and Abidin 2012 and Marine 2005) both suggesting no association. Chambrone et al reported (2011a) a meta-analysis of cohort studies suggesting that periodontal disease was a risk factor for PTB. Inclusion criteria for Chambrone's review were based on periodontal disease severity defined by measuring PPD only, clinical attachment level only and both (PPD and CAL) whereas we included all studies where periodontal status was measured and investigated included cohort studies which did or did not use a secure periodontal case definition according to Nabili et al. (2013). Chambrone

et al (2011a) undertook subgroup analyses based on severity of PD determined by CAL and PPD. The authors found that RR was increased in women with moderate to severe PD. Chambrone et al. (2011a) concluded that while a consistent association was found with ABOs, the high levels of heterogeneity were largely unexplained and of a concern. Consistent with our study the authors concluded that while many studies where of high methodological quality, few met all the quality criteria for a cohort study.

In the most recent review conducted by Ide and Papapanou (2013) separate reviews and meta-analyses are presented for cross-sectional, case control and prospective cohort studies. The review of the cohort studies concurs with our review and supports an association with PTB and LBW. In contrast to the present review, Ide and Papapanou (2013) explored the impact of continuous versus categorical data on ABOs. They noted that when continuous data were used the associations of PD with ABOs were with were attenuated

3.5.3.2   RCTs

Nine systematic reviews were identified during the searches Shah et al (2013); Kim et al., (2012); Rosa et al. (2012); Chambrone et al. (2011b); Foggaci et al. (2011); George et al. (2011); Olivera et al. (2010); Polyzoz et al (2010) (updated from 2009); and Uppal et al., (2010). Table A presents the characteristics of the reviews, Table B presents the AMSTAR assessment for each review, Table C presents the results of individual reviews and all may be found in appendix H. The systematic reviews were appraised using the AMSTAR criteria (Shea et al., 2007) which provide criteria for the quality reporting of systematic reviews. The maximum score is 11. High quality systematic reviews scoring 9, 10 and 11 were undertaken by Kim et al. (2012) (9), Chambrone et al. (2011b) (11),

Foggacci et al. (2011) (10), George et al. (2011) (10), and Polyzoz et al. (2010) (10). In two studies (Kim et al., 2012; Fogacci et al., 2011) a conflict of interest was not stated, whereas George et al. (2011) did not conduct a full assessment of publication bias.

The other reviews had potential biases because they failed to use an a priori design (Shah et al., 2013; Olivera et al., 2010), they failed to adequately search the literature (only one database searched by Olivera et al., 2010) or made no attempt to search for unpublished studies in the grey literature (Shah et al., 2013; Rosa et al., 2012; Olivera et al., 2010; Uppal et a., 2010). It is possible that some studies could have been missed due to lack of comprehensive searching, particularly studies reporting negative findings (i.e. no effect), which would lead to potential publication bias. Quality assessment was not undertaken by Olivera et al. (2010), nor was quality appropriately used to draw conclusions (Olivera et al., 2010).

The four high quality reviews according to AMSTAR Table B in appendix H (Foggaccii et al., 2013; Kim et al., 2012; Chambrone et al., 2011b; Polyzoz et al., 2010) partially support the conclusions of the present review, whereas George et al differs, largely because of the studies the latter included.

Chambrone et al. (2011b) conducted a systematic review with meta-analyses of RCT studies to determine whether NSPT during pregnancy has the potential to reduce the incidence of PTB, LBW and PLBW. Twelve RCT studies with 6813 pregnant women were included. In contrast to Chambrone et al. (2011b), in our review Lopez et al. (2005) was included and Jeffcoat et al. (2011) was excluded because the PTB definition (PTB before 35 weeks of gestation) was outside our criteria. Weldich et al. (2012) had not been published at the time of the

Chambrone review. Chambrone et al. (2011b), based on 38% of studies at low risk of bias and 62% at unclear or high risk of concluded that periodontal treatment during pregnancy did not reduce the incidence of PTB, LBW and PLBW whereas the current review supports the association between NSPT and LBW.

Polyzoz et al. (2009) undertook a meta-analysis to examine the effect of periodontal disease treatment during pregnancy on PTB, LBW and stillbirth. Polyzoz et al. (2009) showed that receiving periodontal treatment was beneficial in preventing PTB. For LBW the difference between treatment and control arm was borderline in favour of treatment. No difference between the treatment arm and the control arm was seen for stillbirth. But this review was later updated in 2009 and contrasting results were found for PTB and stillbirth. Polyzos et al. (2010) reviewed 11 studies including 6558 women in a systematic review with meta analyses of the efficacy of treating periodontal disease to reduce the risk of PTB. The authors included the same group of studies as in the present review, except for Radnai et al. (2009) and Wedlich et al. (2012) which had not been published. The overall analyses demonstrated no benefit to receiving treatment to prevent PTB, LBW, PLBW and stillbirth, which is similar to the findings reported in our meta-analyses of RCTs for PTB and PLBW, though we found a benefit for LBW and stillbirth.

Fogacci et al. (2011) reviewed 10 RCTs included women in a systematic review with meta-analyses of the efficacy of treating PD to reduce the risk of PTB. In contrast to our present review where Lopez et al. (2005) is included. Fogacci et al. (2011) excluded Lopez et al. (2005)| and Olivera et al. (2009) because gingivitis was an entry criterion. Wedlich et al. (2012) had not been published.

Fogacci et al. (2011) findings were similar to the present meta-analysis that found the overall analyses demonstrated no benefit to receiving treatment to prevent PTB but this review found a benefit of NSPT for LBW. Subgroup meta-analysis findings of studies including women with previous PTB findings were similar to the current review results, which found no significant benefit to having NSPT during pregnancy to reduce the events of PTB.

Kim et al. (2012) reviewed 11 studies in a systematic review with meta-analyses of the efficacy of treating periodontal disease to reduce the risk of PTB and LBW and to explore further heterogeneity and bias risks in pooled studies. The authors included all the studies in our review but Wedlich et al. (2012) had not been published at the time of their review. The overall analyses demonstrated no benefit to receiving treatment to prevent PTB or LBW, which is similar to the findings reported in our meta-analyses of RCTs concerning PTB, though we found a benefit for LBW and stillbirth.

George et al. (2011) conducted a systematic review with meta-analyses to determine whether periodontal treatment during pregnancy has the potential to reduce PTB and LBW incidence. Ten studies with 5645 pregnant women were included. In contrast to George et al, in our present review Oliviera et al. (2011) was included. In contrast to the current review, George et al's review showed that periodontal treatment during pregnancy reduced the incidence of PTB and LBW, though no effect was seen on rates of stillbirth. Our review found no association between NSPT and PTB but there were benefits in reducing LBW and stillbirth outcomes.

Most of the recent systematic reviews included many of the same studies as the present review, except Weidlich et al. (2012). Most of the high quality rated

reviews (AMSTAR) report similar findings to the present systematic review of RCTs concerning PTB but different findings for LBW.

3.5.4 Strengths and limitations of the review

The strength of Parts 1 and 2 of this review was the quality standards employed according to PRISMA (Moher et al., 2009). First a priori protocol was designed, a comprehensive search of more than two data bases was conducted including hand searching and searching of the grey literature. There was duplicate selection and extraction of data. A full list of excluded and included studies was prepared, the characteristics of individual studies were assessed using PICO and the scientific quality of studies was assessed using the Newcastle-Ottawa scale and Cochrane risk of bias scale. The methods used to combine the studies were appropriate and sub group analysis described a priori.

The main limitations of the review relate to the conduct of the primary studies, and the predictor (PD) being assessed. The quality of studies may have been acceptable for publication but many important variables for predicting risk of ABO were not adequately recorded and are inadequate for detailed analysis. There was huge variation in when and how PD was identified and assessed, none of the primary studies used a secure definition of PD. Finally ABOs are known to vary in populations, settings, etc. and this degree of clinical diversity produced high levels of heterogeneity, which may have been compounded by the insecurity of definition of PD.

All of the previous systematic reviews report meta-analyses characterized by significant levels of heterogeneity, which is consistent with the present review. The current review intended to conduct a subgroup analysis based on a secure periodontal case definition by Nabili et al. (2013) but our search found no

studies used secure periodontal case definition. Most of the other systematic reviews reported meta- analyses based on subgroup analysis based on diagnosis of periodontal disease such as PPD, CAL or both. Subgroup analyses should be regarded as hypothesis generating rather than conclusive evidence (Higgins 2009) because in general too few studies are included.

3.6   Conclusion

Researching the role that PD including gingivitis may have on ABOs is made difficult because of problems defining PD; measuring PD and relating measures to disease activity; the diversity of risk factors for ABOs and their connection with PD (i.e. smoking, race and ABOs history) and the diversity in population risk for adverse outcomes in different countries and settings.

The evidence in this review suggests that on a simple number count individual cohort studies support an association between ABOs and PD; meta-analyses of cohort studies also supported the association between PD and PTB, LBW or PLBW. In addition, most of the subgroup analyses including those reviewing high quality studies only, subgroup analyses of data by Black and Asian groups, past ABOs history and tobacco use respectively, support the association. The quality of most of the cohort studies is good, but the selection of the cohort and the control group is often poorly reported.

The level of heterogeneity indicates that these results must be viewed with caution. The level of heterogeneity is not reduced in high quality studies suggesting there remains a large amount of clinical diversity, which is poorly understood. A proportion of this is likely to be attributable to the difficulty in defining the predictor (PD) of the outcome (ABOs)

Evidence from small individual RCTs suggested non-surgical treatment of PD may improve periodontal outcomes and may prevent ABOs. In our review, meta-analyses of 13 RCTs suggest that NSPT during pregnancy does not prevent PTB and PLBW but there is evidence for prevention of LBW and stillbirth.

We must therefore conclude that there is evidence for an association between periodontal disease and ABO and that there is no benefit to receiving non-surgical treatment of periodontal disease during pregnancy to prevent PTB and PLBW. There is some evidence for the prevention of LBW and stillbirth. There was no robust evidence for the safety of NSPT during pregnancy.

There remains uncertainty in relation to the efficacy and safety of NSPT to prevent ABOS.

It is reasonable to advise women to maintain good oral hygiene throughout pregnancy to minimise contribution to inflammatory loading. It is also reasonable to advise women that NSPT is effective for treatment for periodontal disease and RCT studies looking at use of NSPT in pregnant women have not reported adverse events.

Women may reduce their risk of LBW and stillbirth by receiving NSPT during pregnancy but this is based on 11 studies for LBW and only four studies for stillbirth.

More high quality studies using a cohort design to test for an association between ABOs and PD are required. The quality of the design of studies may be improved by using STROBE and checking quality using the Newcastle-Ottawa scale.

There is a need for agreement on diagnostic criteria for PD and inclusion criteria for entry into cohort studies i.e. addressing confounders such as smoking, tobacco use, previous experience of ABOs and prevalence and incidence of adverse outcome in the population.

In future, RCTs investigating the efficacy of NSPT to prevent ABOs should also consider consistency in diagnostic criteria, inclusion and exclusion criteria to address heterogeneity issues and should also assess the success of periodontal treatment undertaken. It is recommended that all studies are planned and designed based on the CONSORT criteria.

It is important to have a secure definition for PD. Future studies should use a combination of continuous and categorical data, and partial recordings should be avoided particularly in young populations. As inflammatory loading is a key component of the pathophysiology, additional measures should also be recorded. These include assessment of the microbial composition of oral biofilm and measures of host inflammatory response, taken at more than one time point.

As risk factors for PD and AB co vary, future studies should control the confounders, such as smoking, socioeconomic status, the pregnant woman's age in order to clarify the association between PD and PTB and/or LBW and the prevalence of ABOs in the communities being studied.

In terms of dental health education it seems reasonable to encourage women to maintain optimal oral hygiene to mitigate risk of periodontal disease and gingivitis during pregnancy, and to attend their dentist for oral assessment before, during and after pregnancy.

At present it is unhelpful to women to raise concerns about PD and ABOs, when it is not possible to identify which ABO a woman may be susceptible to and there is no effective way currently to mitigate risk comprehensively.

Chapter 4

Oral health knowledge and perceptions about oral health and self-care amongst pregnant Kuwaiti women: A qualitative study

4.1   Introduction

Pregnancy is thought to be an important and critical period for imparting oral health information and motivating women to adopt positive oral health behaviours (Bates and Riedy, 2012). Studies emphasise the importance of good oral hygiene procedures to prevent maternal gingivitis (Acharya and Bhat, 2009; Adriaense et al., 2009; Ressler-Maerlender et al., 2005). The main goal, therefore, of the oral health care provider regarding pregnant women is to establish and maintain good oral health before and during pregnancy. Basic oral hygiene education may improve oral health and contribute to improved quality of life amongst pregnant women (Zanata et al., 2008).

The literature suggested the need for oral health education to improve oral health behaviour amongst pregnant Kuwaiti women, since these women had self-reported oral health problems, had little awareness of the importance of oral health during pregnancy and avoided dental attendance during pregnancy (Honkala and Al-Ansari, 2005).

Public health researchers have emphasised the importance of understanding the cultural characteristics of the target group in order to provide and design health promotion programmes to better meet that group's needs (Kreuter et al., 2002). Therefore, prior to designing an intervention, it was planned to identify and understand the culture of pregnant Kuwaiti women regarding oral health, in addition to their reported oral health behaviours. There has only ever been one cross-sectional study of reported oral health behaviours and oral health amongst pregnant women in Kuwait (Honkala and Al-Ansari, 2005). The study investigated dental hygiene (reported frequency of brushing and flossing per day), dental and

gum diseases and dental visits. It showed that pregnant women in Kuwait had poor oral health, a high prevalence of dental problems and were fearful of dental treatment. In addition, women reported that they had not received instruction related to personal oral hygiene.

The study was undertaken by Honkala and Al-Ansari (2005) using a questionnaire. There was little opportunity to explore the cultural beliefs and attitudes held about oral health which are known to shape oral health attitudes and behaviours (Sisson, 2008). The questionnaire based design used by Honkala and Al-Ansari (2005) did not allow such an exploration whereas a qualitative research methodology would be a more appropriate approach to explore and understand the underpinning cultural beliefs, perceptions and attitudes that form and shape the oral health behaviours of pregnant Kuwaiti women (Pope and Mays, 2006; Ritchie and Lewis, 2003).

The present study was therefore undertaken to aid understanding of pregnant women's oral health practices and oral health awareness, and motivations in relation to oral health. It was anticipated that, where relevant, these insights could be used to inform the design of an intervention study to improve oral health behaviours amongst pregnant women.

In planning the present study, it was considered important to have an understanding of the individual processes and social context in which oral health behaviours were undertaken with the aid of theory. One such theory-based approach is to use Social Cognitions (SC) (Renz and Newton, 2009; Conner and Norman, 2007). SC explain behaviour as a result of logical information processing

that are said to provide a significant framework for understanding the determinants of adherence to specific health behaviours (Renz and Newton, 2009). SC consists of beliefs, thoughts and attitudes that determine whether or not the person undertakes a specific behaviour. Thus in this study, the data which were derived from the interviews would be scrutinised for the presence of social cognitions which on a psychological theoretical basis (Renz and Newton, 2009; Conner and Norman, 2007) have been used to explain health behaviour. These cognitions were planned to be identified by type i.e. knowledge, beliefs and attitudes, and then categorised as being helpful or unhelpful to oral health. In this way, the qualitative study could help inform and inspire the design of a follow-up intervention study.

4.2   Aim and objectives

The purpose of this qualitative study was twofold: firstly, to investigate oral health knowledge, perceptions, beliefs and attitudes amongst pregnant Kuwaiti women and to explore beliefs and attitudes about improving and maintaining oral health during pregnancy.

Secondly, to map the data derived in the interviews against social cognitions and identify those which were helpful and unhelpful to oral health in this group of women.

The study objectives were:

1. To explore the perceptions, beliefs and attitudes pregnant Kuwaiti women held in terms of oral health during pregnancy.

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2. To explore perceptions, beliefs, attitudes and behaviours in terms of any reported oral health changes during pregnancy.

3. To explore how pregnant Kuwaiti women maintained, promoted and improved oral health during pregnancy.

4. To explore how pregnant woman in Kuwait ranked their oral health against other competing priorities during pregnancy.

5. To investigate pregnant Kuwaiti women's experiences of accessing oral health information and care.

6. To explore barriers for accessing oral health information and care amongst pregnant Kuwaiti women.

7. To identify and map data from the interviews into social cognitions which were helpful and unhelpful to oral health.

4.3   Methods

In-depth interviews were conducted with a purposive sample of 19 pregnant women who were recruited from local government maternity clinics in primary healthcare centres in five government healthcare regions. A topic guide was used to explore a priori research questions derived from the literature, but the topic guide was also added to as the interviews progressed to reflect new themes which emerged from the interviews. The questions in the topic guide aimed to identify and understand in depth the pregnant Kuwaiti women's cultural and social beliefs regarding dental heath before and during pregnancy (see appendix I: Study topic guide).

4.3.1 Selection of study population

All pregnant Kuwaiti women who visited government maternity clinics in the primary healthcare centres in the five healthcare regions in Kuwait were eligible for this study regardless of whether they sought regular or irregular medical care during pregnancy. Two maternity clinics were selected from each of five healthcare regions (a total of 10 maternity clinics). The interviews were conducted between September 2010 to December 2010.

4.3.2 Sampling method

A purposive sample was used to recruit a diversity of participants from different settings. Ritchie and Lewis (2003) defined a purposive sample where: "*the sample units are chosen because they have particular features or characteristics which will enable detailed exploration and understanding of the central themes and puzzles which the researcher wishes to study.*" (p. 78). As this qualitative study aimed to understand the variety and diversity of oral health knowledge and perceptions amongst pregnant Kuwaiti women, purposive sampling was used to select participants from a diverse range of age groups, educational backgrounds, gestation periods and number of pregnancies. To ensure diversity participants were recruited from 10 maternity clinics from five medical catchment areas.

We aimed to recruit approximately three women from 10 different maternity clinics with an approximate sample size of 30 (Ritchie and Lewis, 2003). The recruitment of interviewees was planned to be terminated once no new data emerged and the data were saturated (Pope and May, 2006; Pope et al., 2000).

4.3.2.1   Inclusion criteria

Participants were eligible to participate in this study if they were Kuwaiti, pregnant, attending government maternity clinics in the primary healthcare centres in the five healthcare regions and provided informed consent.

4.3.2.2   Exclusion criteria

Participants who were not pregnant, non-Kuwaitis, or unable to provide the informed consent were excluded.

Pregnant women not from Kuwait were excluded to confine our understanding to pregnant Kuwaiti women's cultural practices and motivations in relation to oral health.

4.3.3 Setting and recruitment

Participants were recruited from 10 local government maternity clinics in five government healthcare regions: Al Asimah, Hawalli, Al Ahmadi, Al Frarwaniyah and Al Jahra. These maternity clinics were available for pregnant women in two shifts: morning shifts (8:00 a.m. to 1:00 p.m.) for three days per week and afternoon shifts (4:00 p.m. to 8:00 p.m.) for one day per week. The investigator of this study (SAK) spread her attendance at selected maternity clinics in order to recruit and interview participants who sought care over the full range of clinic availability.

4.3.4 Conduct of the interview

Permission from health centre authorities was obtained to identify a quiet room in each primary healthcare centre to ensure participants' privacy. The researcher explained the study including the use of a digital recorder to aid accurate reporting

of responses and answered any questions about the study. All pregnant Kuwaiti women who agreed to participate in the study and met the inclusion criteria were given the study information sheet in Arabic (see Appendix J: the information sheet in English and Arabic Language and Appendix K: the consent form in Arabic and English Language). The information sheet explained the study objectives, inclusion criteria, the process of the interviews, right of withdrawal and the researcher's contact details. After participants read and indicated they understood the study information sheet they were asked whether they had any questions about the study and then were required to sign an informed written consent form prior to the interview. Each participant was interviewed on a one-to-one basis.

The researcher had received training in interview techniques and had been observed interviewing in the UK prior to commencing the interviews in this study.

The interviews were conducted in Arabic, the official language in Kuwait. The interview started with a few general questions to make participants feel at ease during the interview. The main research questions were then addressed, giving the participants an opportunity to provide detailed answers. The main research themes derived from the literature and issues that needed clarification were: women's oral health knowledge, perceptions, beliefs and attitudes about oral health, and what women said they did to improve and maintain their oral health during pregnancy. At the end participants were thanked and a shopping coupon with the value of about five Kuwaiti Dinars (£10) was given to each participant to thank them for their time. A study notebook was completed contemporaneously with relevant observations.

4.3.5 Data management and analysis

All interviews were anonymised, transcribed and filed in Microsoft Word immediately after each interview. The transcripts were in Arabic. Selected transcripts were translated into English to enable preliminary analysis, discussion of themes and approach to thematic analysis with co-researchers who were not Arabic speakers. These transcripts were then back-translated to Arabic to ensure the accuracy of the translation. The transcripts were translated twice by different translation agents to ensure the quality and accuracy of the translation.

The analytical process was started after completing the first interview to enable the investigator to refine the interview questions and introduce any new or emerging themes (Pope and Mays, 2006). This approach continued until the last interview was conducted.

The first three interviews were translated into English on the same day as the interviews and sent to the co-researchers to get their feedback and to discuss the interviews content and conduct.

The research data analysis consisted of developing a *thematic framework* (Pope and Mays, 2006). Pope and May (2006) and Ritchie and Lewis (2003) suggest five stages of data analysis using the framework approach: *familiarisation*, *identifying a thematic framework*, *indexing*, *charting*, *mapping* and *interpretation.*

The familiarisation stage is about listening to the tapes and reading the transcripts and notes to identify the key themes. Developing a thematic framework involves identifying the key concepts and themes based on the topic guide questions and the participants' thoughts and views, which evolve and emerge from the interviews.

Indexing (thematic framework) is the application and codification of all the data thoroughly, with numerical codes and short descriptions in each index. Charting is rearranging themes based on the relevant part of the thematic framework. Mapping and interpretation of the emerging themes is based on the research objectives and the themes emerged during the interviews (Pope and Mays, 2006; Ritchie and Lewis, 2003).

A thematic framework (Figure 4.1) was used to group the data into broad themes, and then the data were organised and classified according to the key themes. The thematic analysis included the main a priori determined research themes, in addition to any new themes that emerged directly or indirectly through the interviews (Pope and Mays, 2006). In the event that new subthemes emerged from the data, the existing broad themes were expanded upon in greater depth.

It was decided to analysis the data manually as the final number of interviews came to 19 and were readily coded manually.

A depiction of the stages and processes involved in qualitative analysis

Seeking applications to wider theory/policy strategies	
Developing explanations (answering how and why questions)	**Explanatory Accounts**
Detecting patterns (associative analysis identification of clustering)	
Establishing typologies	
Identifying elements and dimensions, refining categories, classifying data	**Descriptive Accounts**
Summarising or synthesising data	
Sorting data by theme or concept (in cross-sectional analysis)	
Labelling or tagging data by concepts or theme	**Data Management**
Identifying initial themes or concepts	
Raw Data	

Iterative process throughout analysis

Assigning data to refined concepts to portray meaning

↕

Refining and distilling more abstract concepts

↕

Assigning meaning

↕

Generating themes and concepts

Figure 4.1: The Analytical Hierarchy
        (Adapted from Ritchie and Lewis (2003) Qualitative research practice)

4.3.6 Psychological theoretical approach

After identifying the key themes that provided a comprehensive description of pregnant Kuwaiti women's beliefs, attitudes and behaviour, the data were scrutinised for the presence of social cognitions which on a psychological theoretical basis have been used to explain health behaviour. These cognitions were identified by type and then categorised as being helpful or unhelpful to oral health. Social cognition components were used to explore the practices of pregnant women with regard to oral health.

4.3.7 Ethical consideration

Research Ethics approval was obtained from King's College London Research Ethics Committee (BDM/09/10-36) and from the Kuwait Research Ethics Committee.

4.4 Results

While 10 government maternity clinics were originally chosen, three of the seven clinics were discarded because they were used exclusively by non-Kuwaiti pregnant women. Three additional clinics were chosen to replace the excluded maternity clinics, but these clinics also had to be excluded because the attendees were not Kuwaiti nationals. Nevertheless the researcher was able to continue recruitment at the remaining seven maternity clinics until after data saturation.

Thirty-six pregnant Kuwaiti women were approached to participate. Seventeen women refused to participate: eight women reported they were not interested or did not have time; four women said they could not agree to participate without permission from their husbands because they thought that their husbands would

refuse recording of the women's voices as it was culturally unacceptable; and five women were too embarrassed to talk about their oral health because they believed that they had very bad oral health.

Data saturation was becoming obvious after interview 17 and 18, and was clear after interview number 19. The interviews were thus terminated once no new data emerged and the data were saturated (Pope and Mays, 2006; Pope et al., 2000).

4.4.1 Socio-demographic characteristics of the participants

Table 4.1 presents the demographic characteristics of the participants and the location and numbers recruited. Nineteen (N=19) pregnant women were interviewed. The women were aged between 19 to 42 years old; their mean age was 28.8 years old. Nine of the participants had two years of formal education after high school, only three had baccalaureate degrees, three had high school degrees and five had not completed high school. More than half (n=10) of the pregnant women were not employed and described themselves as housewives. The majority of the participants (n=15) had three or fewer children and five of them were in their first pregnancy; four participants had five or more children.

Table 4.1: Demographics of participants attending in the primary healthcare centres

No.	Age	Highest Education level attained	Occupation	No. of Children	Health care region	Health centre
1	32	9th grade in High School	Housewife	0	Al Asimah healthcare region	Al Faihaa primary healthcare centre
2	25	Bachelor of Computer Engineering	Teacher assistant, Engineering College	I		
3	29	Postgraduate Diploma in Communication	Employee	2		
4	27	Bachelor of Science (Sociology)	Teacher	1	Hawalli healthcare region	Al Rumaithiya primary healthcare centre Sabah Al Salem primary healthcare centre
5	22	Secretarial Diploma	Housewife	1		
6	38	Primary School education completed	Housewife	5		
7	26	Postgraduate Diploma in Business	Housewife	1		
8	25	Postgraduate Diploma in Business	Employee	0		
9	25	Secretarial Diploma	Employee	1		
10	19	Student	Student	0	Al Farwaniyah healthcare region	Al Aissami primary healthcare centre
11	33	Bachelor of Islamic Sciences	Housewife	2	Al Ahmadi healthcare region	Al Riqqa primary healthcare centre Qurain primary healthcare centre
12	20	Secretarial Institute	Student	0		
13	27	Postgraduate Diploma in Nursing (two years of study after the fourth intermediate year)	Nurse	0		
14	31	Postgraduate Diploma in Education	Housewife	2		
15	42	10th grade in High School	Housewife	6		

16	39	Postgraduate Diploma in Computer Sciences	Employee	6		
17	33	Completed High School	Housewife	3	Al Jahra healthcare region	Al Qaser primary healthcare centre
18	35	None	Housewife	5		
19	20	Completed High School	Housewife	2		

4.4.2 Research themes

The results were organised and categorised based on the broad themes and sub themes present in the data. The key themes observed were related to poor oral health knowledge; cultural beliefs held about oral health and pregnancy; motivation and laziness and barriers to accessing information and barriers to accessing dental care.

4.4.2.1 Poor oral health knowledge

Pregnant Kuwaiti women lacked oral health knowledge regarding the simple routines and reasons for oral hygiene including: tooth-brushing frequency, toothbrush selection and choice of toothpaste, and flossing. They also lacked information concerning oral health during pregnancy and the impact of pregnancy on oral health and possibly systemic health.

4.4.2.1.1 Brushing

Most of the women reported that they brushed their teeth twice to three times a day and most participants reported that they bushed their teeth in the morning and before bedtime. Some of the participants brushed their teeth using circular strokes and others brushed up and down and used side to side strokes. Most of the

women reported that they did not know what might be the correct brushing technique or how to choose a toothbrush.

> *"I don't know the proper method of brushing; sometimes side to side and others back and forth." Pregnant woman (nulliparous) interview 19, page 1 line19.*

> *"My dentist did not show me the proper brushing method. I brush my teeth by using back and forth strokes." Pregnant woman (nulliparous) interview 12, page 2 line 29.*

Most women reported that prior to pregnancy they brushed their teeth twice a day but that they stopped brushing their teeth or reduced the frequency of tooth brushing during the first trimester due to pregnancy sickness or were upset because their gums bled.

> *"In the first three months of pregnancy I stopped brushing my teeth and using the toothpaste ." Pregnant woman (multiparous) interview 11, page 4 line 13.*

Most of the participants believed that toothbrushes with medium or hard bristles were more effective in cleaning their teeth.

> *"I use a medium bristle tooth brush; it is more effective in cleaning my teeth." Pregnant woman (multiparous) interview 19, page 3 line 6.*

> *"I always choose a tooth brush with a medium bristles; I don't like the hard one or the soft one which is not effective in cleaning the teeth. Pregnant woman (multiparous) interview 3, page 2 line 11.*

"I use any tooth brush, I don't know and I never thought about tooth brushes bristles types." Pregnant woman (primiparous) interview 9, page 2 line 4.

4.4.2.1.2 Toothpastes

Participants reported that they selected toothpastes based on the colour, taste and smell of the paste.

"I select the toothpaste based on its colour because they said (friends and family) that red toothpaste makes the gums pinker." Pregnant woman (multiparous) interview 16, page 3 line 25

4.4.2.1.3 Dental flossing

None of the participants used dental floss regularly and a few thought it might damage teeth.

"I don't know what dental floss is, all I do is I clean my teeth by using tooth brush and toothpaste." interview 11, page 2 line 17.

"I don't use dental floss and I don't like it; it damages my teeth." Pregnant woman (multiparous) interview 16, page 4 line 22.

It was clear that women lacked knowledge regarding dental floss and its importance in preventing periodontal disease. In addition, women needed education regarding selecting appropriate toothpaste since none of the participants were aware of the oral health benefits of toothpastes and none for example reported fluoride as a significant ingredient when selecting toothpaste.

4.4.2.1.4 Oral and periodontal health

a. Personal beliefs about periodontal health

Most of the women reported that they considered tooth brushing part of body hygiene, though no participant associated oral hygiene with gingival health. Indeed gingival health and the prevention of gum disease was rarely commented on or reported on by the participants. There was no awareness of gum disease as a threat to oral health. Further, participants did not know anything about periodontal diseases such as symptoms and/or causes. There was no concern amongst the women in relation to gingival bleeding and few regarded bleeding as abnormal, unhealthy or as an upsetting condition. Some participants noticed that gum bleeding increased during pregnancy but they did not know the reason why this might be and they never connected bleeding gums to pregnancy or considered it a sign of poor plaque control.

> *"I don't have any information about gums; I don't know why my gums are always inflamed." Pregnant woman (primiparous) interview 2, page 2 line 19.*

Many reported that they stopped brushing and/or reduced the frequency of brushing in the day when their gums bled during tooth brushing and some noticed their gums bled more during pregnancy. The data below suggests that some saw this bleeding symptom as a problem but of insufficient seriousness or threat to seek care. Management involved reducing the frequency of brushing or discontinuing brushing which eliminated the problem for women during the period of their pregnancy.

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"I don't have any idea why my gums bled more during pregnancy; and I didn't go to the dentist." Pregnant woman (nulliparous) interview 8, page 3 line 19.

"Bleeding gums is normal; I was used to it even before getting married (getting pregnant)." Pregnant woman (primiparous) interview 9, page 3 line 18.

At most women responded to gum bleeding by reducing their brushing frequency.

"If I'm brushing my teeth and my gums start bleeding I will gargle and if it increases, I will continue brushing. But rather than doing it [brushing] twice a day, I'll just do it once a day." Pregnant woman (multiparous) interview 15, page 4 line 28.

The low level of oral health knowledge concerning gingival and periodontal health was not anticipated amongst pregnant Kuwaiti women by the researcher, and reflected much lower levels than she had encountered as a practising dental hygienist in Kuwait. The participants were not aware of the important role of tooth brushing in preventing oral disease. It became clear that pregnant women needed basic oral health education concerning gingival and periodontal health. In addition women needed to receive information about the relationship between gingival and periodontal health and pregnancy.

b. Dental decay

In contrast to their lack of awareness of periodontal diseases, women were more aware of dental decay as a disease. They believed that eating food containing sugar was the only cause of dental decay. They reported that eating food

containing sugar most of the time might lead to dental decay; they also reported that eating food containing sugar before bedtime would harm the teeth and cause dental decay. Some of the participants also believed that drinking tea and coffee was another cause of dental decay. Others believed that drinking cold or hot drinks led to weakened teeth and dental decay.

"Food containing sugar causes tooth decay." Pregnant woman (multiparous) interview 19, page 5 line 13.

"I think eating food containing sugar has an effect on oral health, eating food containing sugar causes dental decay." Pregnant woman (multiparous) interview 14, page 3 line 8.

"As I know that tea and coffee harm teeth, when I drink coffee or tea I directly brush my teeth, even when I eat chocolate." Pregnant woman (primiparous) interview 2, page 2 line 10.

"Type of food and drink might affect the teeth and gums. For example, drinking tea and coffee colours the teeth, drinking fizzy drink causes cavities in the teeth and eating hard food might fracture the teeth." Pregnant woman (multiparous) interview 11, page 3 line 4.

It was clear that the participants were mostly aware of dental decay but they did not have correct and accurate information regarding the causes and prevention of dental decay.

Pregnant Kuwaiti women had no information about oral health during pregnancy. Women reported that there was no effect of pregnancy on oral health. Most of the women believed that dental pain during pregnancy was common and occurred mostly in the first trimester. Others considered dental pain to be common during pregnancy and believed that it would vanish after giving birth without receiving any dental treatment.

"I don't know what may affect my teeth and gum health during pregnancy". Pregnant woman (primiparous) interview 2, page 3 line 11.

Participants reported that prior to this interview with the researcher they had never been asked about their oral health during pregnancy.

"I don't know what to tell you! I don't have any background concerning dental health and pregnancy. For me, I'm not thinking of my teeth during pregnancy; pregnancy is down there and the mouth is up here [participant gestures to her bump and her mouth]. I don't experience any differences in my mouth." Pregnant woman (nulliparous) interview 1, page 2 line 37.

"I know nothing about pregnancy and oral health; I don't have any information about oral health during pregnancy." Pregnant woman (primiparous) interview 5, page 4 line 21.

Most of the pregnant women reported that they felt that they lacked oral health information but found it difficult to identify a professional source of advice. Women tended to rely on informal networks and sources of information. Family and friends

were commonly cited sources of information. None of the women contested the validity of the information coming from family and friends.

Other sources included advertisements that related to oral hygiene aids such as those for toothbrushes, toothpaste, and mouth wash.

> *"I have never been advised during my pregnancy to take care of my dental health." Pregnant woman (primiparous) interview 2, page 3 line 10.*

Most of the participants requested oral health information and an education programme and blamed the health care system in Kuwait for their lack of oral health knowledge. The majority of women suggested that they would like an oral health leaflet or booklet as a reference for oral health. A minority of women suggested having face to face oral health education.

> *"In fact you have asked me so many questions, I don't know what to say or answer these questions. I would like to have any booklet or leaflet so we can learn about the oral health and pregnancy." Pregnant woman (multiparous) interview 19, page 5 line 14.*

It was clear from the interviews that women had gaps in their knowledge of how to maintain oral health during pregnancy.

4.4.2.1.5 Dental visiting

In general, all participants said they did not visit dental clinics regularly and usually only attended should urgent treatment be needed. They also reported that they avoided dental treatment during pregnancy and were afraid of receiving dental treatment because they thought that it might harm the baby.

Accordingly most of the participants postponed any needed dental treatment until after giving birth. A small number of women reported that they sought emergency dental treatment during pregnancy but the dentist refused to provide any dental treatment until they had a medical clearance from their obstetricians. This would suggest that dentist's actions were in some cases reinforcing women's concerns about the safety of dental treatment.

"I don't visit dental clinic regularly, I just go when I have toothache" Pregnant woman (multiparous) interview 11, page 3 line 10.

"I don't go to the dentist during pregnancy because the dentist would not treat me, I need anaesthesia for dental treatment and they avoid anaesthesia for pregnant women." Pregnant women (multiparous) interview 19, page 5 line 10.

"The dentist said she (the dentist) wouldn't provide any treatment for me, yes." Pregnant woman (multiparous) interview 15, page 6 line12.

"I went to the dentist during the first trimester he did not provide any treatment for the dental pain. After completing the first trimester, I went back to the dentist and he asked me to check with my doctor first whether she agreed or not for me to have dental treatment, I had a medical clearance from her and received dental treatment." Pregnant woman (multiparous) interview 6, page 6 line 8.

Women lacked knowledge in a number of oral health areas including simple oral hygiene, dental and gingival health, dental visiting and oral health during

pregnancy. Women reported never receiving any type of education or information regarding oral health during pregnancy. It would appear that oral health education is needed urgently amongst pregnant Kuwaiti women to provide basic oral health knowledge and information.

Table 4.2 column one summarises and presents the current evidence-based dental health education key messages for adults, including pregnant women, derived from the recent literature. In column two of Table 4.2 this is contrasted with knowledge of dental health key messages held by women in the study sample. The table shows the very low level of knowledge concerning oral health amongst participants. In comparing the two columns, it is clear that almost all the women's knowledge and information was incorrect and inaccurate.

Table 4.2: Kuwaiti pregnant women's knowledge of key dental health education messages

Key messages for dental health education derived from the literature	Women's current levels of oral health knowledge (derived from qualitative study)
Toothbrushes	
- Adults should use a small headed brush with soft bristles to maximise the efficiency of plaque removal. - Adults should brush their teeth twice a day for a minimum of two minutes. - It is essential to brush before bed time and any other occasion during the day - Brushing twice a day with fluoride toothpaste is efficient in reducing tooth decay. - Brushing twice a day for two weeks will stop gums bleeding. All recommendations sourced from DH/British association for the study of community dentistry (2009).	- Using toothbrushes that have medium or hard bristle. ✗ - Brushing twice to three times a day. ✓ - Stop brushing during the first three months of pregnancy due to pregnancy sickness. ✗ - Stop brushing and reduce the time of tooth brushing due to bleeding gums. ✗ - Don't know the proper method of brushing. ✗ - Brushing techniques: side to side, up and down, or circular motion. ✗

Toothpastes	
• Adults should brush their teeth twice a day with fluoridated toothpaste to prevent dental decay. • The action of brushing and plaque removal prevents gum disease. All recommendations sourced from DH/British association for the study of community dentistry (2009).	• Choosing toothpaste that contains mints to make the mouth fresh. ✘ • Choosing toothpaste that is red colour to make the gums pink and healthy. ✘ • No specification, use any toothpaste. ✘
Dental flossing	
• Adults should clean between their teeth once a day by using dental floss or interdental brushes. All recommendations sourced from DH/British association for the study of community dentistry (2009).	• Either no information or knowledge of dental floss or know about dental floss but never use it. ✘
Oral health	
• Adults should brush their teeth twice a day with fluoridated toothpaste to prevent tooth decay. • Adults should be encouraged to spit out excess toothpaste or to rinse with small amount of water. • Adults should control sugar intake by limiting to mealtimes to prevent dental decay. All recommendations sourced from DH/British association for the study of community dentistry (2009).	• Drinking cold and hot drinks or water affects oral health. ✘ • Drinking cold or hot drinks led to weakened teeth and decay. ✘ • Eating food contacting sugar causes tooth decay. ✓ • Tea and coffee causes decay ✘ • Eating something very sweet would hurt the tooth (eating sweets causes tooth ache). ✓ • Smoking affects the colour and the shape of the teeth. ✓✘
Gum health	

• To prevent gum disease:
  ○ Adults should brush their teeth systemically twice a day by using soft and small headed toothbrush.
  ○ And should floss once a day before bed time.
 	
All recommendations sourced from DH/British association for the study of community dentistry (2009).
	• Bleeding gums may have an effect on the foetus. ✘
	• Don't know the reasons for gum inflammation. ✘
	• Nothing affects the gums. ✘
	• Spices and citrus food such as lemon and orange may inflame the gums. ✘
	• Inflamed gums are characterised by bleeding, bad smell and dark colour. ✓
	• Do not have any information about the reason for increasing amount of gum bleeding during pregnancy. ✘
	• 'Tooth brush sensitivity' is the reason for bleeding during brushing. ✘

- Pregnancy does not affect the gums. ✘
- Dark gums contain dried blood which can be cured by rinsing with warm water and salt for five minutes. ✘

Pregnancy and oral health

- Maintaining oral health during pregnancy is essential.
- Pregnant women should brush their teeth systemically twice a day by using soft and small headed toothbrush and fluoridated toothpaste.
- Pregnant women should brush their teeth twice a day for a minimum of two minutes before bed time and on any other occasion during the day.
- They should floss once a day before bed time.
- Pregnant women should be encouraged to spit out excess toothpaste or to rinse with small amount of water.
- Control sugar intake by limiting to mealtime to prevent dental decay.
- Pregnant women should visit the dental clinic regularly.
- Avoid frequent intake of acidic foods or drinks – keep them to mealtimes.
- Do not brush immediately after eating or drinking acidic food or drinks.
- Do not brush immediately after vomiting.
- Chew sugarless or xylitol-containing gum after eating.
- Use a teaspoon of baking soda (sodium bicarbonate) in a cup of water as a rinse after vomiting to neutralise acid.

   All recommendations sourced from New York State Department of Health (2006).

- The mouth and pregnancy are not connected. ✘
- Pregnancy is below (part of the body) and the mouth is up (in the face) - how they would connect? ✘
- Having pain in the teeth during the first three months of pregnancy is normal. ✘
- Don't have any information about pregnancy and oral health. ✘
- Never have had any advice or education concerning oral health during pregnancy. ✘
- Increase tooth brushing to avoid tooth decay during pregnancy. ✘
- Stop brushing during the first three months of pregnancy due to pregnancy sickness. ✘
- Stop brushing and reduce the time of tooth brushing due to bleeding gums. ✘
- Bleeding gums are normal during pregnancy. ✓ (It happens if plaque is present!!)
- Dental treatment is not safe during pregnancy, it harms the fetus. ✘
- Drinking a lot of milk during pregnancy avoids tooth ache. ✘
- Tolerating the dental pain during pregnancy is what pregnant woman can do to protect her fetus. ✘
- Pregnancy increases the rate of tooth decay. ✘
- Fetus absorbs the calcium from mother's teeth and bone. ✘
- Pregnancy weakens the teeth. ✘
- Having tooth ache during pregnancy is due to calcium deficiency (the fetus absorbed calcium from the teeth and bone). ✘
- Drinking milk will give back the calcium that has been absorbed and prevent tooth ache during pregnancy. ✘

	• Taking calcium prevents the tooth ache during pregnancy. ✗
	• Losing a tooth with each pregnancy is normal. ✗
	• The teeth may be weaker after the birth. ✗

Regular dental visits	
• Adults should visit dental clinic regularly	• Dental treatment is not safe during pregnancy, it harms the fetus. ✗
• Dental care is safe and effective during pregnancy.	• Tolerating the dental pain during pregnancy all what pregnant woman can do to protect her fetus. ✗
• Pregnancy by itself is not a reason to postpone routine dental care and necessary treatment for oral health problems.	
• First trimester diagnosis and treatment, including needed dental x-rays, can be undertaken safely to diagnose dental disease that need immediate treatment.	
• Dental prophylaxis and treatment during pregnancy should be preferably undertaken during early second trimester but definitely prior to delivery.	
• Emergency dental care is safe at any time during pregnancy.	
• Check with your GP and OBs re any problems with your mouth and need to attend the dentist (New York State Department of Health 2006).	
All recommendations sourced from New York State Department of Health (2006).	

✓=correct information; ✗= incorrect information

4.4.2.2   Cultural beliefs about oral health and pregnancy

There were some cultural beliefs which indicated that women thought that

pregnancy had a bad effect on their long term oral health, these beliefs were

possibly inherited from parents, family and friends. Most of the pregnant Kuwaiti

women believed that a woman tended to lose a tooth with each pregnancy.

"I knew several pregnant women who extracted 2 or 3 teeth because of pregnancy then they only have 5 to 6 teeth left and they said that we lost a tooth with each pregnancy." Pregnant woman (multiparous) interview 14, page 7 line 20.

"It is normal to have dental pain during pregnancy." Pregnant woman (multiparous) interview 14, page 6 line 19.

There was a common belief that pregnancy caused and/or accelerated dental decay. Most of the participants believed that it was normal to have dental pain, mostly during the first trimester of pregnancy. A small number of the participants believed that increasing the frequency of tooth brushing per day might avoid dental decay during pregnancy. Some women believed that pregnant women must tolerate dental pain during pregnancy to protect her foetus from the possibility of harm from dental treatment.

"I have dental pain from the first three months of my pregnancy; I can't do anything just take Panadol (paracetamol." Pregnant woman (primiparous) interview 7, page 3 line 11.

Women were able to provide plausible explanations for why their teeth were more vulnerable during pregnancy in biological terms. They believed that the foetus absorbed the calcium and Vitamin D from the mother's teeth. They also believed that drinking milk during pregnancy would replenish the absorbed calcium and Vitamin D. This biological explanation was further corroborated by another belief,

which attributed pain in the teeth and bone to losing calcium and Vitamin D during pregnancy. This pain could also be treated by drinking milk. This belief was reinforced by medical professionals in Kuwait. Some women reported that the obstetricians told them to drink a large amount of milk to avoid dental pain and to replace the depleted calcium.

"As I am pregnant and scared for my baby, you know – it [the baby] absorbs everything. They [her family and friends] told me to take care, so as a rule I compensate wherever I can. It absorbs all the calcium from the bones and teeth. They [her family and friends] told me that after the pregnancy my teeth would fall out, you'd feel they're falling out." Pregnant woman (nulliparous) interview 13, page 5 line 10.

"I had a toothache from the beginning of my pregnancy until the eighth month of pregnancy. My doctor told me this was because of a calcium deficiency, and she prescribed special milk – milk formulated for babies that has high amount of calcium." Pregnant woman (multiparous) interview 6, page 5 line 1.

Most of the pregnant Kuwaiti women also believed that dental treatment might affect the foetus' health. The majority of participants said they avoided going to dental clinics during pregnancy even for dental pain or emergency dental treatment because they believed that dental treatment would harm their foetus. Participants

who were having a course of dental treatment stopped their dental treatment when they knew that they were pregnant.

> *"The pulp of this tooth (upper right first molar) is infected, I can't have it treated. I am afraid that dental treatment would affect my baby." Pregnant woman (multiparous) interview 3, page 3 line 7.*

> *"When they (family) told me that I must not receive dental treatment during pregnancy; I became afraid that dental treatment may harm my baby." Pregnant woman (nulliparous) interview 8, page 4 line 7.*

It appeared also that this belief was reinforced by their dentists.

> *"I had dental pain from the first three months of pregnancy so I went to the dental clinic; the dentist told me that he couldn't treat me or prescribe antibiotics, so he told me to take Panadol." Pregnant woman (primiparous) interview 7, page 3   line14.*

Few women if any challenged the oral health information enshrined in these cultural beliefs about oral health.

It was clear that cultural beliefs received from parents, family and friends had a significant role in shaping perceptions of dental health during pregnancy. All of these unhelpful cultural beliefs needed to be corrected. Unfortunately, the oral and health care workers reinforced these beliefs instead of correcting them (according to the participants). It would appear that pregnant Kuwaiti women needed a comprehensive health education programme to receive correct knowledge and

information regarding oral health and pregnancy which might have an impact in changing in women's beliefs and attitudes.

4.4.2.3   Motivation and laziness

Maly khalg is a Kuwaiti term that has been used to represent several different meanings: lack of motivation, laziness, not in the mood to do things.

A small number of pregnant Kuwaiti women considered dental treatment safe during pregnancy, but *maly khalg* was cited as the reason for not seeking the needed oral health care. *Maly khalg* was also used as an excuse by a few of the participants, who reported that they knew that they should brush their teeth twice a day.

None of the participants reported visiting the dental clinic for regular preventive dental visits. In general, participants lacked motivation and did not wish to seek dental care for needed dental treatment or perform the correct daily oral hygiene routine. This might be related to the lack of knowledge and underestimation concerning the importance of oral health during pregnancy. These women did not have accurate information regarding oral health and pregnancy. But even in women who felt a need and reported that they thought dental treatment was safe, *maly khalg* was a strong influence.

> *"I am not feeling any pressure when pregnant to brush my teeth, but I am always lazy and don't move." Pregnant women (nulliparous) interview 12, page 6 line 23.*

"I have toothache and I know that visiting the dentist and having my teeth treated during pregnancy is safe, but I didn't go to the dental clinic because I am not motivated (maly khalg)." Pregnant woman (multiparous) interview 3, page 4, line 3.

4.4.2.4 Barriers to accessing dental health care and oral health knowledge
a. Beliefs about dental health care access

Women in the study believed that dental clinics in the government healthcare system would not provide dental treatment for pregnant women. Some participants reported that they thought that dental treatment could be provided for pregnant women in the second trimester but only after receiving medical clearance for treating a dental emergency, suggesting that few attended routinely for dental checking. A small number of women however did report that they received needed dental treatment in a private clinic during pregnancy. However, as reported earlier, some dentists themselves seemed to discourage dental treatment during pregnancy.

"When they (the dentist) knew I was pregnant, they told me 'to go away.' You can't visit dentists, and if you ask them anything they don't answer you properly, or they answer in just one word." Pregnant woman (nulliparous) Interview 13, page 6 line 32.

b. Unmet needs to oral health information

Few women felt a need to seek information on oral health from their dentist:

"Even the most senior doctors, not even ones who have just graduated, say, 'Hello, I have patients and I'm busy' etc., and you don't get anything [oral health information] from them." Pregnant woman (nulliparous) Interview 13, page 6 line 32.

This was the only woman who had sought advice, and she had been dismissed by her dentist because she felt he was too busy with other things.

"If you seek advice it's like you're taking up their time and if you are somebody's patient, they say 'OK, OK' and give you some treatment, but no one can really have words with them because they (the dentist) are under stress and anxious all the time." Pregnant woman (nulliparous) interview 13, page 7 line 2.

The only woman in our interviews who was aware of dental health during pregnancy and sought information was dismissed by the dentist. So the only source of information available was her family, friends and other pregnant women.

c. Lack of trust

A minority of women reported a lack of trust in dental treatment provided by the government healthcare system. Some women complained that they had received inaccurate diagnoses or had experienced poor quality dental treatment.

"Only one thing I didn't like. At my first visit, the dentist told me that I have nine teeth with decay, so he told me that in each dental visit he will treat one tooth. At the second visit, I found another dentist, who told me that I didn't

have any decay, he said you might be susceptible to dental decay, that my

teeth have deep fissures, so I don't need fillings. Now I have dark fillings

that look very bad and are not nice". Pregnant woman (primiparous)

interview 2, page 2, line 25.

4.4.3   Theoretical approach

4.4.3.1 Identification and categorisation of data into social cognitions

After identifying the key themes, the psychological theoretical constructs derived

from the literature on social cognitions (SC) was used as a tool to explore the study

themes. The SC components derived from the literature were mapped against the

raw data to identify the relevant theoretical constructs that might explain study

themes. Five social cognitions components could be identified from the data: oral

health knowledge, attitude, subjective norms, barriers to oral hygiene and dental

attendance, and intention to undertake mouth care and attend the dentist (see

Table 4.3).

In relation to the construct of knowledge, pregnant Kuwaiti women did not know

even basic oral hygiene information (except for tooth brushing frequency, reported

brushing once or twice per day) such as how to brush teeth effectively, select the

proper toothbrushes, use of dental floss as a hygiene aid, and how to choose

toothpaste. Pregnant Kuwaiti women had no knowledge of periodontal diseases

and were not aware of the causes of gingival bleeding. Most women thought that

bleeding gums were normal. Women did not have any accurate information

concerning pregnancy and oral diseases. Most women reported that having pain in

the teeth during the first three months of pregnancy was normal and many said that dental treatment was not safe during pregnancy because it might harm their foetus. Women also thought that pregnancy weakened the teeth and the foetus absorbed calcium from the mother's teeth and bones.

Obviously an oral health education programme is needed to address the oral health knowledge gap and correct the misinformation, as this lack of information is contributing to poor oral hygiene practices.

The attitude constructs which emerged from the data were based on the following findings: while the majority of the women reported they brushed their teeth twice a day, they stopped brushing during the first three months of pregnancy due to pregnancy sickness. The minority of women, who knew about dental floss, tended to avoid using it because they thought that it would harm their teeth. Most of the women expected to have dental diseases during pregnancy such as dental decay and tooth loss, and most reported that they would avoid dental treatment during pregnancy because it was unsafe. Women were mostly ambivalent about mouth care during pregnancy and dental attendance.

Attitudes are shaped based on the individual's knowledge, evaluations and experience. This study showed that Kuwaiti women had a very low level of knowledge concerning oral health which might possibly have affected their attitude towards oral health. Without access to information and skills (i.e. how to brush and to floss, the relationship between gingival and periodontal health during pregnancy) it is unclear how women might form different, more helpful attitudes. Thus women

need oral health education to identify the correct oral health information and knowledge that might enhance their attitude toward oral health.

The subjective norms construct, which is the perception of social norms and pressure to perform behaviour, is based predominantly on information provided by family members or friends. Friends and families were the people from whom most women reported that they had received their oral health information. This information was often inaccurate and was not challenged by participants. Some women reported that they had received information regarding the harm of receiving dental treatment during pregnancy from dentists and health care providers too. It was clear that family and friends' thoughts and information were important to participants. Providing oral health education might help women to consider and share the correct information and knowledge before they comply with their family and friends' advice.

Barriers relating to dental care were a lack of trust in state-provided dental treatment, the actualised experience of dentists refusing to treat women when pregnant and fear that mouth care and dental attendance might harm the foetus. This latter belief was supported and reinforced by the behaviour of dental and health care providers (according to participants). In providing accurate oral health information to women, it is possible that some of these reported access and treatment barriers could be reduced or eliminated.

In terms of the intention construct, this was deemed relevant as was based on the self-report intention of almost all pregnant Kuwaiti women to seek dental health care after giving birth. It is possible that correcting women's knowledge concerning

the importance of having optimal oral health before and during pregnancy, as well

as the safety of dental treatment during pregnancy, might help to encourage

women to plan to receive dental health care during pregnancy.

Table 4.3 presents the SC components that were identified in the study. In column

2 of Table 4.3 examples of women's knowledge, attitude, subjective norms,

barriers and intentions derived from the study data are presented.

Table 4.3: The social cognitions identified and categorised from the study with examples

Social Cognitions	Social cognitions identified in the study data
Oral health knowledge	Poor oral health knowledge in relation : Brushing • Using toothbrushes that have medium or hard bristles • Stop brushing during the first three months of pregnancy due to pregnancy sickness. • Stop brushing and reduce the time of tooth brushing due to bleeding gums. • Don't know the proper method of brushing • Brushing techniques: side to side, up and down or circular motion. Toothpaste selection. • Choosing toothpaste that contains mints to make the mouth fresh. • Choosing toothpaste that is red colour to make the gums pink and healthy. • No specification, using any toothpaste. Flossing • Don't know what a dental floss is. • Know about dental floss and never use it. Gum health • Don't know the reason for gum inflammation. • Nothing affects the gums. • Spices and citrus food such as lemon and orange may inflame the gums. • Tooth brush sensitivity' is the reason of the bleeding during brushing. • Dark gums contain dried blood which can be cured by rinsing with warm water and salt for five minutes Dental Decay • Drinking cold or hot drinks leads to weaken the teeth and

	decay.
	• Tea and coffee causing decay.
	• Eating something very sweet would hurt the tooth (eating sweets causes tooth ache).
	• Smoking affects the colour and the shape of the teeth
	Dental decay and pregnancy
	• Pregnancy increases the rate of tooth decay
	• The teeth may be weaker after the birth.
	Gum health and pregnancy
	• Do not have any information about the reason for increase in gum bleeding during pregnancy.
	Oral health and pregnancy
	• Pregnancy does not affect the oral health.
	• Pregnancy is down and the mouth is up (in the face) - how would be connected?
	• Having pain in the teeth during the first three months of pregnancy is normal.
	• Don't have any information about pregnancy and oral health.
	• Foetus absorbs the calcium from mother's teeth and bone.
	• Pregnancy weakens the teeth.
	• Never have any advice or education concerning oral health during pregnancy.
	Dental attendance and pregnancy
	• Visiting dental clinic only for emergency or having dental pain (not during pregnancy).
	• Dental treatment is not safe during pregnancy, it harms the foetus
	Sufficient oral health knowledge in relation to:
	Brushing
	• Brushing twice to three times a day.
	Gum health
	• Inflamed gums are characterised by bleeding, bad smell and dark colour.
	Gum health and pregnancy
	• Bleeding gums may have an effect on the foetus.
Attitude	Unhelpful attitudes towards oral health in relation to:
	Brushing and pregnancy
	• Stop brushing during the first three months of pregnancy due to pregnancy sickness.
	• Stop brushing and reduce the time of tooth brushing due to bleeding gums.
	Dental decay and pregnancy
	• Drinking a lot of milk during pregnancy avoids tooth ache.
	• Drinking milk will give back the calcium that has been absorbed and prevent tooth ache during pregnancy.
	• Taking calcium prevents the tooth ache during pregnancy
	Oral health and pregnancy
	• Losing a tooth with each pregnancy is normal
	• Oral health is not a concern during pregnancy

	Dental attendance and pregnancy
	• Tolerating the dental pain during pregnancy all what pregnant woman can do to protect her fetus
	• Avoid going to dentist during pregnancy.
	• Visit dentist during the last months of pregnancy only whenever having dental pain.
	Helpful attitudes towards oral health in relation to
	• Increasing tooth brushing to avoid tooth decay during pregnancy.
Barriers to behaviour around oral hygiene and mouth care and barriers to access	Barriers to mouth care
	• Stop brushing and reduce the time of tooth brushing due to bleeding gums.
	• Stop brushing during the first three months of pregnancy due to pregnancy sickness.
	• Do not have any information about the reason of increasing amount of gum bleeding during pregnancy.
	Barriers to dental access
	• Dentists avoid treating pregnant women.
	• Dental treatment during pregnancy would harm the foetus.
	• Laziness is the reason for not seeking dental treatment during pregnancy.
	• Cost of dental treatment (in private practice).
	• Lack of trust in dentist treatment (government dental clinic).
	• Long waiting list for dental clinic.
	• Working hours for government dental clinic and appointments.
Subjective norms	Unhelpful subjective norms in relation to:
	Friends and others say pregnant women should not go to the dentist during pregnancy
	• I didn't go to the dentist because my family said the dentist would refuse to treat me, he/she would give me painkiller.
	• My friends told me don't go to the dentist; dentist did not provide a treatment for pregnant women.
	• My family told me that I could not go to the dental clinic during pregnancy.
	• There were twenty women and they were all told the same thing' dentists did not treat pregnant women'
	Friends and others say pregnant women are told by dentists that the baby absorbs calcium from the teeth which cause dental pain.
	• My friends told me that they were complaining from their teeth during pregnancy and the dentist told them this was because the baby absorbed the calcium from their teeth.
	Helpful subjective norms in relation to :
	Friends and others say pregnant women can use some products for mouth care
	• My mother always told me that water and salt acts as an antiseptic.

Intention	Helpful Intentions
	<u>Intentions reported to clean teeth after pregnancy is over</u> • I intended that I will clean my teeth after giving birth. Intentions reported to have dental treatment (extractions) after pregnancy • I have tooth ache and I am going to extract my teeth after giving birth. Intentions reported to attend the dentist for a check-up once the pregnancy is over • After giving birth I will go to the dentist to check up on my teeth.

4.5 Discussion

The pregnant Kuwaiti women who were the participants in this qualitative study had very poor oral health knowledge. They lacked very basic oral knowledge and health information concerning how often to brush their teeth, reasons underpinning simple oral hygiene routines or the causes and symptoms of oral diseases. Furthermore; the participants were unaware of the effect pregnancy could potentially have on oral health. Cultural beliefs about oral health and pregnancy were unhelpful in the sense that women had seemingly logical, pseudoscientific explanations (though incorrect) for how pregnancy damaged teeth. These beliefs influenced women's attitude to oral health. For example, women avoided or stopped dental care during pregnancy because they believed that dental treatment harmed their unborn baby, they thought that dental pain was common and ordinary during pregnancy and that drinking milk could cure the pain during pregnancy. No woman questioned the accuracy or validity of the information enshrined within these cultural beliefs. This is surprising given that some of these women were well educated and many have had access to information from many other data sources, including the internet. At the same time women expressed an interest in getting more information. That may have been stimulated to do so by the study interviews.

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Women also held fatalistic views about the inevitability of oral disease and their ability to prevent or control it. Most participants had acquired a perception that dentistry was unsafe during pregnancy, though few had expressed any need for dental care. The very few participants who considered dental treatment safe during pregnancy reported that they lacked motivation and were reluctant to seek dental care. The reasons for this lack of motivation were unclear. It might be a result of their poor knowledge concerning oral health and pregnancy; some was explained by the women as 'maly khalg' - a general feeling of apathy. This apathy was related to life in general and was not confined to dentistry or feelings about going to the dentist. Barriers that prevented access to oral health care and knowledge were also identified.

Five social cognition components were identified which are known to determine behaviour. The five components were: knowledge, attitudes, subjective norms, barriers and intention.

It was clear from the interviews that Kuwaiti women initially felt that they had good oral health knowledge; they looked at the researcher with surprise when asked about the oral health in general and the relationship between oral health and pregnancy. Initially some clearly felt that these questions were ridiculous. Women thought that they had enough information and knowledge about oral health. During the course of the interviews they appeared to realise that they did not have sufficient information concerning oral health (e.g. tooth paste selection and/or the causes of bleeding gums) and oral health and pregnancy. They tried to answer the questions, but they did not have adequate information to answer. They became increasingly aware of the gap in their knowledge. They used phrases such as: 'I

don't know what to tell you'; 'I don't have any idea about pregnancy and oral health'; 'I never thought of this'; and 'is there any connection between pregnancy and oral health?' By the end of the interviews women complained about their lack of oral health knowledge and blamed the health care system, dentists and their doctors for their poor levels of oral health knowledge. In addition, they asked several questions regarding oral health and suggested several methods for health care professionals to deliver oral health education to pregnant women. They requested a written flyer or booklet concerning oral health education in general and during pregnancy in particular; some suggested that oral health education should be part of the monthly maternal care they received in maternal clinics.

The women's questions regarding oral health were answered by the researcher at the end of the interviews. The interviews might have stimulated women's concerns about oral health. It might also have encouraged women to ask several questions concerning their oral health as well as that of their children and relatives. For example at the end of the interview, the researcher answered questions related to oral hygiene such as brushing and flossing techniques and the selection of tooth brushes and tooth paste. Women wanted to know what gum disease was and how to cure it. They also asked about their oral health during pregnancy, as well as their children's oral health.

The findings in this study confirm the study by Honkala and Al-Ansari (2005), who found that expectant mothers had oral health problems, were fearful of dentistry and had little awareness of the importance of oral health during pregnancy. But in contrast to Honkala and Al-Ansari, this study gave an insight into the level and specifics of the oral health knowledge gap held by Kuwaiti women. It also provided

insight into important cultural beliefs and barriers to mouth care and oral health care. For instance this study found that pregnant Kuwaiti women avoided dental treatment during pregnancy not because they were afraid of dental treatment but because they thought that dental treatment might harm their unborn baby; they considered dental pain normal and common during pregnancy, and believed that it could be cured by drinking milk.

The findings from this study are also consistent with those from other countries and settings. Hashim (2012) and Ozen et al. (2012) also found that pregnant women experienced dental problems, avoided dental treatment during pregnancy, were irregular dental attendees and held incorrect beliefs regarding dental health during pregnancy. The idea of 'losing a tooth for every pregnancy' is a common belief amongst pregnant women in more than one setting. Poor oral health knowledge, the lack of connection between poor oral health and pregnancy and the avoidance of dental care during pregnancy found in the present study was also reported by Scambler (UK: 2010), Detman (USA: 2010) and Keirse and Plutze (South Australia: 2010). In contrast to the present study however, pregnant women in the United Arab Emirates and Turkey appear more aware of the relationship between pregnancy and oral health. It is interesting that Kuwaiti women have poorer knowledge than some of their nearest neighbours.

The underestimation and lack of awareness of oral health amongst pregnant Kuwaiti women might be potentially explained by the way in which oral health services are delivered in Kuwait. Oral health services mainly concentrate on treatment for pain relief and dental emergencies (Behbehani and Scheutz, 2004). The oral health care system in Kuwait either has no place for or attributes low

priority to oral heath prevention and education. There are no clear strategies for oral health prevention, education or regular check-ups, for adults in general or for pregnant women in particular. Preventive services are available only for children in kindergartens and primary schools (Behbehani and Scheutz, 2004). This hypothesis is supported by a study of Kuwaiti adults' oral hygiene knowledge and practice, which confirmed that oral health knowledge was poor, and that most adults reported multiple oral health problems which were all readily preventable (Al-Shammari et al., 2007a). Another study by Al-Shammari et al. (2007b) assessed the barriers to seeking preventive dental care by Kuwaiti adults. The authors found that 57% of the participants did not have preventive dental care due to a belief that visiting the dentist was only necessary for dental emergencies or pain relief. It would appear that the belief that dental care is only necessary for treatment of disease is reinforced by the way it is delivered in Kuwait. Adults in Kuwait do not attend the dentist for check-ups because they are not aware that they are important, nor does the system provide preventive dental care.

All of the barrier themes that emerged from this study might be considered barriers for pregnant Kuwaiti women in adopting positive oral health behaviours. Barriers to oral health access have been classified by the Federation Dentaire International (FDI) into three main factors: the first was patient factors such as lack of perceived need, anxiety, and lack of access (Cohen, 1987). The second factor was health care professions, including factors such as inadequate manpower resources, training inappropriate to changing needs and demands and insufficient sensitivity to patients' needs (Cohen, 1987). The third factor was insufficient public support of attitudes conducive to health, inadequate oral health care facilities, inadequate oral

health manpower and insufficient support for research by the government (Cohen, 1987). In the present study, the barriers that prevent access to oral health care in Kuwait might be categorised into the three main elements of the FDI classifications: the first element was related to the pregnant women themselves, who lacked a perceived need for oral health care due to a lack of oral health knowledge, cultural beliefs and a lack of motivation. Women also lacked access; they reported that dentists avoided giving dental treatment to pregnant women. The second element was the unhelpful attitude held by dentists. According to the participants in this study, dentists were not happy to treat pregnant women or to give any oral health advice or information. Kuwaiti dentists themselves may need appropriate training to understand and provide dental care for pregnant women. The third element was the Kuwaiti Ministry of Public Health. As noted above, the latter was responsible for the delivery of dental services. There was a lack of access to dentists who were happy to treat pregnant women and a lack of provision of preventive services. Women indicated a lack of trust in dental treatment provided by the state health system, and obviously lacked access to oral health knowledge. The third element would also be related to the approach to the delivery of dental services in Kuwait. Currently, dental services are treatment orientated and provided in response to necessary clinical treatment. There is no preventive dental service element provided to adults in Kuwait. Thus the barriers to oral health knowledge and oral health care are embedded and perpetuated by how the health care system is delivered.

In this study, Kuwaiti women had very low levels of oral health knowledge and there was an absence of oral health resources to provide accurate oral health

information. This lack of emphasis was further compounded by the way in which health care was delivered. Thus, it is argued that pregnant Kuwaiti women did not have sufficient oral health knowledge and information to make appropriate decisions concerning their oral health.

It would appear that medical and dental professionals who might be expected to fill this information gap also had poor knowledge and understanding of the relationship between oral health and pregnancy, so future work should focus on training Kuwaiti dental and health care professionals about prevention. Dentists in this study (according to the participants) appeared to suggest that dental treatment might not be safe, while medics (according to the participants) were advising women to drink milk to cure dental pain caused by low calcium. It is clear that there is a need for dental health education amongst dentists and health care workers looking after pregnant women in Kuwait.

Western health psychologists have examined the social psychological theories of health research in order to understand how to predict and to change health behaviours. They have designed interventions based on social psychological theories to understand and change modifiable health behaviours. Social cognition models (SCMs) are currently the most frequently used theories used to explore and understand health behaviours (Conner and Norman, 2007). At the same time, as shown in the previous chapter, SCMs do not reliably predict behavioural changes. It has been suggested (Asimakopoulou and Daly, 2009) that SCM is not a 'one size fits all' event and perhaps individual components from SCMs may be more helpful in designing interventions than the model as a whole.

Recently, a move away from using SCMs to help support behavioural change has taken place and alternative theories are currently at the forefront of the behavioural change arena. One of these is the COM-B model (Michie et al., 2011). The COM-B components are capability, motivation and opportunity. They are said to interact and underpin behavioural change (Michie et al., 2011). COM-B suggests that it is important to change the capability, motivation and opportunity to change behaviour (Michie et al., 2011). Capability is concerned with the ability of the individuals to engage in a specific behaviour based on having the necessary knowledge and skills to accomplish it. Motivation is concerned with the individual's strong ability and intention to perform the target behaviour as well as making a clear decision regarding the behaviour. Opportunity is concerned with environmental factors that lie outside the individual's ability to perform and endorse the behaviour (Michie et al., 2011). This behavioural system helps understand some of the major determinants of why behaviour may or may not be performed. The system also aids in determining any limitations of behaviour and what needs to change in order to change behaviour (Michie et al., 2011). So in applying this system to the social cognitions which seemed to be important in explaining poor oral health behaviour, it could be argued that pregnant Kuwaiti women currently do not fulfil any of these three factors to perform positive oral health behaviours. The participants had poor knowledge concerning dental health (capability), did not have the motivation to engage in optimal oral health behaviour and lacked the opportunity due to barriers to access dental health knowledge and care.

In this case, it could be reasoned that the dental health education intervention has to start from one very basic point and that is to address capability; in order to be

capable of improving one's oral health it is obvious that some correct knowledge about the topic will be needed. Thus, the most plausible, obvious first step of any intervention would be to start with providing and correcting women's oral health knowledge.

The social and behavioural literature has emphasised the importance of underpinning behavioural change interventions with a theoretical framework (Abraham et al. 2009; Michie et al. 2013). However, although this aspiration is clearly put forward in the literature, detailed guidance of which psychological theory should be used and under what circumstances is non-existent (Michie et al. 2013). In this study the identified social constructs which appeared to be important in shaping behaviour were poor knowledge, unhelpful attitudes and subjective norms, barriers to accessing dental health care and oral health knowledge. On a positive note many pregnant women expressed the intention to clean their teeth and attend the dentist once their pregnancy was over. So supporting women to act on this intention would be crucial.

Thus, changing the oral heath behaviour of pregnant Kuwaiti women might be facilitated by a social cognition approach. The use of social cognition models has been used frequently in western countries, especially in Britain for many years, but has never been used in Middle Eastern countries including Kuwait (except Iran). Indeed there is emerging evidence that relying on one model alone is flawed (Asimakopoulou and Daly, 2009).

According to the COM-B system, pregnant Kuwaiti women lacked capability, opportunity and motivation. It is clear that low levels of basic oral health knowledge

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and information prevented women from engaging and changing their health behaviour. It is well known, however, that behaviour does not change simply as a result of education (Conner and Norman, 2007). Education may impact knowledge, but such changes do not necessarily translate into behavioural change (Conner and Norman, 2007). However, the oral health intervention has to start at a level that is appropriate for participants. Thus, it was decided that the dental health education intervention should start with capability as a first step to provide and correct oral health knowledge that might encourage women to engage in proper dental health behaviour.

4.5.1 Quality of qualitative study

The Cabinet Office, the Government Chief Social Researcher's Office in the UK (Spencer et al., 2003), has designed and published a quality framework to assess and evaluate the quality of the qualitative research. The framework has considered several methods used in qualitative studies such as interviews, focus groups, observation and documentary analysis. It contains four main research guiding principles: *contributory*, *defensible in design, rigorous in conduct* and *credible in claim.*

The first principle was contributory, which means that the research should provide broader knowledge and understanding in a particular field. Before undertaking this study, the researcher attended training courses in qualitative interviewing, data handling and data analysis led by Liz Spencer, who is a well-known expert in qualitative research. This included observation and training of the researcher in interviewing techniques.

In order to develop the topic guide, the researcher undertook a comprehensive review of the literature to develop an understanding and knowledge of current evidence-based guidelines and state of knowledge concerning oral health and pregnancy, as well as studies describing the oral health knowledge amongst pregnant women in Kuwait and in other countries.

As it was important to understand the specific context of how oral health care is delivered in Kuwait, the researcher also developed an understanding of the maternity care system in Kuwait to help in selecting the most appropriate maternity centres in which to undertake the study.

The second principle was defensible in design, which means a qualitative approach was used as it was the most appropriate method to answer the research questions. In this study, the researcher selected maternity centres that provided a private room to interview women confidentially and to allow them to talk freely and in depth without any distractions. The researcher also selected different maternity centres across Kuwait to ensure variety in the social and cultural contexts of the target group. The inclusion and exclusion criteria were determined before undertaking the study. The researcher presented herself as a PhD candidate, and did not mention that she was a dental hygienist to avoid the impact of the researcher on the participants.

The third principle was rigorous in conduct. This means that the research should be accomplished by systematic collection, analysis and interpretation of the qualitative data. The researcher applied this principle by using a topic guide to ensure the systemic conduct of the interviews. The first three interviews were

translated into English on the same day and sent to the co-researchers to obtain their comments and enquiries regarding the questions and interviews, in order to update the topic guide before completing the interviews.

The interviews were audio taped and transcribed verbatim. Several women considered audio recording culturally unacceptable, so the researcher explained to them that these tapes would be used only for the research purpose and only the researcher would listen to these tapes. Most of the women were convinced and a small number refused as they believed that they needed their partner's approval.

The analysis started from the first interviews by using the framework approach described above. Selected transcripts were translated into English to enable preliminary analysis, discussion of themes and approaches to thematic analysis with the co-researchers, who were not Arabic speakers. These transcripts were then back-translated to Arabic to ensure the accuracy of translation. The transcripts were translated twice by different translation agents to ensure the quality and accuracy of the translation.

The last principle was credible in claim, meaning that the research should offer well–founded arguments about the importance of the evidence generated. This research addressed a gap in knowledge by providing new information, explanations and clarifications concerning oral health amongst pregnant Kuwaiti women. This research also clarified the social and cultural context underpinning the oral health behaviour amongst pregnant Kuwaiti women.

4.5.2 Limitations of the study

This study had a number of limitations. One issue was that this study investigated perceptions, beliefs and attitudes that affected oral health behaviour only amongst pregnant Kuwaiti women who attended government maternity clinics. It would be important to include pregnant Kuwaiti women who sought maternal care from private maternity clinics for a better understanding of oral health behaviour amongst Kuwaiti women during pregnancy. In addition, many pregnant Kuwaiti women refused to participate in this study. Two main reasons were cited: they refused to have their voices recorded, as this was considered culturally unacceptable, and they were uncomfortable with discussing their oral health. So it is possible that those women in most need, or those who were most influenced by cultural factors, were omitted from the study.

Another issue to consider is the purposive sample. It was hoped to approach pregnant women from a diverse range of age groups, educational background, gestation period and number of pregnancies. However the researcher could not select the sample to ensure such diversity because of the small number of the pregnant women who visited the maternity centre at the interview time. Also several women refused to participate, as mentioned above, either because they needed permission from their partner or they were uncomfortable talking about their oral health. Nevertheless the sample did include a diverse range of women in terms of backgrounds, socioeconomic status and surprisingly highly educated women.

Another issue to consider is reflexivity. The researcher was Kuwaiti and has had children and so may have been very aware of subtle nuances and cultural

practices. However the researcher is a dental hygienist and has worked for many years treating women who have plaque induced disease during pregnancy. It is possible that this experience could have biased interviews or affected their interpretation. The use of an additional researcher to independently code the reviews may have gone some way towards addressing this potential bias. However, the researcher was surprised at the low level of oral health knowledge, which was much higher than she had experienced in her clinical practice in Kuwait.

Another possible limitation is socially desirable responding. Many women may not have accurately reported their oral health behaviours because they were embarrassed to report less than optimal behaviours. But, given the low levels of oral health knowledge within the group, it seems unlikely that this occurred. Indeed the low levels of knowledge were reported in other quantitative studies in Kuwait (Honkala, Al-Ansari, 2005).

An additional limitation concerns oral and health professionals. The professional's attitudes and behaviours in this study are presented based on pregnant Kuwaiti women's views and experiences. Since the aim of this study was to investigate pregnant Kuwaiti women's perceptions and beliefs concerning oral health, the researcher did not interview the oral and health care professionals in order to investigate the accuracy of the reported information. Future research should investigate dentists and health care team attitudes to oral health and pregnancy to confirm and challenge the findings from the present study.

4.6   Conclusion

This study provided an in-depth understanding of pregnant Kuwaiti women's perceptions, beliefs and attitudes in relation to oral health. The women had low levels of oral health knowledge and information. They had unhelpful cultural beliefs concerning oral health during pregnancy, and were unaware of the effect of pregnancy on oral health. Pregnant women lacked motivation to seek dental care even when they considered dental treatment safe during pregnancy. The attitudes of dentists, unhelpful cultural beliefs and a lack of motivation were identified as barriers to accessing oral health care and seeking oral health knowledge.

The emerging themes showed that pregnant Kuwaiti women lack all three components of the COM-B model's factors to change their oral health behaviour. The participants lacked capability, motivation and opportunity, which are considered significant factors in changing behaviour. As a result, the first stage of changing oral health behaviour would be to correct and improve oral health knowledge and skills (capability), which might in turn change pregnant women's attitudes, beliefs and behaviours towards oral health.

The study indicates a need for dental public health strategies to establish an oral health plan that aims to improve and change pregnant Kuwaiti women's knowledge, attitudes, beliefs and behaviours concerning oral health, but also the knowledge and attitudes of dentists and other health care workers looking after women before and during pregnancy.

Chapter 5

The effect of dental health education with or without a planning intervention on adherence to dental health related behaviours in pregnant women: A Randomised Controlled Trial

5.1 Introduction

The qualitative study described in chapter four provided an understanding of Kuwaiti pregnant women's knowledge, perceptions, beliefs and attitudes concerning dental health in general and during pregnancy in particular. The qualitative study primarily found women lacked basic knowledge and held incorrect information concerning dental health. The following barriers were identified that inhibited pregnant Kuwaiti women to undertake positive dental health behaviours: lack of dental health knowledge, a perception that dentists were too busy to give dental health advice, and the negative attitudes and beliefs held by women in relation to dental health and behaviours. Five social cognition constructs (knowledge, attitudes, subjective norms, barriers to accessing dental health care and intention) were identified that might help to change and improve pregnant Kuwaiti women's behaviour towards dental health.

The most notable finding from the qualitative study was the overall lack of basic dental health knowledge amongst women. This finding was not particular to pregnant women; it was a general trend noted amongst adults in Kuwait and in line with previous work (Al-Shammari et al., 2007; Al-Hussaini et al., 2003) . Abraham et al. (2009) considered that knowledge was a first key psychological target in a behaviour change intervention to assist participants to acquire accurate information and knowledge about their health behaviour. So, the main focus of the proposed intervention would simply emphasise providing and correcting dental health knowledge amongst pregnant Kuwaiti women as a first step to correct their dental health behaviour. There was no attempt to define a more complex intervention.

The intervention design was based on the Consolidated Standards of Reporting Trials guidance (CONSORT) (Moher et al., 2010) which provides guidance on reporting and quality standards in the conduct of randomised controlled trials (RCTs). This allows an evidence-based and high quality RCT to be presented. CONSORT guidance has been used widely and is now followed by the most recent RCTs (Gouttebarge et al., 2014; Proudfoot et al., 2013; Samaan et al., 2013; Ramírez et al., 2011; Jonsson et al., 2009).

The following sections first justify the role of changing knowledge in enhancing and changing health behaviour in the proposed intervention. Then, a justification of the planning component is provided. The researcher decided to assess planning in this intervention as the literature has highlighted the efficacy of planning in changing and enhancing health behaviour (Pakpour and Sniehotta, 2012; Suresh et al., 2011). Finally there is an explanation of dental health adherence as it was the main outcome of this intervention.

5.1.1 Justification of changing knowledge

While the study was designed to tackle the five social constructs identified in the qualitative study, the main focus would primarily be on improving and correcting dental health knowledge amongst pregnant Kuwaiti women. Abraham et al. (2009) considered that knowledge was a first key psychological target in a behaviour change intervention to assist participants to acquire accurate information and knowledge about their health behaviour. In addition, according to the COM-B model, capability (knowledge) is one of three significant elements (Capability, Opportunity and Motivation) in understanding behaviour change. It is known that although knowledge is necessary for the uptake of health behaviour, it is not

sufficient for the adoption of health behaviours (Conner and Norman, 2007). The researcher identified the target group needs in the qualitative study and decided to start an intervention at a level appropriate for the participants. It was thought that providing basic dental health knowledge for pregnant Kuwaiti women would be important and appropriate as a first step for participants who had low levels of dental health knowledge. Thus, the intention in this intervention was to focus primarily on knowledge. The method chosen was a Dental Health Education (DHE) intervention.

Secondly, it was also considered important to assess the role of the other four identified SCM constructs (attitudes, subjective norms, barriers to accessing dental health care, and intention) identified in the qualitative study, in improving dental health behaviour amongst pregnant Kuwaiti women.

5.1.2 Justification for adding planning to the intervention

Planning was not identified in the qualitative study as a construct, but most women reported that they stopped brushing during pregnancy either because of pregnancy sickness or gingival bleeding. Kuwaiti women underestimated the role of dental hygiene in preventing dental diseases and the importance of maintaining good dental hygiene during pregnancy. Women reported that they usually brushed their teeth regularly (once to twice a day) before pregnancy. Almost all participants reported that they never used dental floss. So, it would be important to enhance and encourage women's adherence with tooth brushing and dental flossing effectively and regularly during pregnancy by conducting an action plan.

Implementation intentions encourage the individuals to plan and specify exactly

when, where, and how they will engage in a specific behaviour (I intended to do *x*

whenever the situational conditions *y* are met) (Gollwitzer, 1999). Dental studies

have found that implementation intention increased the chances of adherence with

dental hygiene behaviour (Suresh et al., 2011; Milne et al., 2002). Clarkson et al.

(2009) and Pakpour and Sniehotta (2012) demonstrated the importance of

developing an action plan to encourage regular tooth brushing. Schüz et al. (2006)

demonstrated the importance of developing an action plan to promote regular

flossing. Therefore, it was decided to include planning in this intervention to

encourage women to conduct a dental hygiene action plan and specify exactly

when, where, and how they would engage in brushing and flossing behaviours.

Thus, planning was added to the intervention.

5.1.3   Dental health adherence outcomes

Adherence is defined as 'the extent to which a person's behaviour, such as taking

medication, following a diet, and/or executing lifestyle changes, corresponds with

recommendations the person has agreed with a healthcare provider'

(Asimakopoulou and Daly, 2009, p. 626). Adherence is measured by whether or

not the patient adheres to suggested treatments or instructions. In terms of dental

health professionals, the key dental health education messages that dentists would

like their patients to adhere to are: brush teeth twice a day with fluoridated tooth

paste, floss once a day, reduce the consumption of sugar and visit the dentist

regularly (DH/British Association for the Study of Community Dentistry, 2009).

These key messages were to be addressed in the proposed intervention into the

written documents (leaflet and booklet) which was the mode of delivery of information requested by the participants in the qualitative study.

This intervention was designed to include three conditions; the first condition was a Treatment as usual (TAU) that provided a dental hygiene leaflet and demonstration of tooth brushing and dental flossing; the second condition provided a dental health education (DHE) booklet based on the SCM constructs which were verified as appropriate from the previous qualitative study. This would allow us to assess whether SCM-based DHE was better than standard care provided in TAU. The third condition provided TAU and the SCM-based DHE intervention plus a planning component to assess the effectiveness of planning and whether it would provide any additional benefits to SCM-based DHE.

Effective dental hygiene (tooth brushing and dental flossing) have been shown to be important in the prevention of dental and periodontal diseases (Turner et al., 1994). Failure to maintain good and effective dental hygiene might lead to dental and periodontal treatment failure. As a result, adherence with effective tooth brushing and dental flossing has the potential to maintain good dental health. In this intervention, the outcome examined was adherence with tooth brushing and dental flossing instructions. As we could not observe this directly, proxy measures were used. These were the Gingival Index (GI) (Loe and Silness, 1963*)* and the Plaque Index (PI) (Sillness and Loe, 1964). The use of PI and GI as proxies of adherence is well established in interventional studies of this type (Renz and Newton, 2009). Therefore in this study, adherence with dental health instructions with regard to plaque control was measured objectively by using two outcomes, the GI (Loe and Silness, 1963*)* and the PI (Sillness and Loe, 1964).

The GI was used as an objective measure of participants' adherence with regular and effective brushing and flossing. The GI was used to assess a change in severity of gingivitis based on colour, consistency and bleeding. A reduction in gingivitis would indicate at least a recent two week consistent improvement in dental hygiene behaviour (Lim et al., 1996). The GI would measure the gingival health changes between Time 1 and Time 2 of the proposed intervention and whether the participants adhered to the recommended dental hygiene measures. GI is an effective index to measure the gingival condition pre- and post-intervention (Darby and Walsh, 2009). Effective and regular tooth brushing and flossing are the most effective methods to prevent periodontal disease that is caused by dental plaque.

The PI was also used as a measure of participants' adherence to the DHE. The PI would assess the changes in plaque accumulation between Time 1 and Time 2 of the proposed intervention. PI would help in assessing the adherence to proper and effective tooth brushing and flossing techniques. It measures effective plaque removal in the last 24 hours.

In summary therefore, this intervention focused on providing women with dental health education during and after pregnancy to improve their dental health knowledge. The interventions also tackled the four constructs identified from the qualitative study. A planning element was also included to explore its usefulness in supporting behaviour change

5.2 Aim

The aim of this study was to assess the efficacy of dental health education (DHE) with or without a planning intervention on adherence with dental health-related behaviours amongst Kuwaiti pregnant women.

5.3 Research hypotheses

It was hypothesised that knowledge and social cognition constructs which underpinned the planning and delivery of the intervention would influence adherence with dental health behaviour (specifically self-reported and objective measures of dental hygiene behaviour).

It was further hypothesised that different levels of the intervention would affect psychological constructs levels in the three groups.

5.4   Methods

5.4.1 Participants

All Kuwaiti pregnant women who were in the second trimester of gestation (four to seven months) and attended the selected government maternity healthcare clinics from 8th of February 2011 to 30th of August 2011 were eligible and invited to participate in this study, regardless of whether they sought regular or irregular medical care during pregnancy.

5.4.2 Inclusion criteria

Participants were eligible for inclusion in the study if they complied with the following criteria:

- They were expectant mothers who were in the second trimester (4 to 7 months) of pregnancy and recruited from the selected government maternity healthcare centres.

- They provided informed consent.

- They did not have pregnancy complications such as high blood pressure and other pregnancy complications.

- They did not have chronic conditions which might have an impact on periodontal disease e.g. diabetes.

- They did not smoke or use tobacco.

- They agreed to follow up.

- They were Kuwaiti nationals.

5.4.3 Exclusion criteria

Participants were excluded from the study if any of the following criteria were present:

- They were not pregnant.

- They were pregnant in the first trimester.

- They were unable to provide informed consent.

- They had pregnancy complications.

- They had no teeth.

- They smoked or used tobacco products.

- They were not Kuwaiti nationals.

5.4.4 Recruitment

Participants were recruited from three maternity healthcare clinics which were part of the government primary healthcare centres provided by the Public Health Ministry of Kuwait: Qurain Primary Healthcare Centre, Al Riqqa Primary Healthcare Centre and Sabah Al Salem Primary Healthcare Centre.

The Kuwaiti pregnant women in this intervention were recruited from the same government maternity clinics which participated in the previous qualitative study, to build on the findings of the qualitative study and ensure the intervention was culturally sensitive and appropriate by using the same population. It was anticipated that understanding and insight into this population would be maximised.

The previous qualitative study undertaken with pregnant women indicated that most Kuwaiti pregnant women sought their maternal health care in private clinics and hospitals rather than government primary healthcare centres. In order to maximise recruitment, three government maternity healthcare clinics were selected which were known to have a high throughput of women and which would allow recruitment of the required number of Kuwaiti pregnant women. The researcher and a dental hygienist attended these clinics to recruit women from the waiting room of the maternity clinics.

Participants were invited to participate in this study by the researcher, dental hygienist and the nurses who worked in the maternity clinics. All eligible participants received the study information sheet (see appendix L) and were asked to read and sign the consent form (see appendix M). The dental hygienist was trained by the researcher in how to approach women to invite participation.

5.4.5 The study design

This study design was an intervention which was a longitudinal single blind randomised controlled trial. The CONSORT guidance was used to plan the design of this RCT (Figure 5.1) (Moher et al., 2012, Schulz et al., 2010). The main outcome of the intervention was to assess knowledge and secondly the following social cognition constructs: attitudes, subjective norms, barriers, intention, and planning. In addition self-report and objective measures of dental health behaviours were assessed.

It was decided to include subjective and objective measurements of adherence as reliance on self-report might provide over optimistic results. Objective measures such as the PI and GI indices would allow an accurate assessment of behaviour over the period of the intervention.

The intervention consisted of a booklet which was specially developed by the researcher to be culturally sensitive. The booklet involved pictures of pregnant women that represented Kuwaiti women including covered headed and uncovered headed women as seen in Kuwait society. This was in contrast to most of the dental health booklets and flyers used in dental healthcare services in Kuwait that involved pictures of western women. The booklet provided information concerning basic dental health information that women might require in general and during pregnancy. The booklet was designed according to a widely used evidence-based toolkit for prevention (DH/British Association for the Study of Community Dentistry, 2009) and practising evidence-based guidelines on dental healthcare during pregnancy and early childhood provided by the New York State Department of Health (New York State Department of Health, 2006).

5.4.6 Study outcomes

Adherence to dental health instructions was chosen as the outcome variable measured through a primary outcome of decrease in plaque accumulation and a reduction in severity of gingivitis, measured through the PI (Sillness and Loe, 1964) and GI (Loe and Silness, 1963) respectively. Secondary outcomes were changes in participants' dental health knowledge, attitudes, subjective norms, barriers and intention, measured through a self-administered questionnaire. In addition self-reported questions related to tooth brushing and dental flossing in the past seven days and participants' oral health was recorded.

Before the main study, pilot work was conducted to assess the questionnaire in terms of timing, understanding of questions and layout. The pilot questionnaire was tested on 12 women similar to the population to be studied in the maternal child clinics. The questionnaire was completed in 20 to 30 minutes. Three questions had typographical errors which made the questions difficult to understand. A small number of participants also reported that questions were repeated several times and the researcher explained that each time the question referred to different issues. For example, 'my family thinks it is important that I brush my teeth daily'; 'my family thinks I should floss my teeth every day' and 'my family thinks it is important that I eat healthy snacks'.

One question was reported by women to be difficult to understand and the researcher amended and re-wrote this question as 'How important would you say that not eating sweet snacks is to the health of your teeth?'

5.4.7 Allocation and allocation concealment

Women were randomly allocated to three groups (ratio: 1:1:1) using a randomisation table that was generated by a statistician specifically for this study. The DH gave the participant a number based on the sequence of their participation and after completing the questionnaire and clinical assessments, the DH sent the women with their number to the researcher who delivered the intervention in a private office based on their number. The researcher delivered all three arms of the intervention.

5.4.8   The design

This study was designed to repeat measurements over a four week period. Four weeks was chosen as a practical period in which to measure changes in the dental health behaviour, particularly as the study had to be planned around women's attendance at the maternity clinic. Several previous studies looking at changes in dental hygiene behaviour have used four week periods such as Barker (1994), Beck and Lund (1981), Buunk-Werkhoven et al. (2009), Pakpour and Sniehotta (2012) and Suresh et al. (2011).

At Time 1 (first visit) eligible expectant mothers were asked by a dental hygienist (DH) to complete a self-administered questionnaire that assessed dental health behaviour based on the selected constructs of SCMs identified in the qualitative study. In addition, women were asked to self-report their dental health and to report their dental hygiene behaviour (tooth brushing and dental flossing) during the last seven days. Then, the DH assessed the plaque scores and gingival health by PI (Sillness and Loe, 1964) and GI (Loe and Silness, 1963).

The DH was trained and calibrated to assess PI and GI by an experienced periodontist who was based at the dental faculty in the Dental Institute, Kuwait University. The inter-examiner agreement between the gold standard and the DH was 95% for PI and 91% for GI. It was not feasible to conduct intra-examiner variability during the study, as most participants left the clinic once their examinations were complete and were unwilling to stay after their scheduled appointment.

The researcher provided the eligible women with a dental bounty pack to include a toothbrush, a family strength fluoridated toothpaste, and a packet of dental floss.

The first group received treatment as usual (TAU), which was a dental hygiene information leaflet that was available in the waiting room of dental clinics in Kuwait (see appendix N: Tooth brushing and flossing tips). While government maternity and dental clinics in Kuwait do not habitually offer any dental health education leaflets or instructions, it was felt that the presence of a DH warranted some information from the dental team to the participant, regarding dental health. Therefore, the TAU group in this study received the basic dental health information leaflet. The leaflet simply provided information about dental health skills related to tooth brushing and flossing times, tooth brushing and flossing techniques, the sequence of brushing, toothbrush selection, and tooth brushing duration. Furthermore, the researcher provided a brief discussion and explanation of the dental hygiene information covered in the leaflet with the participants. In addition the researcher showed them brushing and flossing techniques on a plastic model of the mouth as would occur in routine dental practice in Kuwait. The researcher used a script for the discussion of the dental health information to ensure that all

participants got the same dental health information. The information leaflet and subsequent discussion is considered TAU in Kuwait dental clinics at present.

The second group was the DHE intervention group who were provided with the dental hygiene information leaflet, discussion as per the TAU group, but in addition they received a dental health education booklet (se appendix O). The booklet was designed to be culturally sensitive and address the SCM constructs identified in the previous qualitative study. Participants were asked to read the booklet before leaving the research intervention venue and encouraged to ask any questions concerning the information in the booklet. The third group was the DHE and planning group (DHE&P); they received the same intervention as the DHE group, but in addition they were asked to write their plan of when, where and how they would brush and floss their teeth, what obstacles would stop them from doing so and how they would overcome these obstacles (see appendix P: Action plan for tooth brushing and flossing).

The three groups were provided with the same amount of interaction time demonstrating the tooth brushing and dental flossing methods.

After four weeks (Time 2), the groups returned and had their gingival health and plaque scores assessed by the DH who was masked to the group allocation. In addition, the DH asked them to complete a second questionnaire, which was the same as in Time 1. At the end of the trial, women in the TAU group were offered the DHE intervention. The questionnaire was provided after the examination.

The study procedure is summarised in Figure 5.1 and the research design in Table 5.1
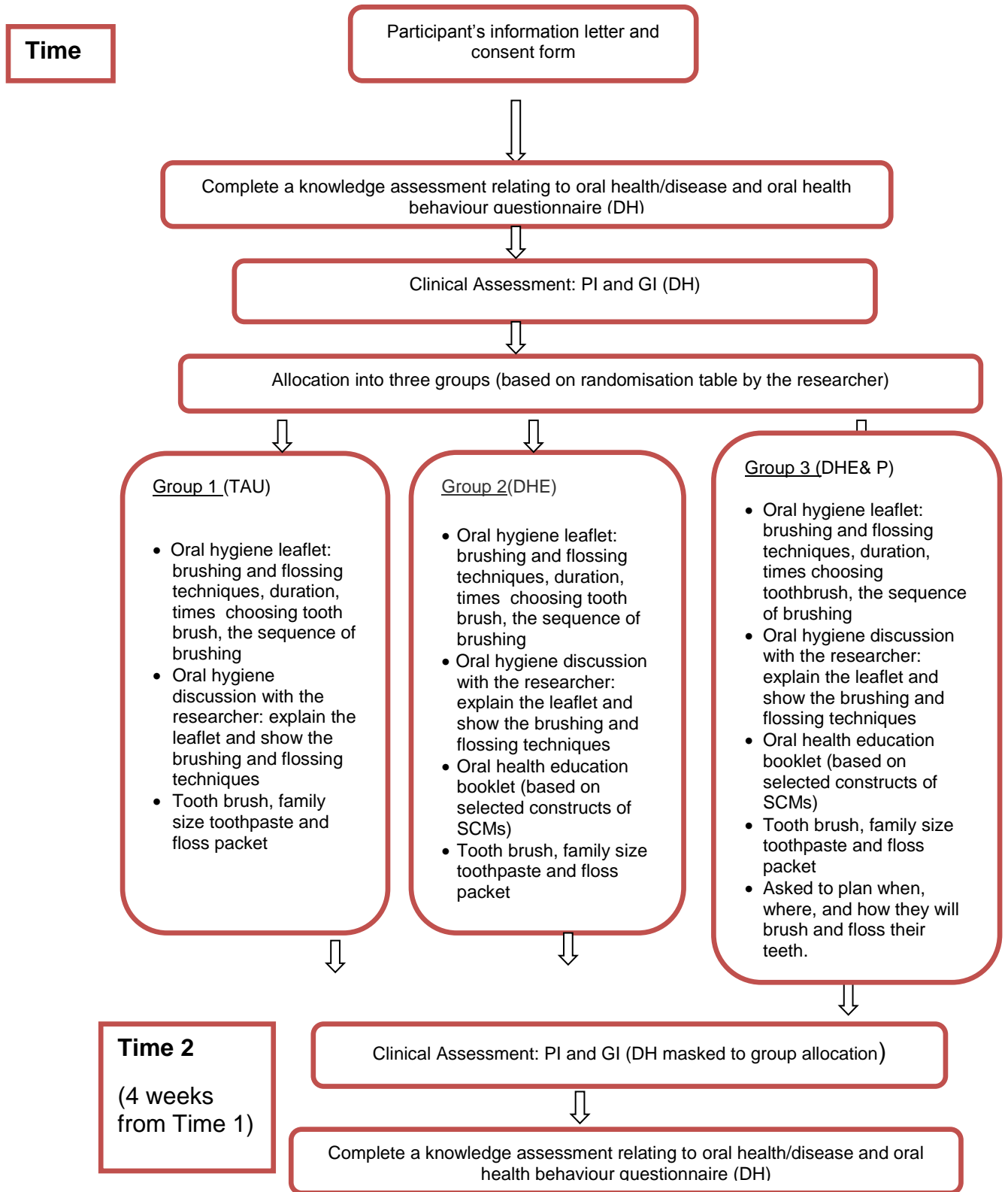
Figure 5.1: Flow chart of the study procedure

Table 5.1: Research design

Time 1		
Group 1	Group 2	Group 3
Complete dental health behaviour questionnaire	Complete dental health behaviour questionnaire	Complete dental health behaviour questionnaire
↓	↓	↓
PI and GI assessment	PI and GI assessment	PI and GI assessment
↓	↓	↓
Receive dental hygiene leaflet	Receive dental hygiene leaflet	Receive dental hygiene leaflet
↓	↓	↓
Discuss and explain dental hygiene technique	Discuss and explain dental hygiene technique	Discuss and explain dental hygiene technique
↓	↓	↓
Show brushing and flossing techniques	Show brushing and flossing techniques	Show brushing and flossing techniques
↓	↓	↓
Receive toothbrush, family size toothpaste, and dental floss	Receive toothbrush, family size toothpaste, and dental floss	Receive toothbrush, family size toothpaste, and dental floss
	↓	↓
	Receive dental health education booklet based on SCM constructs	Receive dental health education booklet based on SCM constructs
		↓
		Ask to write plan of when, where, and how they will brush and floss their teeth.

Time 2 (4 weeks after Time 1)		
Group 1	Group 2	Group 3
Assess PI and GI (2nd time)		
↓		
Complete dental health behaviour questionnaire (2nd time)		

5.4.9 Measurements

5.4.9.1   Clinical measurements

a. Plaque Index (PI) (Sillness and Loe, 1964)

The PI was used to assess the change in plaque accumulation between Time 1 and Time 2 and to evaluate the adherence with tooth brushing techniques. PI indicates the effectiveness of plaque removal. As plaque may accumulate within 24 hours, the PI indicates the dental health behaviour which has undertaken 24 hours prior the intervention assessment. This index uses a four point scale (0 to 3) as follows:

- Score 0 = the tooth surface is clean.
- Score 1 = the tooth surface appears clean, but dental plaque can be removed from the gingival third with a sharp explorer.
- Score 2 = plaque is visible along the gingival margin.
- Score 3 = the tooth surface is covered with abundant plaque.

b. Gingival Index (GI) (Loe and Silness, 1963)

The GI is an index used to evaluate the gingiva by assessing the levels of gingival inflammation and bleeding before and after the intervention. The purpose of GI was to record the progress of gingival health, which showed participants' adherence to dental hygiene instruction. This index uses a four point scale (0 to 3) as follows:

- Score 0 = absence of inflammation.
- Score 1 = mild inflammation, slight change in colour and little change in texture.
- Score 2 = moderate inflammation; moderate glazing, redness, oedema, and hypertrophy; bleeding on pressure.

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- Score 3 = severe inflammation; marked redness and hypertrophy; tendency to spontaneous bleeding.

PI and GI were used to assess all participants' pre- and post-intervention to measure objectively their adherence with dental health instructions. PI and GI were assessed for six teeth representing the six sextants of the mouth (Loe and Silness, 1963) including: the maxillary right first molar, maxillary right lateral incisor, maxillary left first premolar, mandibular left first molar, mandibular left lateral incisor and mandibular right first premolar. These six teeth were used to measure the GI and PI as described by Ramfjord et al. (1967, 1957). Four surfaces (distal, buccal, mesial and lingual) for each tooth were recorded (Loe and Silness, 1963).

In assessing the PI then GI, the DH recorded from the maxillary arch: right first molar, right lateral incisor and left first premolar, then the mandibular arch: left first molar, left lateral incisor then right first premolar.

The Kuwait Ethical Committee granted approval for the study on the understanding that "*This study will not be performed on pregnant women and neonates and all participants have the right to withdraw from the study at any time*" (see appendix Q). The committee were reluctant to approve any invasive procedure such as probing or staining of the teeth on pregnant women. After the researcher had negotiations with the committee to gain their permission, the decision was made to modify PI and GI and assess by simply using good light and a disposable dental mirror in pre- and post-intervention assessments. No probing took place.

Thus, for the PI the presence of plaque for score 1 may have been underestimated and for the GI the presence of bleeding in score 2 and 3 would have been underestimated. However, the visible signs of score 2 and 3 would be visible in good light. As the same calibrated hygienist examined all women in all conditions, any systematic variations in recording of these would have been similar across the three groups.

5.4.9.2 SCM questionnaire

The questionnaire was divided into three main sections: Section A assessed general dental health knowledge and dental health knowledge relating to pregnancy including questions about women's self-rated dental health status. Women's self-report of their dental health behaviours concerning tooth brushing and flossing, over the last seven days, were reported on in Section B. In Section C, women were asked about their information regarding tooth brushing, dental flossing, dental and gum diseases, snacks and regular dental visits.

Most of the items included in the questionnaire used previously validated items taken either from the Dental Health Promotion Evaluation Toolkit (Watt et al., 2004) or had been derived from other similar research (Buglar et al., 2010; Defranc et al., 2008; Al-Attas, 2007; Conner and Norman, 2007; Schüz et al., 2006; Alwaeli and Al-Jundi, 2005; Lavin and Groarke, 2005). The items were modified to be suitable for the target group. There were seven additional items which came from the qualitative study: *'If you are a pregnant woman and find your gums bleed when you brush, you should: stop brushing and/or reduce the amount of time you brush your teeth'; 'You should change your toothbrush after 3 to 4 months'; 'Could you please write what is dental floss and what might be the effects of using dental floss?'; 'You should rinse with a large amount of*

water after brushing'; 'If you are a pregnant woman suffering from pregnancy sickness, you should brush immediately after vomiting'; 'Bleeding gums are to be expected in pregnancy' and, 'Visiting the dental clinic during pregnancy is not safe'. As there were only seven items, the researcher decided not to pursue detailed assessment of validity.

The questionnaire was designed to assess *knowledge* mainly. The SCMs constructs relating to: *attitudes, subjective norms, barriers,* and *intention* were assessed as well. The questionnaire also addressed five self-reports of dental health behaviours which were related to tooth brushing, flossing, dental decay and gum disease, snacks and visiting the dentist regularly (see appendix R: Questionnaire of dental health for Kuwaiti pregnant women).

Knowledge was measured by 27 multiple-choice questions about dental health and pregnancy. Women were asked to tick one correct answer for each one of six questions, for example, Compared with non-pregnant women, should pregnant women brush: 'more frequently', 'less frequently', 'the same', or 'don't know'. Participants were asked to tick more than one appropriate answer in two questions for example: 'If you thought that pregnancy affects the teeth and gums, how might that process happen? (You can choose more than one): 'baby takes calcium from the teeth', 'vomiting because of morning sickness can cause dental erosion', 'pregnancy accelerates dental decay', 'pregnancy accelerates gum disease', 'hormonal changes during pregnancy make the gums bleed', 'pregnancy has no effect on dental cavity' or/and 'other''. There were 19 statements that women were asked to decide whether they thought were true, false or didn't know by answering 'yes', 'no' or 'don't know' for example: Do you think that your diet and nutrition during pregnancy will affect your teeth: 'yes',

'no', or 'don't know'; and; Smoking has an effect on the unborn child: 'true', 'false' or 'don't know' (see Table 5.2: SCM assessments: Knowledge.)

Attitude was measured by 11 questions: two questions were assessed by six item Likert-type scales that ranged from 'extremely likely' to 'extremely unlikely' for example: 'Brushing my teeth twice a day for 2 to 3 minutes will keep my gums healthy'. Eight questions were assessed by six item Likert–type scales that ranged from 'strongly agree' to 'strongly disagree' for example: 'I think that flossing my teeth every day would increase my resistance to gum disease'.

In addition, one question was assessed by five item Likert-type scales ranging from 'very important' to 'not at all important'. For example; 'How important would you say that not eating sweet snacks is to the health of your teeth?' (see Table 5.2: SCM assessments: Attitude).

Subjective norms were measured by five questions assessed by six-item Likert-type scales that ranged from 'strongly agree' to 'strongly disagree' scales, for example: 'My family thinks it is important that I brush my teeth daily' (see Table 5.2: SCM assessments: Subjective norms).

Barriers to brushing, flossing, having healthy snacks, and visiting the dentist regularly were measured by 12 questions that were assessed by six item Likert-type scales that ranged from 'strongly agree' to 'strongly disagree' scales, for example: 'I am afraid I would not be able to seek dental treatment during pregnancy' (see Table 5.2: SCM assessments: Barriers).

Intention to brush, floss, have healthy snacks, and visiting the dentist regularly were measured by five questions and each was assessed by six item Likert-type scales that ranged from 'strongly agree' to 'strongly disagree', for example:

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'I intend to seek dental treatment during pregnancy' (see Table 5.2: SCM assessments: Intention).

Table 5.2 presents all the SCM constructs questions that were included in the study questionnaire.

Table 5.2: SCM constructs assessments

SCM constructs	Questions
Knowledge	1. If you thought that pregnancy affects the teeth and gums, how might that process happen? (You can choose more than one) ○ Baby takes calcium from the teeth. ○ Vomiting because of morning sickness can cause dental erosion. ○ Pregnancy accelerates dental decay. ○ Pregnancy accelerates gum disease. ○ Hormonal changes during pregnancy make the gums bleed. ○ Pregnancy has no effect on dental cavity. ○ Other (please specify)_____ 2. Do you think that you might lose a tooth for every pregnancy? (True, False, Don't know) 3. Do you think that your diet and nutrition during pregnancy will affect your teeth? (Yes, No, Don't know) 4. Smoking has an effect on the unborn child. (True, False, Don't know) 5. Could you please write what dental floss is? (Open question and scored in SPSS as Correct, Incorrect , Don't know) 6. What might be the effects of using dental floss? (Open question and scored in SPSS as Correct, Incorrect, Don't know) 7. Compared with non-pregnant women, should pregnant women brush ○ More frequently ○ Less frequently ○ The same ○ Don't know 8. A softer toothbrush is better than a hard one for cleaning my teeth. (Yes, No, Don't know) 9. A large-headed toothbrush is less efficient at cleaning teeth than a small-headed toothbrush. (Yes, No, Don't know) 10. You should brush your teeth after each meal to prevent tooth decay. (True, False, Don't know) 11. Brushing my teeth will improve the condition of my gums. (True, False, Don't know)

12. I am unsure of the best way to brush my teeth.
    (True, False, Don't know)

13. You should change your toothbrush after 3 to 4 months.
    (True, False, Don't know)

14. Brushing my teeth with fluoride toothpaste will help prevent tooth decay.
    (True, False, Don't know)

15. Bleeding gums are a sign of gum disease.
    (True, False, Don't know)

16. You should rinse with a large amount of water after brushing.
    (True, False, Don't know)

17. Flossing my teeth will improve the condition of my gums.
    (Yes, No, Don't know)

18. Do you think that pregnancy has any effects on the teeth and/or gums?
    o   Teeth only
    o   Gums only
    o   Gums and teeth
    o   Pregnancy has no effect on the teeth and gums
    o   Other (please specify)
    o   Don't know

19. What do you think can be done to stop teeth decaying?
    o   Brush my teeth regularly
    o   Avoid sugary food
    o   Go to the dentist
    o   Cannot be avoided
    o   Don't know
    o   Other (specify)

20. What do bleeding gums indicate?
    o   Inflamed gum
    o   Healthy gum
    o   Receding gums
    o   Don't know
    o   Other (please specify)

21. What causes inflamed gum disease in pregnant women? (You can choose more than one)
    o   Dental plaque
    o   Hormonal changes
    o   Neglecting brushing
    o   Plaque and neglecting
    o   All of the above
    o   Other (please specify)
    o   Don't know

22. Do you think that pregnancy sickness has any effects on the teeth and/or gums?
    o   Teeth only
    o   Gums only
    o   Gums and teeth
    o   I don't think pregnancy sickness has any effect on the dental cavity
    o   Other

23. Do you think eating snacks between meals is:
    o   Very good for your health
    o   Good for your health

24. Sugary snacks and drinks are best limited to mealtimes.
(Yes, No, Don't know)

25. You should visit the dentist regularly for a check-up even if you are pregnant.
(Yes, No, Don't know)

26. If you are a pregnant woman and find your gums bleed when you brush, you should stop brushing and/or reduce the amount of time you brush your teeth.
(True, False, Don't know)

27. If you are a pregnant woman suffering from pregnancy sickness, you should brush immediately after vomiting.
(True, False, Don't know)

Attitude

1. Brushing my teeth twice a day for 2 to 3 minutes will keep my gums healthy.

Extremely likely	Likely	Neither likely nor unlikely	Unlikely	Extremely unlikely	Don't know

2. Brushing my teeth twice a day for 2 to 3 minutes will get rid of plaque.

Extremely likely	Likely	Neither likely nor unlikely	Unlikely	Extremely unlikely	Don't know

3. I think that flossing my teeth every day would increase my resistance to gum disease.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

4. Having dental problems is a normal part of pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

5. Bleeding gums are to be expected in pregnancy

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

6. Aching and rotten teeth are to be expected in pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

7. I find there is very little I can do to prevent myself getting dental problems during pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

8. Choosing sugar free snacks between meals is very important.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

9. How important would you say that not eating sweet snacks is to the health of your teeth?

Very important	Fairly important	Not important	Not at all important	Don't know

10. Going to the dentist regularly will keep me from having trouble with my teeth and gums.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

11. Going to the dentist is better than other ways of looking after your teeth.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

Subjective norms

1. My family thinks it is important that I brush my teeth daily.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

2. My family thinks I should floss my teeth every day.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

3. My family thinks I should seek dental treatment when I have dental problems during pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

4. My family thinks it is important that I eat healthy snacks.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

5. My family thinks that it is normal to see the dentist regularly for a check-up even if I am pregnant.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

Barriers

1. My gums will bleed when I brush

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

2. Tooth brushing is painful.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

3. My teeth will break when I brush.

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Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

4. My gums will bleed when I floss.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

5. My teeth will break when I floss.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

6. Dental flossing is painful.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

7. I am afraid I would not be able to seek dental treatment during pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

8. I am afraid I would not be able to limit food containing sugar to mealtimes only.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

9. I am afraid I would not be able to visit the dentist regularly.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

10. Visiting the dental clinic is time consuming.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

11. Dental treatment is expensive.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

12. Visiting the dental clinic during pregnancy is not safe.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

Intention

1. I intend to brush my teeth twice a day regularly.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

2. I intend to use dental floss regularly.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

3. I intend to seek dental treatment during pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

4. From now on, I intend to avoid snacks (food or drinks) as much as possible.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

5. I intend to go to the dentist for a check-up regularly.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

5.4.9.3 Planning of dental health behaviour: tooth brushing and dental flossing

The planning of dental health behaviours through an action plan (implementation intention) was completed by the third group only. The intervention consisted of an action plan concerning tooth brushing and dental flossing, brushing and flossing obstacles, and how to overcome these obstacles (see appendix P for the action plan for tooth brushing and flossing).

5.4.10 Information gaps identified in qualitative study and key messages

In order to develop the intervention, the researcher identified information gaps concerning dental health knowledge in the qualitative study. The literature was then reviewed and the key contemporary evidence-based advice was compiled based on two sources: DH/British Association for the Study of Community Dentistry, 2009; New York State Department of Health, 2006). The intention was to correct the existing inaccurate dental health information and fill information gaps in relation to pregnancy and dental health, with evidence-based advice and in a culturally appropriate way.

The toolkit by DH/British Association for the Study of Community Dentistry (2009) was used as an evidence-based toolkit for dental heath prevention

guidance and covered issues such as selecting toothbrushes and toothpaste, dental flossing, tooth brushing frequency, tooth brushing techniques and sugar consumption. In addition, other basic dental health information items were selected in relation to dental caries, gum disease and fluoride.

The Dental Health Care During Pregnancy and Early Childhood Practice Guidelines (New York State Department of Health, 2006) was used to obtain evidence-based professional messages and advice concerning dental health during pregnancy. As mentioned earlier, the qualitative study found that pregnant Kuwaiti women were not aware of the importance of having optimal dental health during pregnancy. For instance, women reduced tooth brushing frequency or stopped tooth brushing during pregnancy either because of gum bleeding or morning sickness. Pregnant Kuwaiti women believed that dental problems were part of the process during pregnancy and women made no connection between gum bleeding and pregnancy. Women also avoided dental treatment during pregnancy. The Dental Health Care During Pregnancy and Early Childhood Practice Guidelines (New York State Department of Health, 2006) provided basic dental health information and knowledge for pregnant women concerning morning sickness, gum disease and dental treatment during pregnancy. The researcher also included information to address the knowledge gap regarding pregnancy sickness and 'losing a tooth' as a normal outcome of pregnancy.

The qualitative study also found that participants reported they preferred to receive information in the form of a written flyer or booklet. The researcher therefore delivered health information and professional recommendations using a booklet.

The booklet consisted of nine sections that included information in relation to: pregnancy and dental health, pregnancy and gum health, pregnancy and tooth decay, pregnancy sickness and dental health, pregnancy and going to the dentist, tooth brushing, toothpaste, dental flossing, and top tips to help protect your teeth and gums throughout pregnancy. The booklet also provided the recommended doses for fluoridated toothpaste for children and adults.

Table 5.3 summarises how the gaps in information related to dental health identified in the qualitative study shaped the present study's intervention. In column 1, the table summarises the inaccurate and low level of women's knowledge in relation to dental health and pregnancy. The current evidence-based information is derived from DH/British Association for the Study of Community Dentistry (2009) and New York State Department of Health (2006); the current evidence-based message is written in contrasting red. The middle column displays the new information provided in the booklet used in the intervention, while the final column includes the questionnaire items that measured the SCM outcomes in women who participated in the study.

Table 5.3: Summary of Kuwaiti pregnant women's knowledge, attitude, subjective norms, barrier and intention, professional dental health messages and dental health knowledge booklet and questions.

Women's current levels of dental health knowledge (derived from qualitative study)	Dental health knowledge in the booklet	Questions
<u>Toothbrushes</u> Using toothbrushes that have medium or hard bristles Current advice is that adults should use a small headed brush with soft bristles to maximise the efficiency of plaque removal (DH/British Association for the Study of Community Dentistry, 2009).	<u>Toothbrushes</u> Select the toothbrush that has: ✓ small head, ✓ soft bristles (information is also available in the leaflet)	A large-headed toothbrush is more efficient at cleaning teeth than a small-headed toothbrush. (True,false,don't know) (Watt et al., 2004). False is the correct answer. A softer toothbrush is better than a hard one for cleaning my teeth. (True, false, don't know) (Watt et al., 2004). True is the correct answer.
<u>Toothpastes</u> • Choosing toothpaste that contains mint to make the mouth fresh. • Choosing toothpaste that is red colour to make the gums pink and healthy. • No specification, using any toothpaste. Current advice is that adults should brush their teeth twice a day with fluoridated toothpaste to prevent dental decay. The action of brushing and plaque removal prevents gum disease (DH/British Association for the Study of Community Dentistry, 2009).	It is not enough to choose the toothpaste according to the smell and colour; it should be chosen according to fluoride that protects teeth from decay. Brushing your teeth regularly with a fluoride containing toothpaste can help prevent dental decay, but it can also keep the mouth fresh and is good for the gums and may make people feel their mouth is fresh.	Brushing my teeth with fluoride toothpaste will help prevent tooth decay. (True, false, don't know) (Watt et al., 2004). True is the correct answer.

Tooth brushing
- Brushing 2 to 3 times a day.
- Stop brushing during the first 3 months of pregnancy due to pregnancy sickness.
- Stop brushing and reduce the time of tooth brushing due to bleeding gums.
- Don't know the proper method of brushing.
- Brushing techniques: side to side, up and down, or circular motion.

Current advice is that adults should brush their teeth twice a day for a minimum of 2 minutes. It is essential to brush before bedtime and any other occasion during the day (DH/British Association for the Study of Community Dentistry, 2009)

Brushing twice a day with fluoride toothpaste is efficient in reducing tooth decay. Brushing twice a day for 2 weeks will stop gums bleeding (DH/British Association for the Study of Community Dentistry, 2009).

Tooth brushing
Brush your teeth twice a day; brush before bedtime and any other occasion during the day for 2 to 3 minutes. (Information is also available in the leaflet.)

Brushing twice a day with fluoride toothpaste is efficient in reducing tooth decay. Brushing twice a day for 2 weeks will stop gums bleeding.

Compared with non-pregnant women, should pregnant women brush (Alwaeli and Al-Jundi, 2005).
- more frequently
- less frequently
- the same
- I don't know

The same is the correct answer.

You should brush your teeth after each meal to prevent tooth decay. (True, false, don't know) (Watt et al., 2004).

False is the correct answer.

I am unsure of the best way to brush my teeth (Watt et al., 2004).
(True, false, don't know)

False is the correct answer.

Brushing my teeth will improve the condition of my gums. (True, false, don't know) (Watt et al., 2004).

True is the correct answer

You should change your toothbrush after 3 to 4 months. (True, false, don't know)

True is the correct answer.

Dental flossing Know about dental floss and never use it. Current advice is that adults should clean between their teeth once a day by using dental floss or interdental (DH/British Association for the Study of Community Dentistry, 2009).	Dental flossing Dental floss is a soft string for cleaning spaces between the teeth. To clean between your teeth effectively, remember to Clean between your teeth gently once a day by using dental floss. Floss before brushing (also available in the leaflet).	Could you please write what is dental floss and what might the effects be of using dental floss? (open question) Flossing my teeth will improve the condition of my gums. (True, false, don't know) (Modified) (Watt et al., 2004). True is the correct answer.

Dental health
• Drinking cold and hot drinks or water affects your dental health (teeth sensitivity).
• Drinking cold or hot drinks leads to weaken the teeth and decay.
• Tea and coffee causing decay.
• Eating something very sweet would hurt the tooth (eating sweets causes toothache).
• Smoking affects the colour and the shape of the teeth.
 	
Current advice is that adults should brush their teeth twice a day with fluoridated toothpaste to prevent tooth decay (DH/British Association for the Study of Community Dentistry, 2009).
Adults should be encouraged to spit out excess toothpaste or to rinse with small amounts of water (DH/British Association for the Study of Community Dentistry, 2009). Adults should control sugar intake by limiting to mealtimes to prevent dental (DH/British Association for the Study of Community Dentistry, 2009).
	Pregnancy and dental health
	Some Kuwaiti pregnant women have incorrect beliefs and information concerning dental health during pregnancy. Did you know that pregnancy does not cause or accelerate tooth decay? It is what you eat and drink that might affect your teeth. Eating and drinking sugar content food has an effect on your teeth. Healthy diet is good for your dental health. If you have tooth ache during pregnancy that means you might have dental decay and you should go to the dentist.
	
	Pregnancy is a unique time in a woman's life. Many changes in a woman's body occur during pregnancy. These changes and how you respond to these changes (for example changing what you eat and drink or stop brushing your teeth during the first 3 months of pregnancy) can include changes to the health of your teeth, mouth and gums. It is important to know that dental diseases are preventable. By making simple changes in your hygiene routine and diet you can help
		How do you rate your dental health status? (Boggess et al., 2010)
		  o Excellent
		  o Good
		  o Fair
		  o Poor
		  o Very poor
		
		Do you think that pregnancy has any effects on the teeth and/or gums? (Al-Attas, 2007)
		  o Teeth only
		  o Gums only
		  o Gums and teeth
		  o Pregnancy has any effect on the teeth and gums
		  o Other (please specify)___
		  o Don't know
		
		Gums only is the correct answer.
		
		Smoking has an effect on the unborn child? (True, False, Don't know) (Alwaeli and Al-Jundi, 2005)
		
		True is the correct answer.

Gum Health

- Bleeding gums may have an effect on the foetus.
- Don't know the reasons for gum inflammation
- Nothing affects the gums
- Spices, citrus food such as lemon and orange may inflame the gums.
- Inflamed gums are characterized by bleeding, bad smell and dark colour.
- Do not have any information about the reason for increasing amount of gum bleeding during pregnancy
- 'Toothbrush sensitivity' is the reason for bleeding during brushing
- Pregnancy does not affect the gums.
- Dark gums contain dried blood which can be cured by rinsing with warm water and salt for 5 min.

Current advice to prevent gum disease is that adults should brush their teeth systemically twice a day by using a soft and small headed toothbrush (DH/British Association for the Study of Community Dentistry, 2009). Adults should floss once a day before bedtime (DH/British Association for the Study of Community Dentistry, 2009).

prevent dental disease both in pregnancy and for the rest of your life. By adopting these simple changes you could also prevent dental disease in your family.

Pregnancy and gum health.

Some Kuwaiti pregnant women thought that bleeding gums is normal or said they did not know why their gums bled. You should know that gum bleeding is one of the signs of gum inflammation. Gum disease is caused by plaque, a film that forms on your teeth every day. Pregnant women are more likely to have bleeding gums because pregnancy hormones make their gums more sensitive and irritated by the presence of dental plaque. Healthy gums are pinkish, firm and no bleeding

We would like you to think about any changes in your mouth since you became pregnant. You may have noticed that your gums seem to bleed more easily since you have been pregnant. This can happen because of hormonal changes in a woman's body. You can stop this happening by simply brushing your teeth and flossing your teeth.

We advise that you brush your teeth twice a day before bedtime and on one other occasion during the day. You may have morning sickness and prefer not to brush

If you thought that pregnancy affects the teeth and gums, how might that process happen? (You can choose more than one) (Al-Attas, 2007)

- o Baby takes calcium from the teeth
- o Vomiting because of morning sickness can cause dental erosion
- o Pregnancy accelerates dental decay
- o Pregnancy accelerates gum disease
- o Hormonal changes during pregnancy make the gums bleed more easily
- o Pregnancy has no effect on dental cavity
- o Other(please specify)_____

Hormonal changes during pregnancy make the gums bleed more easily is the correct answer.

Have you lost one tooth for each pregnancy?
- o Yes
- o No
- o Don't know

No is the correct answer.

Pregnancy and dental health
- Pregnancy does not affect dental health
- Pregnancy is below (part of the body) and the mouth is up (in the face); how would they be connected?
- Having pain in the teeth during the first 3 months of pregnancy is normal.
- Don't have any information about pregnancy and dental health.
- Never had any advice or education concerning dental health during pregnancy.

Current advice to maintain dental health during pregnancy is that pregnant women should brush their teeth systemically twice a day by using soft and small headed toothbrushes and fluoridated toothpaste. Pregnant women should brush their teeth twice a day for a minimum 2 minutes before bedtime and any other occasion during the day. They should floss once a day before bedtime. Pregnant women should be encouraged to spit out excess toothpaste or to rinse with a small amount of water. They should control sugar intake by limiting to mealtimes to prevent dental decay. Pregnant women should visit a dental clinic regularly (New York State department of health, 2006).

your teeth first thing in the morning. If this is the case, we suggest you wait for the sickness to pass and then brush your teeth.

Pregnancy by itself does not harm the teeth or gums and brushing and flossing can help prevent dental problems.

Pregnancy and tooth decay

Women are at no greater risk to tooth decay because they are pregnant. However some women alter their eating and drinking or stop brushing their teeth during pregnancy and may inadvertently start adding sugar to their diet which puts them at risk for dental decay. Some Kuwaiti pregnant women believed that pregnancy had an active role in dental decay or accelerating dental decay, losing teeth, or calcium deficiency. Dental decay during pregnancy is caused by increased sugar snacks and adding sugar to foods and drinks consumed at mealtimes. Brushing your teeth regularly with a fluoride containing toothpaste can help prevent dental decay.
Fluoride is an element that protects the teeth from decay. It serves to prevent, control and stop tooth decay. Fluoride can be found naturally in water and food or added to dental hygiene products such as toothpaste and mouthwash. When you brush your teeth with fluoridated toothpaste, we recommend that you spit out or rinse with a small amount of water

Do you think that you might lose a tooth for every pregnancy? (Al-Attas, 2007)
- o Yes
- o No
- o Don't know

No is the correct answer.

Do you think that your diet and nutrition during pregnancy will affect your teeth? (Al-Attas, 2007)
- o Yes
- o No
- o Don't know

Yes is the correct answer.

What do bleeding gums indicate? (Alwaeli and Al-Jundi, 2005)
- o Inflamed gums
- o Healthy gums
- o Receding gums
- o Don't know
- o Other (please specify)_____

Inflamed gums is the correct answer.

What causes inflamed gum disease in pregnant women? (You can choose more than one) (Alwaeli and Al-Jundi, 2005).
- o Dental plaque
- o Hormonal changes

rather than rinse your mouth with a large amount of water. In this way you increase the time fluoride is in contact with your teeth giving better protection

<u>Pregnancy sickness and dental health</u>

Did you know that frequent nausea and vomiting may lead to the loss of the outer layer of the tooth (enamel)? The enamel is the hard, protective coating of the tooth, which protects the sensitive dentine underneath. When the enamel is worn away, the dentine underneath is exposed, which may lead to pain and sensitivity. Acidic foods such as pickles, lemons, oranges, and grapefruits, and drinks such as lemon and orange juices, and fizzy drinks, can also cause loss of the outer layer.

Some pregnant women experience a lot of sickness during pregnancy and may find it useful to follow the following tips to protect their teeth.

- Avoid frequent intake of acidic foods or drinks – keep them to mealtimes.
- Do not brush immediately after eating or drinking acidic food or drinks.
- Do not brush immediately after vomiting.
- Chew sugarless or xylitol-containing gum after eating.
- Use a teaspoon of baking soda (sodium bicarbonate) in a cup of water as a rinse after vomiting to

o   Neglecting brushing
o   Plaque and neglecting
o   All of the above
o   Other(please specify)_____
o   Don't know

Hormonal changes is the correct answer.

If you are a pregnant woman and find your gums bleed when you brush, you should: Stop brushing and/or reduce the amount of time you brush your teeth (True, false, don't know).

False is the correct answer.

Brushing my teeth with fluoride toothpaste will help prevent tooth decay (True, false, don't know) (Watt et al., 2004).

True is the correct answer.

What do you think can be done to stop teeth decaying? (Watt et al., 2004).
o   Brush my teeth regularly
o   Avoid sugary food
o   Go to the dentist
o   Cannot be avoided
o   Don't know
o   Other (specify)

Avoid sugary food is the correct answer.

You should brush your teeth after each meal to prevent tooth decay (True, false, don't know) (Watt et al., 2004).

neutralize acid.

You should rinse with a large amount of water after brushing (True, false, don't know).

False is the correct answer.

<u>Pregnancy and going to the dentist</u>

Many women are concerned about going to the dentist while they are pregnant. Did you know that:

- Dental care is safe and effective during pregnancy.
- Pregnancy by itself is not a reason to postpone routine dental care and necessary treatment for dental health problems.
- First trimester diagnosis and treatment, including needing dental x-rays, can be undertaken safely to diagnose dental disease that need immediate treatment.
- Dental prophylaxis and treatment during pregnancy should be preferably undertaken during early second trimester but definitely prior to delivery.
- Emergency dental care is safe at any time during pregnancy.
- Check with your GP and OBs re any problems with your mouth and need to attend the dentist.

Do you think eating sugary snacks between meals is: (Watt et al., 2004)
- ○ Very good for your health
- ○ Good for your health
- ○ Neither good nor bad for your health
- ○ Bad for your health
- ○ Very bad for your health
- ○ Don't know

Very bad for your health is the correct answer.

Sugary snacks and drinks are best limited to mealtimes. (True, false, don't know) (Watt et al., 2004).

True is the correct answer.

You should visit the dentist regularly for a check-up even if you are pregnant (True, false, don't know) (Watt et al., 2004).

Do you think that pregnancy sickness has any effects on the teeth and/or gums? (Al-Attas, 2007).
- o Teeth only
- o Gums only
- o Gums and teeth
- o I don't think pregnancy sickness has any effect on the dental cavity
- o Other

Teeth only is the correct answer.

If you are a pregnant woman suffering from pregnancy sickness, you should brush immediately after vomiting (True, false, don't know).

False is the correct answer.

Kuwaiti pregnant women's attitudes (derived from qualitative study)	Information in the booklet	Questions
- Increasing tooth brushing to avoid tooth decay during pregnancy. - Stop brushing during the first 3 months of pregnancy due to pregnancy sickness. - Stop brushing and reduce the time of tooth brushing due to bleeding gums. - Know about dental floss and never use it.	- Brush twice a day. (Also available in the leaflet). - Clean between your teeth gently once a day by using dental floss. (Also available in the leaflet). - Floss before brushing. (Also available in the leaflet). - Avoid frequent intake of acidic foods or drinks – keep them to	Brushing my teeth twice a day for 2 to 3 minutes will keep my teeth and gums healthy. (Extremely likely; likely; neither likely nor unlikely; unlikely; extremely unlikely; don't know) (Watt et al., 2004). Extremely likely is the correct answer. Brushing my teeth twice a day for 2 to 3

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- Bleeding gums are normal during pregnancy.
- Having pain in the teeth during the first 3 months of pregnancy is normal.
- Dental treatment is not safe during pregnancy, it harms the foetus.
- Drinking a lot of milk during pregnancy avoids toothache.
- Tolerating the dental pain during pregnancy all what pregnant woman can do to protect her foetus.
- Pregnancy increases the rate of tooth decay.
- Foetus absorbs the calcium from mother's teeth and bones.
- Pregnancy weakens the teeth.
- Having toothache during pregnancy is due to calcium deficiency (the foetus absorbs from the teeth and bones).
- Drinking milk will give back the calcium that has been absorbed and prevent toothache during pregnancy.
- Taking calcium prevents the toothache during pregnancy.
- Losing teeth with each pregnancy is normal.
- The teeth may be weaker after the birth.

Current advice is that women should brush their teeth twice a day with fluoridated

mealtimes.
- Do not brush immediately after eating or drinking acidic food or drinks.
- Do not brush immediately after vomiting.
- Chew sugarless or xylitol-containing gum after eating.
- Use a teaspoon of baking soda (sodium bicarbonate) in a cup of water as a rinse after vomiting to neutralise acid.

<u>Pregnancy and going to the dentist</u>

Many women are concerned about going to the dentist while they are pregnant. Did you know that:

- Dental care is safe and effective during pregnancy.
- Pregnancy by itself is not a reason to postpone routine dental care and necessary treatment for dental health problems.
- First trimester diagnosis and treatment, including needed dental x-rays, can be undertaken safely to diagnose disease processes that need immediate treatment.
- Dental prophylaxis and treatment during pregnancy, preferably during early second trimester but definitely prior to delivery.
- Emergency dental care is safe at any time during pregnancy.

minutes will get rid of plaque. (Extremely likely; likely; neither likely nor unlikely; unlikely; extremely unlikely; don't know) (Watt et al., 2004).

Extremely likely is the correct answer.

I think that flossing my teeth every day would increase my resistance to gum disease. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Lavin and Groarke, 2005).

Strongly agree is the correct answer.

Having dental problems is a normal part of pregnancy. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Watt et al., 2004).

Strongly disagree is the correct answer.

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- Check with your GP and OBs re any problems with your mouth and need to attend the dentist.

Dental visits

- Visiting dental clinic only for emergency or having dental pain (not during pregnancy).

- Avoid going to dentist during pregnancy.

- Visit dentist during the last months of pregnancy only whenever having dental pain.

- Dental health is not a concern.

- I intended that I will clean my teeth after giving birth.

- I have toothache and I am going to extract my teeth after giving birth.

- After giving birth I do go to the dentist to check-up on my teeth.

Top tips to help protect your teeth and gums throughout pregnancy

- Brush your teeth twice a day with fluoridated toothpaste.
- Brushing your teeth before bedtime is most effective.
- Floss your teeth once a day before bedtime.
- Spit out after brushing or use a small amount of water and do not rinse with a large amount of water your mouth.
- Limit the food and drinks containing sugar to mealtimes.
- Regular visits to dental clinic for check-ups are important to prevent dental diseases.

Bleeding gums are a sign of gum disease (True, false; don't know) (Watt et al., 2004).

True is the correct answer.

Bleeding gums are to be expected in pregnancy. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know).

Strongly agree is the correct answer.

Aching and rotten teeth are to be expected in pregnancy. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Watt et al., 2004).

Strongly disagree is the correct answer.

I find there is very little I can do to prevent myself getting dental problems during pregnancy. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Watt et al., 2004).

Strongly disagree is the correct answer.

Choosing sugar free snacks between meals is very important for your dental health. (Strongly agree; agree; undecided;

et al., 2003).

disagree; strongly disagree; don't know) (Watt et al., 2004).

Strongly agree is the correct answer.

How important would you say that not eating sweet snacks is to the health of your teeth? (Very important; fairly important; not important; not at all important; don't know) (Watt et al., 2004).

Very important is the correct answer.

Going to the dentist regularly will keep me from having trouble with my teeth and gums. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Watt et al., 2004).

Strongly agree is the correct answer.

Going to the dentist is better than other ways of looking after your teeth. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Watt et al., 2004).

Strongly agree is the correct answer.

Kuwaiti pregnant women's barriers (derived from qualitative study)	Information in the booklet	Questions
• Stop brushing and reduce the time of tooth brushing due to bleeding gums.	Brushing your teeth regularly with a fluoride containing toothpaste can help prevent dental decay.	My gums will bleed when I brush. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know)

- Stop brushing during the first 3 months of pregnancy due to pregnancy sickness.
- Do not have any information about the reason of increasing amount of gum bleeding during pregnancy.
- Dentist avoid treating pregnant women.
- Dental treatment during pregnancy would harm the foetus.
- Laziness is the reason for not seeking dental treatment during pregnancy.
- Cost of dental treatment (in private practice).
- Lack of trust in dentist treatment (government dental clinic).
- Long waiting list for dental clinic.
- Working hours for government dental clinic and appointments.

We advise that you brush your teeth twice a day before bedtime and on one other occasion during the day. You may have morning sickness and prefer not to brush your teeth first thing in the morning. Pregnancy by itself does not harm the teeth or gums and brushing and flossing can help prevent dental problems. Visiting dentists regularly is important to prevent dental diseases (New York State Department of Health, 2006)

- Limit the food and drinks containing sugar to mealtimes.
- Regular visits to a dental clinic for check-ups are important to prevent dental diseases.
- Dental care is safe and effective during pregnancy.
- Pregnancy by itself is not a reason to postpone routine dental care and necessary treatment for dental health problems.
- First trimester diagnosis and treatment, including needed dental x-rays, can be undertaken safely to diagnose disease processes that need immediate treatment.
- Dental prophylaxis and treatment during pregnancy, preferably during early second trimester but definitely prior to delivery.
- Emergency dental care is safe at any time during pregnancy.
- Check with your GP and OBs re any problems with your mouth and need to attend the dentist.

(Buglar et al., 2010).

Strongly disagree is the correct answer.

Tooth brushing is painful. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Buglar et al., 2010).

Strongly disagree is the correct answer.

My teeth will break when I brush. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Buglar et al., 2010).

Strongly disagree is the correct answer.

My gums will bleed when I floss. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Buglar et al., 2010).

Strongly disagree is the correct answer.

My teeth will break when I floss. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Buglar et al., 2010).

Strongly disagree is the correct answer

Dental flossing is painful. (Strongly agree; agree; undecided; disagree; strongly

disagree; don't know) (Buglar et al., 2010).

Strongly disagree is the correct answer.

I am afraid I would not be able to seek dental treatment during pregnancy. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Conner and Norman, 2007).

Strongly disagree is the correct answer.

I am afraid I would not be able to limit food containing sugar to mealtimes only. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Conner and Norman, 2007).

Strongly disagree is the correct answer.

I am afraid I would not be able to visit the dentist regularly. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Conner and Norman, 2007).

Strongly disagree is the correct answer.

Visiting a dental clinic is time consuming. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Defranc et al., 2008).

Strongly disagree is the correct answer.

<table>
<tr><td colspan="3">Dental treatment is expensive. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Defranc et al., 2008).

Strongly disagree is the correct answer.

Visiting a dental clinic during pregnancy is not safe. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know).

Strongly disagree is the correct answer.</td></tr>
</table>

Kuwaiti pregnant women subjective norms (derived from qualitative study)	Information in the booklet	Questions
• My friends told me that they were complaining from their teeth during pregnancy and the dentist told them this was because the baby absorbed the calcium from their teeth. • I didn't go to the dentist because my family said the dentist would refuse to treat me, he/she would give me painkiller. • My friends told me don't go to the dentist; the dentist did not provide a treatment for pregnant women. • My family told me that I could not go to the dental clinic during pregnancy. There were twenty women and they were all told the same thing, 'dentist did not treat pregnant	We advise that you brush your teeth twice a day before bedtime and on one other occasion during the day. You may have morning sickness and prefer not to brush your teeth first thing in the morning. Pregnancy by itself does not harm the teeth or gums and brushing and flossing can help prevent dental problems.	My family thinks it is important that I brush my teeth daily. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Defranc et al., 2008). Strongly agree is the correct answer. My family thinks I should floss my teeth every day. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Lavin and Groarke, 2005). Strongly agree is the correct answer. My family thinks I should seek dental treatment when I have dental problems

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women'.

- My mother always told me that water and salt acts as an antiseptic.

during pregnancy.
(Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Lavin and Groarke, 2005).

Strongly agree is the correct answer.

My family thinks it is important that I eat healthy snacks.
(Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Lavin and Groarke, 2005).

Strongly agree is the correct answer.

My family thinks that it is normal to see the dentist regularly for a check-up even if I am pregnant. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Lavin and Groarke, 2005).

Strongly agree is the correct answer.

Intention (outcomes)	Information in the booklet	Questions
• I intended to clean my teeth after giving birth. • I have toothache and I am going to extract my teeth after giving birth. • After giving birth I do go to the dentist to check-up on my teeth.	Top tips to help protect your teeth and gums throughout pregnancy • Brush your teeth twice a day with fluoridated toothpaste. • Brushing your teeth before bedtime is most effective. • Floss your teeth once a day before bedtime. • Spit out after brushing and do not rinse your mouth.	I intend to brush my teeth twice a day regularly. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Schüz et al., 2006). Strongly agree is the correct answer. I intend to use dental floss regularly. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Schüz et al., 2006).

- Use a fluoride mouth rinse daily at a different time of tooth brushing.
- Limit the food and drinks containing sugar to mealtimes.
- Regular visits to a dental clinic for check-ups are important to prevent dental diseases.

Strongly agree is the correct answer.

I intend to seek dental treatment during pregnancy. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Schüz et al., 2006).

Strongly agree is the correct answer.

From now on, I intend to avoid sugary snacks (food or drinks) as much as possible. (Strongly agree; agree; undecided; disagree; strongly disagree; don't know) (Defranc et al., 2008).

Strongly agree is the correct answer.

I intend to go to the dentist for a check-up regularly.(strongly agree; agree; undecided; disagree; strongly disagree; don't know)(Defranc et al., 2008)

Strongly agree is the correct answer

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5.4.11 Randomisation and masking

A DH, who assessed the women's eligibility, undertook the pre- and post-clinical assessment and administered the questionnaires to participants. She was masked to the groups' allocation at Time 1 and Time 2. The researcher randomly allocated the participants into one of the three groups based on their given number: SC (TAU) group, DHE group and DHE&P group following the randomisation table that had been generated by a statistician. The researcher was masked to participants' baseline GI and PI and their scores on the questionnaire. The researcher delivered the intervention to the three groups and undertook the data entry. The analysis was undertaken with co-authors who were masked to the group allocation during data analysis.

5.4.12 Sample size calculation

This study was designed to have 80% power, at the 5% significance level, to detect changes of 25% vs 50% in the proportions of mothers assessed to have improved GI, for which 66 women per group are required. This sample size also provided 80% to detect effects of size 0.5 and above between the groups in terms of the clinical outcomes of the plaque and gingival indices. Since a 20% loss to follow up was anticipated, a total of N=82 mothers were to be enrolled per group.

5.4.13 Statistical analysis

The following analyses were planned: first the characteristics of participants in each group were to be presented using simple descriptive statistics. This would include the following variables:

Characteristics of participants:

1. Age.

2. Education.

3. Monthly income.

4. Occupation.

5. Number of children.

6. Number of pregnancies.

Next, a mixed analysis of variance (ANOVA) was undertaken (with repeated measures on time, between measures on type of intervention) to compare the means between the three groups on the clinical assessment (PI and GI) and the following constructs: knowledge, attitude, subjective norms, barriers, intention.

Finally, bivariate analyses were undertaken to assess any change in pre- and post-intervention. The McNemar-Bowker was undertaken for the following variables:

1. Self-reported dental health rate

2. Brushing during the past week.

3. Flossing during the past week.

5.4.14   Ethical Considerations

Research ethics approval was obtained from King's College London Research Ethics Committee (BDM/10/11-32) and from the Kuwait Research Ethics Committee. All participant documents including the information sheet, consent form, questionnaire, dental hygiene skills leaflet, booklet, and brushing and dental action plan sheet, were translated into Arabic and back translated into English to ensure accuracy of translations.

5.5 Results

5.5.1 Characteristics of respondents

5.5.1.1 Description of the participants

Two hundred and thirty two (N=232) pregnant women were asked to participate in the study. Twenty-nine (N=29) refused to take part and 32 women were excluded because they were in the third trimester, so they did not match the inclusion criteria. One hundred and seventy one (N=171) women who agreed to participate and who matched the inclusion criteria were asked to sign the consent form and complete the Time 1 questionnaire. Seventeen participants (N=17) did not complete Time 1 measures either because they were not interested or said they did not have time to complete the questionnaire. One hundred and fifty four (N=154) pregnant women completed all measurements at Time 1; the distribution of participants across interventions was N=53 in TAU group, N=53 in DHE group and N=48 in DHE&P group. At Time 2; N=90 out of 154 participants returned for their follow-up visits. The distribution of the participants who completed Time 2 was: N=28 TAU group, N=30 DHE group and N=32 DHE&P group. Eighteen pregnant (N=18) women were excluded at this stage due to pregnancy complications: (N=7) from TAU group, eight (N=8) from DHE group and three (N=3) from DHE&P group. These women were referred to the maternity hospital by their obstetricians for further care. Twenty-nine (N=29) of the participants (N=13 TAU; N=11 DHE; N=5 DHE&P) who completed Time 1 did not return to their follow-up visits. The researcher attempted to contact them but the participants either did not answer the phone call or return the text messages, or they decided to seek maternity care in private maternity clinics and hospitals so they refused

coming back to complete the follow-up (see Figure 5.2 flow chart of pregnant women participants and group allocations).
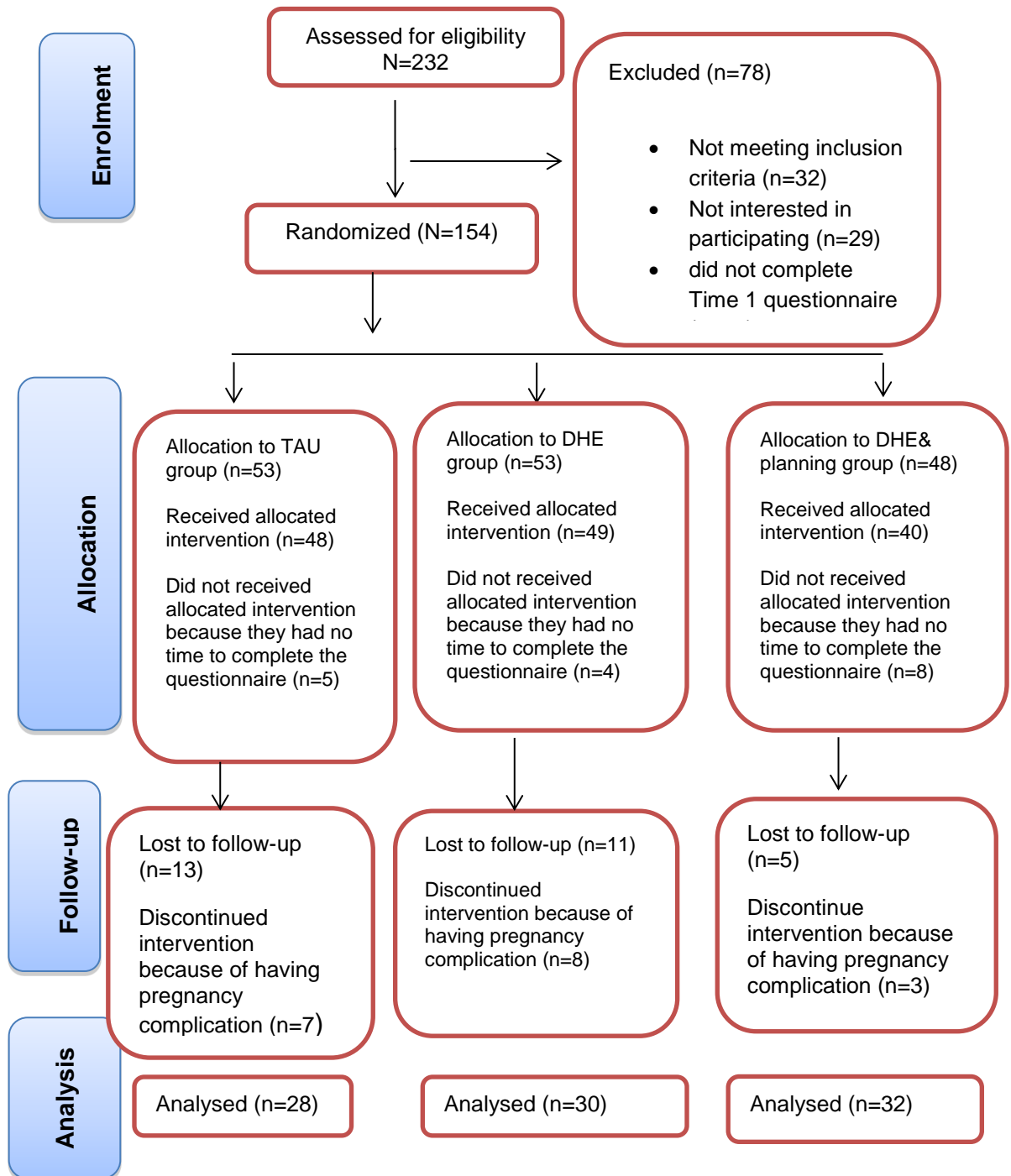
Figure 5.2: Flow chart of pregnant women participants and group allocations

5.5.1.2 Socio-demographic characteristics

The participants' ages ranged from 19 to 40 years, with a mean age of 27.8 (SD 5.4). The mean number of children was 2.1 (SD 1.8). More than a quarter of the women (27%) were in their first pregnancy. The number of children ranged from having no children to having eight children. The mean number of previous pregnancies was 2.2 (SD 2.0). The number of previous pregnancies ranged from a first pregnancy to ten previous pregnancies (see Table 5.4: baseline characteristics of the participants.)

Ten% (N=9) of respondents had no formal education or had only completed primary school; 32% (N=29) of respondents completed high school; 3% (N=32) of respondents completed two years of formal education after high school; and 22% (N=20) reported having a bachelor's degree. There was a significant difference between the three groups concerning the highest educational levels (P=. 021). The data suggested that the DHE group had a tendency for inclusion of more educated participants (had a bachelor's degree) compared to the two other groups and the SC group had more participants with lower education levels (see Table 5.4).

Just over a quarter of the respondents (26% N=23) were not working, 19% (N=17) of respondents were students, 32% (N=29) were working as secretaries or services personnel, 4% (N=4) were technicians, and 19% (N=17) were teachers.

Ten participants did not respond to the monthly family income, also several participants were not accurate in responding to this question. Women might be sensitive or thought it inappropriate to declare their family income; however some participants claimed that they did not know their husband's monthly income so they reported their own monthly allowance instead of the family income.

For more than a quarter of the respondents (27% N=24) income was less than 750 KD (£1500), 34% (N=30) were between 751 and 1250 KD (£1502 and £2500), and 19% (N=17) had higher than 1751 KD (£3502) as a monthly income.

Table 5.4: Baseline characteristics of the pregnant women participating in the study

Variable	Total (N=90)	Group1 (TAU) (N=28)	Group2 (DHE) (N=30)	Group3 (DHE&P) (N=32)	P
Age					0.403
Mean (SD)	27.8(5.4)	28.8(5.7)	27.7(5.6)	26.97(4.8)	
Range	19-40 yrs.	19-40 yrs.	19-38 yrs.	20-38 yrs.	
Highest educational level % (N)					0.021*
No formal education or primary education	10.0 (9)	5.6 (5)	1.1 (1)	3.3 (3)	
High school	32.2 (29)	14.4 (13)	7.8 (7)	10.0 (90	
Diploma (two years studying after high school)	35.6 (32)	5.6 (5)	13.3 (12)	16.7 (15)	
Bachelor (four years after high school)	22.2 (20)	5.6 (5)	11.1 (10)	5.6 (5)	
Total	100 (90)	31.1 (28)	33.3 (30)	35.9 (32)	
Occupation % (N)					0.445
Housewife/not working	25.6 (23)	10.0 (9)	8.9 (8)	6.7 (6)	
Student	18.9 (17)	6.7 (6)	3.3 (3)	8.9 (8)	
Secretary, services personnel, etc.	32.2 (29)	7.8 (7)	10.0 (9)	14.4 (13)	
Technician	4.4 (40)	2.2 (2)	2.2 (2)	0.0 (0)	
Teacher	18.9 (17)	4.4 (4)	8.9 (8)	5.6 (15)	
Total	100 (90)	31.1 (28)	33.3 (30)	35.6 (32)	
Monthly income % (N)					0.636
Less than 750	26.7 (24)	10.0 (9)	8.9 (8)	7.7 (7)	
751-1250	33.4 (30)	8.9 (8)	12.2 (11)	12.1 (11)	
	15.6 (14)	3.3 (3)	4.4 (4)	7.7 (7)	

1251-1750		3.3 (3)	5.5 (5)	4.4 (4)	
	18.9 (17)				
More 1751		25.6 (23)		31.9 (29)	
Total	88.9 (80)		31.1 (28)		
Number of children					0.292
Mean (SD)	2.06 (1.81)	2.21 (1.91)	2.33 (1.84)	1.66 (1.66)	
Number of previous pregnancy					0.177
Mean (SD)	2.21(1.99)	2.46(2.22)	2.53(2.03)	1.69(1.66)	

*P ≤0.05

5.5.2 Reliability analysis

Reliability analysis for the questionnaire was undertaken by using Cronbach's alpha. The test was undertaken for all questionnaire items (60 items) which was 0.843. Then the test was undertaken for the five constructs items separately. The score for knowledge was 0.751 (27 items), the Cronbach's alpha was improved to 0.850 after omitting one item which was; 'you should change your toothbrush after 3 to 4 months'.

Cronbach's alpha for attitude (11 items) was 0.698, the reliability score improved to 0.703 by deleting one item, 'aching and rotten teeth are to be expected in pregnancy'.

The Cronbach's alpha was 0.594 for subjective norms (five items) and by deleting one item, 'my family think I should floss everyday', the score improved to 0.613.

The Cronbach's alpha for barriers (12 items) was 0.632 and improved to 0.654 by deleting one item, 'visiting dental clinic during pregnancy is not safe'. The Cronbach's alpha for intention (5 items) was 0.370.

Cronbach's alpha test indicated a good level of reliability for the overall questionnaire and for knowledge and attitude items. The reliability scores were acceptable for subjective norms and barrier items. However, the Cronbach's alpha

test indicated low and unacceptable reliability for intention which might be because of the small number of the items (5 items) included so the intention items were omitted from statistical analysis in addition to individual items as discussed earlier.

5.5.3 SCM constructs

The questionnaire assessed four SCM constructs and reported oral health behaviours.

5.5.3.1 Responses scoring and missing values

5.5.3.1.1 Responses scoring

The correct responses for items relating to the knowledge construct were scored 1 and the incorrect answer scored 0. In order to ensure that reverse scoring did not affect the measure, the positive responses to attitudes, subjective norms and barriers were scored from 5 to 1 and negative responses were scored from 1 to 5.

This meant a high score always meant a positive attitude, positive subjective norms and reduced barriers. The individual variables making up the four SCM constructs measures have been presented in Table 5.2.

5.5.3.1.2 Missing values

Table 5.5 summarises the missing values of SCM constructs at Time 1 and Time 2. According to Brace et al. (2009) SPSS does not compute a new variable with missing values. So the new variable of the SCM constructs was computed by replacing missing items with the mean scores for that variable (Brace et al., 2009).

Table 5.5: Frequency of SCM constructs missing values in Time 1 and Time 2

SCMs constructs	N of missing values Time 1	N of missing values Time 2
Knowledge	16	11
Attitude	17	5
Subjective norms	1	2
Barrier	2	2

5.5.4 Analysis of primary outcomes

Testing the hypothesis that the intervention (TAU, DHE, or DHE&P) affected clinical outcomes (PI and GI) differently

a. Plaque Index (PI)

The total mean value for PI improved from 1.453 (Time 1) to 0.854 (Time 2). The mean improvement in the three intervention groups was as follows: TAU from 1.481 to 0.952, DHE from 1.417 to 0.851 and DHE&P from 1.462 to 0.771 (see Figure 5.3).

There was a significant effect of time: [$F_{(1, 87)}$ =94.343, P=0.0001]. However, the interaction between time and intervention groups was not significant: [$F_{(2, 87)}$ = 0.664, P=0.517], nor was there a difference between-groups: [$F_{(2, 87)}$ = 0.368, P=0.693] (see Table 5.6).

There was an improvement in the dental health behaviour (PI) in all groups regardless of group allocation. This means that participants were brushing their teeth effectively more post intervention, regardless of intervention group (see Figure 5.3).

Table 5.6: Mixed factor ANOVA to PI (N=90)

Source	Df	F	Sig.
Time	1	94.343	0.0001
Time* study groups	2	.664	0.517
Study group	2	.368	0.693
Error (Time)	87		

*P ≤.05
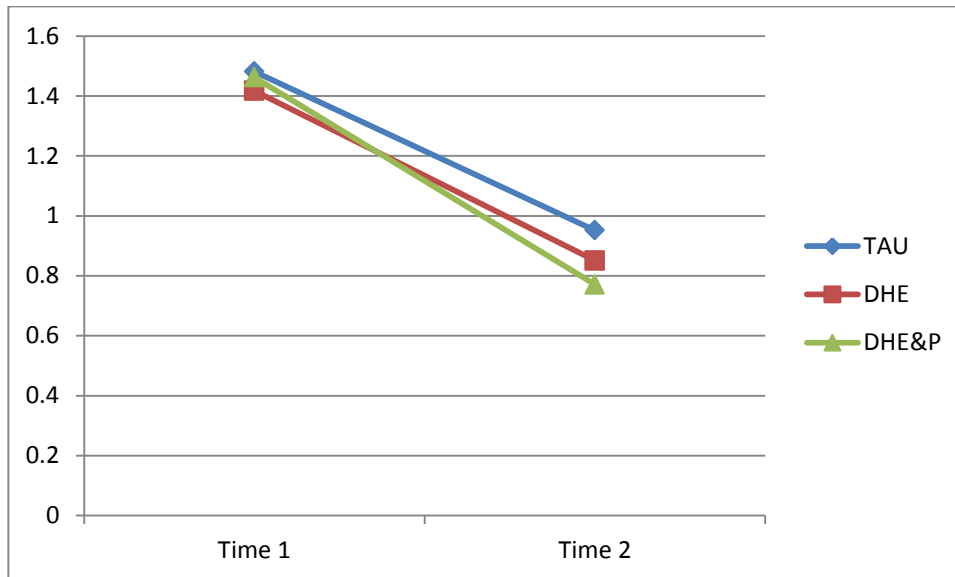
Figure 5.3: Time by intervention groups on PI

b. **Gingival Index (GI)**

The total mean value of GI improved from 1.6556 (Time 1) to 1.1556 (Time 2). The mean improved in the three intervention groups: TAU from 1.644 to 1.283, DHE from 1.649 to 1.142 and DHE&P from 1.672 to 1.057 (see Figure 5.4).

There was a significant main effect of time: [F (1, 87) = 73.138, P=0.0001].

However, the interaction between time and intervention groups was not significant:

[F (2, 87) = 1.600, P=0.208] and there was no significant between-group effect: [F (2, 87) =. 334, P=0.717] (see Table 5.7). There was an improvement in dental health behaviour as assessed by GI in all groups (see Figure 5.4).

Table 5.7: Mixed factor ANOVA to GI (N=90)

Source	df	F	Sig.
Time	1	73.138	0.0001
Time* study groups	2	1.600	0.208
Study group	2	.334	0.717
Error (Time)	87		

*P ≤.05
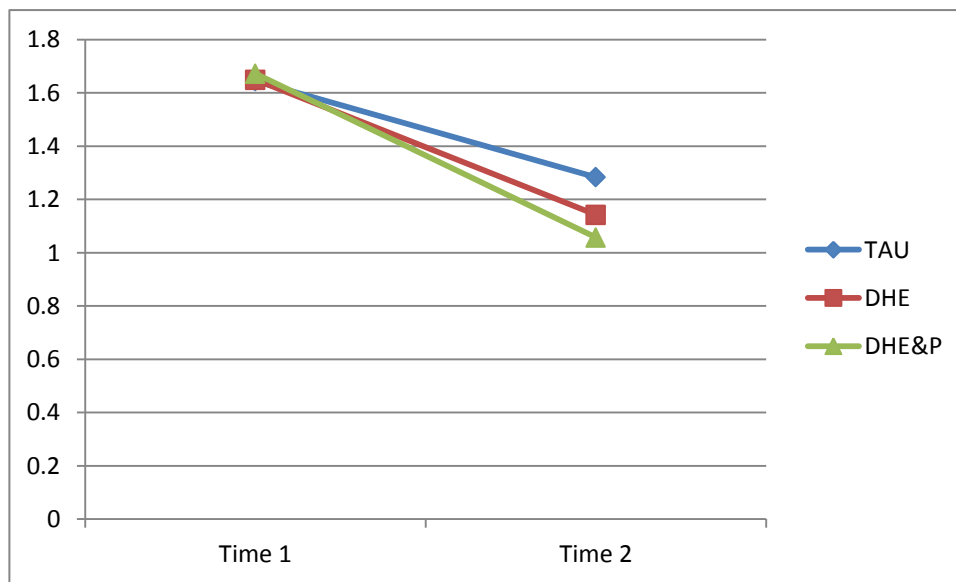
Figure 5.4: Time by intervention groups on GI

5.5.5 Analysis of secondary outcomes

5.5.5.1 Continuous variable results

Testing the hypothesis that the intervention (TAU, DHE, or DHE&P) affected SCM constructs differently

Mixed ANOVA analyses (with repeated measures on time, between measures on type of intervention) were used to assess changes across the three-intervention groups and as a function of time on SCM constructs: dental health knowledge, attitude, subjective norms and barriers. The individual variables contributing to each construct score have been presented already in Table 5.2.

a. Knowledge

The questionnaire asked the participants to respond to 36 questions (27 main questions were asked, but in two questions women were asked to choose more than one answer) that measured dental health knowledge concerning tooth brushing, dental flossing, dental and gum diseases, snacks and regular dental visits. One item 'you should change your toothbrush after 3 to 4 months' was found to be unreliable so it was deleted from the knowledge questions analysis. The correct responses were scored 1 and the incorrect responses were scored 0. The overall mean for dental health knowledge increased from Time 1 to Time 2 (N=90) from 8.79 to 14.61. The mean values for dental health knowledge before the intervention (Time 1) were 8.71 for TAU group (N=28), 8.67 for DHE group (N=30), and 8.97 for DHE&P group (N=32). The mean for dental health knowledge increased in the post intervention period (Time 2) in all three groups. TAU group was 14.04, DHE group was 14.53, and DHE&P group was 15.19. The range of

knowledge scores on the scale was small in Time 1 and increased in Time 2 within the three groups, regardless of the intervention (see Figure 5.5).
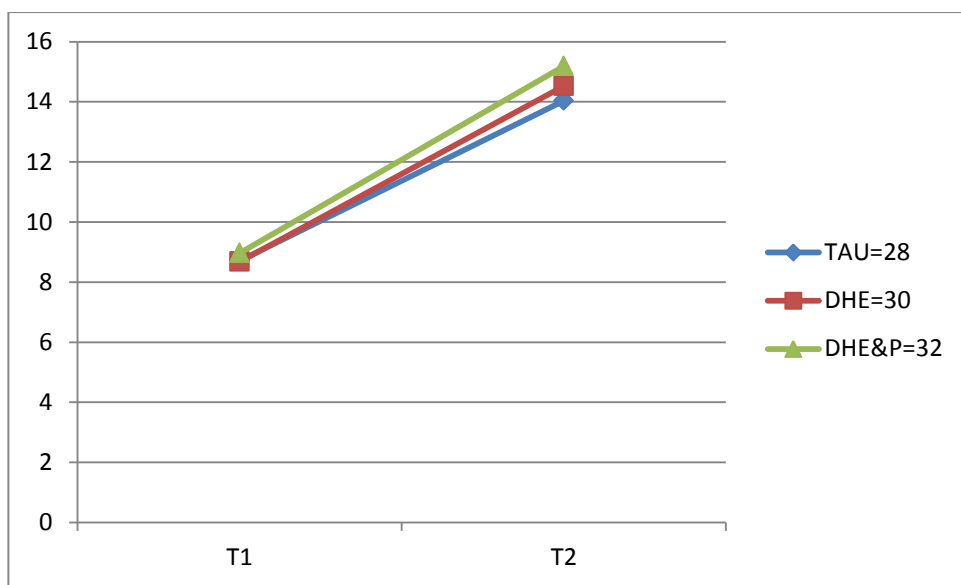
Figure 5.5: Time by intervention groups on dental health knowledge

All groups had an increased knowledge mean score between Time 1 and Time 2. However, there was no difference by type of intervention as illustrated in Figure 5.5 A mixed factor ANOVA demonstrated a group mean effect of time on the knowledge scores [$F_{(1, 87)}$ =295.63, P=0.0001]. There was no significant interaction effect between time and intervention groups: [$F_{(2, 87)}$ = 0.593, P=0.555]. There was no significant difference between the groups [$F_{(2, 87)}$ =1.068, P=0.348] (see Table 5.8).

The result suggested that there was no superior benefit attributable to the type of intervention in the three study groups. That is, dental health knowledge improved in similar ways between Time 1 and 2, irrespective of the intervention delivered (see Figure 5.5).

Table 5.8: Mixed factor ANOVA for dental health knowledge (N=90)

Source	df	F	Sig.
Time	1	295.63	*0. 0001
Time* study groups	2	0.593	0.555
Study group	2	1.068	0.348
Error (Time)	87		

*P ≤.05

b. Attitude

The questionnaire asked the participants to respond to 11 questions that measured the dental health attitudes towards tooth brushing, dental flossing, dental and gum diseases, having healthy snacks and regular dental visits. One item was deleted as it was shown to be unreliable, "Aching and rotten teeth are to be expected in pregnancy". As described earlier, the positive responses of attitude were scored from 5 to 1 and negative responses were scored from 1 to 5.

The overall mean of dental health attitudes increased from Time 1 to Time 2 (N=90) from 2.91 to 3.60. This meant that women developed more positive attitudes to brushing, flossing, having healthy snacks and regular dental visiting post intervention (see Figure 5.6). The mean values for dental health attitude increased within groups as well. The mean before the intervention (Time 1) was 2.86 for TAU group (N=28), 2.91 for DHE group (N=30), and 2.96 for DHE&P group (N=32). The dental health attitudes mean values increased post intervention (Time 2) among the three groups: TAU group was 3.48, DHE group was 3.59, and DHE&P group was 3.69. Figure 5.6 shows the attitude means improvements from Time 1 to Time 2.

Although all attitude scores improved post intervention, there was no difference by the type of intervention.
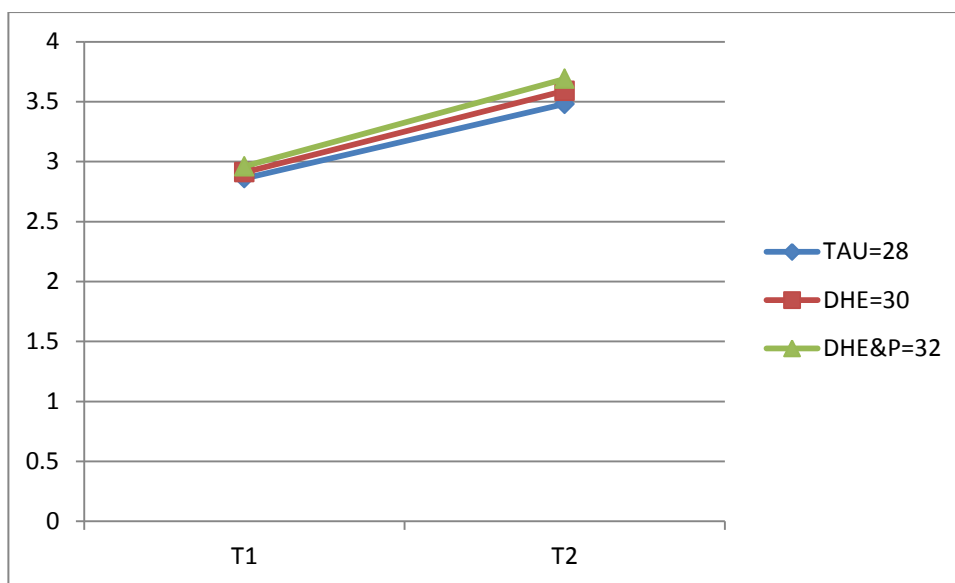
Figure 5.6: Time by intervention groups on dental health attitude

A mixed factor ANOVA demonstrated that there was a significant main effect of time: [$F_{(1, 87)}$ = 47.107, P =0.0001]. There was no significant interaction between time and intervention groups: [$F_{(2, 87)}$ = 0.085, P=0.918]. The main effect of the intervention design was also not significant, [$F_{(2, 87)}$ = 0.613, P=0.544] (see Table 5.9).

Table 5.9: Mixed factor ANOVA for dental health attitude (N=90)

Source	Df	F	Sig.
Time	1	47.107	*0.0001
Time* study groups	2	0.085	0.918
Study group	2	0.613	0.544
Error (Time)	87		

*P ≤0.05

c. Subjective norms

The questionnaire asked the participants to respond to five questions that measured subjective norms concerning tooth brushing, dental flossing, dental and gum diseases, snack consumption and regular dental visits. One item was unreliable, 'my family think I should floss everyday', so it was deleted. The four questions were scored from 5 to 1. The higher score represents the positive responses.

The overall subjective norms total mean value increased from 3.75 (Time 1) to 4.07 (Time 2). The mean values increased within the groups as well. The mean of TAU group (N=28) was 3.48 in Time 1 and increased to 3.89 in Time 2; the mean of DHE group (N=30) was 3.84 in Time 1 and increased to 4.07 in Time 2; and DHE&P group (N=32) was 3.91 in Time 1 and increased to 4.22 in Time 2 (see Figure 5.7).
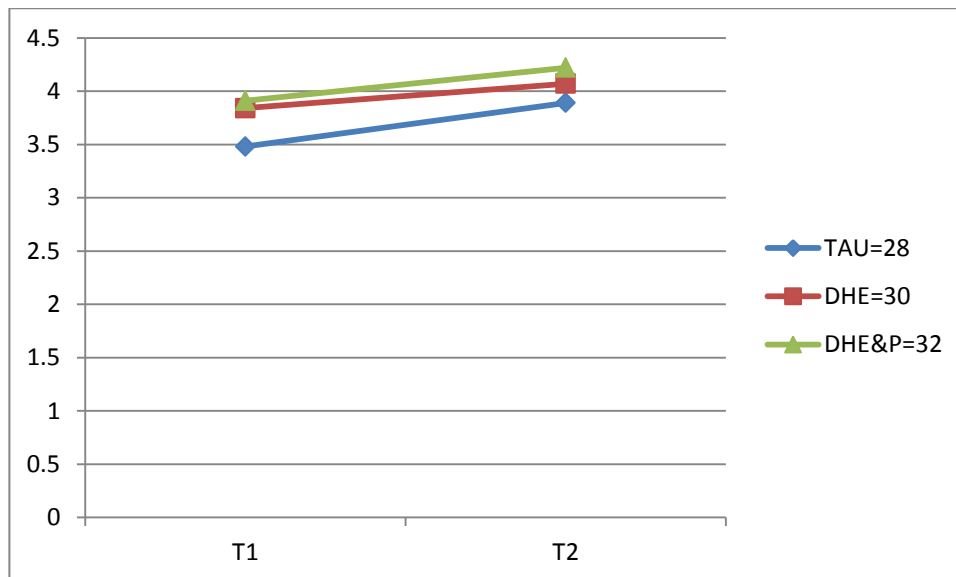
Figure 5.7: Time by intervention groups on subjective norms

Mixed factor ANOVA showed that there was a significant within group main effect of time subjective norms: [F (1,87)= 9.297, P=0.003]. There was no significant interaction between time and intervention groups: [F (2,87)= 0.236, P=0.790]. There was no significant difference between groups [F (2,87)= 2.562, P=0.083] (see Table 5.10).

Table 5.10: Mixed factor ANOVA for subjective norms (N=90)

Source	df	F	Sig.
Time	1	9.297	*0. 03
Time* study groups	2	0.236	0.790
Study group	2	2.562	0.083
Error (Time)	87		

*P ≤0.05

The result suggested that there was a significant effect of the time; however, there was no significant effect of interaction between study groups and intervention, as well as, type of intervention design. There was an improvement across all intervention groups (see Figure 5.7).

d. Barriers

The barriers construct assessed the dental health barriers that prevented participants from brushing, flossing, having healthy snacks and visiting the dentist regularly. Dental health barriers were assessed by 12 questions. One item was omitted that was found to be unreliable 'visiting dental clinic during pregnancy is not safe'.

i. Tooth brushing barriers

The questionnaire asked the participants to respond to three questions that measured the tooth brushing barriers. The scoring has been reversed from the original questionnaire; therefore a higher score denotes perception of fewer barriers.

The total mean value of tooth brushing barriers barely increased from 3.39 (Time 1) to 3.85 (Time 2). The mean values increased amongst the groups: TAU group (N=28) mean was 3.18 in Time 1 and 3.53 in Time 2; DHE group (N=30) mean was 3.48 in Time 1 and 3.96 in Time 2; and DHE&P group (N=32) was 3.48 in Time 1 and 4.04 in Time 2 (see Figure 5.8).
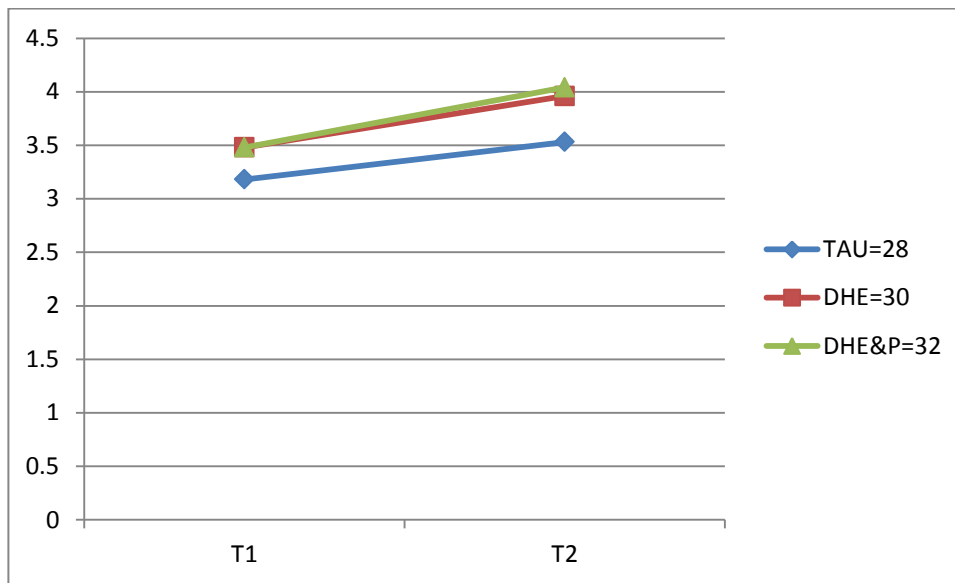
Figure 5.8: Time by intervention groups on tooth brushing barriers

There was a significant main effect of time: [F (1, 87)= 13.254, P=0.0001] and no significant interaction between time and intervention groups: [F (2, 87)= 0.230, P=0.795]. There was also no significant difference between groups [F (2, 87) = 3.056, P=0.052] (see Table 5.11).

Table 5.11: Mixed factor ANOVA for tooth brushing barriers (N=90)

Source	df	F	Sig.
Time	1	13.254	*0.0001
Time* study groups	2	0.230	0.795
Study group	2	3.056	0.052
Error (Time)	87		

*P ≤0.05

The data suggested that there was an effect of time but no unique benefit for one particular intervention group. There was a difference between the TAU group and the other two groups at Time 1. However, the three intervention groups improved regardless of the type of intervention and perceived fewer barriers to tooth brushing post intervention (see Figure 5.8).

ii.   Dental flossing barriers

The questionnaire asked the participants to respond to three questions that measured the dental flossing barriers. The scoring has been reversed from the original questionnaire; therefore a higher score denotes perception of fewer barriers.

The total mean value of dental flossing barriers increased from 2.19 (Time 1) to 3.21 (Time 2). The mean values increased amongst the groups as well: TAU group

(N=27) from 2.09 to 2.86; DHE group (N=29) was 2.17 to 3.35 and DHE&P group (N=32) was 2.30 to 3.40 (see Figure 5.9).
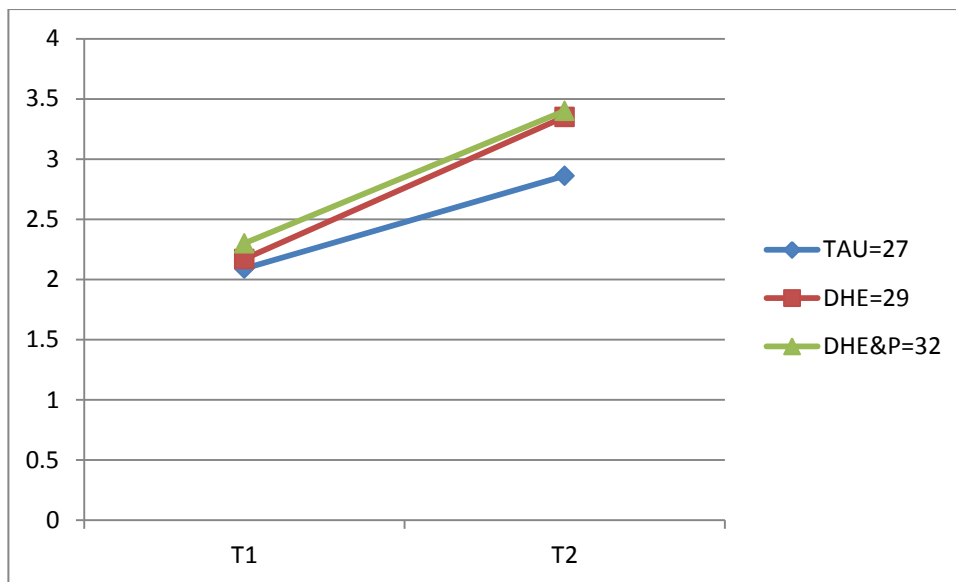
Figure 5.9: Time by intervention groups on dental flossing barriers

There was a significant effect of time, [F (1, 85) = 31.724, P=0.0001]. There was no significant interaction between time and intervention groups: [F (2, 85)= 0.444, P= 0.643] and no significant differences between groups: [F (2, 85)= 0.876 P=0.420] (see Table 5.12).

This means that there was some improvement between the groups, regardless of the type of intervention, and women perceived fewer barriers to dental flossing at Time 2 (see Figure 5.9).

Table 5.12: Mixed factor ANOVA for flossing barriers (N=88)

Source	df	F	Sig.
Time	1	13.254	*.0.0001
Time* study groups	2	0.230	0.795
Study group	2	.876	0.420
Error (Time)	85		

*P ≤.05

iii. Regular dental attendance barriers

The questionnaire asked the participants to respond to five questions which measured dental attendance barriers. However, one item was excluded which was unreliable. The scoring has been reversed from the original questionnaire; therefore a higher score denotes perception of fewer barriers.

The total mean value of regular dental clinic attendance barriers did not improve; it was 2.403 in Time 1 and 2.405 in Time 2, which means that pregnant women felt they had not overcome the attendance barriers at Time 2. The mean values did not change amongst TAU group (N=28) from Time 1 (2.35) to Time 2 (2.35), however the mean of DHE group (N=30) slightly decreased from 2.65 to 2.47 and DHE&P group (N=32) increased from 2.21 to 2.39 (see Figure 5.10).

There was a tendency therefore for women in the DHE&P to perceive fewer barriers to attendance post intervention; however this effect was not statistically significant.
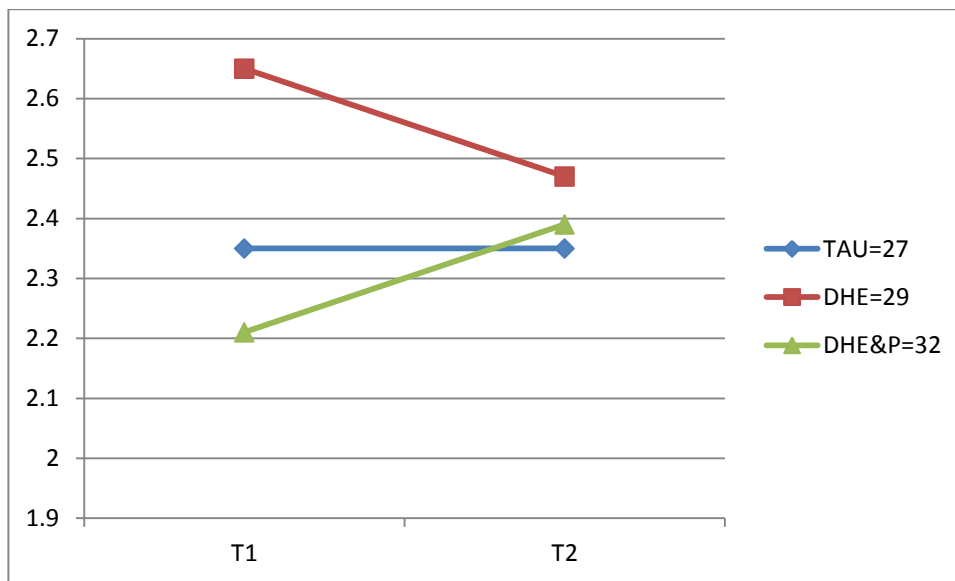
Figure 5.10: Attendance barriers mean in Time 1 and Time 2

There was no significant effect of time: [F (1,87)= 0.001, P=0.981], or interaction between time and intervention groups: [F (2, 87)=1.168, P=0.361], or between intervention groups: [F (2, 85)=1.168, P=0.316] (see Table 5.13). There was no change in this construct at any time and in any group.

Table 5.13: Mixed factor ANOVA for regular dental attendance barriers (N=90)

Source	df	F	Sig.
Time	1	.001	0.981
Time* study groups	2	1.168	0.361
Study group	2	1.168	0.316
Error (Time)	87		

*P ≤0.05

iv.   Healthy snacks barrier

The questionnaire asked the participants to respond to one question that assessed limiting food containing sugar to mealtimes. The scoring has been reversed from the original questionnaire; therefore a higher score denotes perception of fewer barriers.

The total mean value of barriers to healthy snacks increased from 2.26 (Time 1) into 2.85 (Time 2). The mean values increased between: TAU group from 2.00 to 2.46, DHE group was 2.37 to 2.93 and DHE&P group from 2.38 to 2.85.

There was a significant main effect of time: [$F_{(1,85)}$= 9.900, P=0.002]. However, the interaction between time and intervention group was not significant: [$F_{(2,85)}$ = 0.163 P=0.850], and there was no significant difference between groups [$F_{(2,85)}$ = 1.782, P=0.174] (see Table 5.14).

Table 5.14: Mixed factor ANOVA of healthy snacks barriers (N=88)

Source	df	F	Sig.
Time	1	9.900	*0.002
Time* study groups	2	.163	0.850
Study group	2	1.782	0.174
Error (Time)	85		

*P ≤0.05

Figure 5.11 shows that TAU group started from a lower point than the DHE and DHE&P groups in Time 1, i.e. they ate fewer healthy snacks. There was an improvement on the healthy snack barriers in all groups so participants perceived

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fewer barriers to limit the food containing sugar to mealtimes only in Time 2.
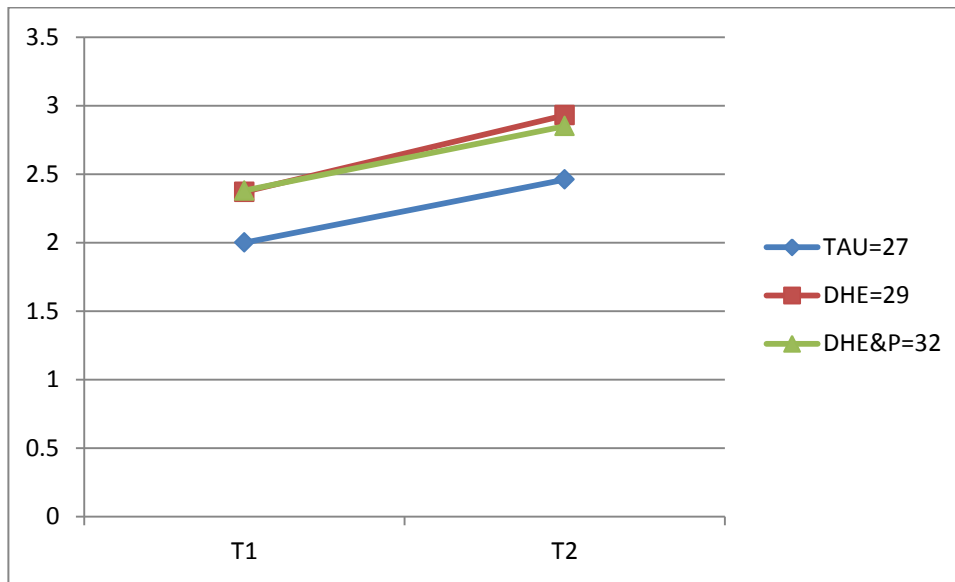
Figure 5.11: Time by intervention groups on healthy snack barriers

5.5.5.2 Categorical variables results

a. **Self-rating of dental health**

The questionnaire asked the participants to rate their dental health on five point scales that included 'excellent', 'good', 'fair', 'poor' and 'very poor'. Most of the participants reported that they had good (46%) or fair (38%) dental health status; however, only 7% reported that they had excellent dental health, 9% reported having poor and 1% reported having very poor dental health. Post intervention, half of the participants (50%) reported that their dental health status was fair and 33% reported that they had good dental health. More participants rated their dental health as poor (12%) in Time 2 and 2% reported that they had excellent dental health, and only 1% reported having very poor dental health (see Figure 5.12: Percentage of dental health rate at Time 1 and Time 2).
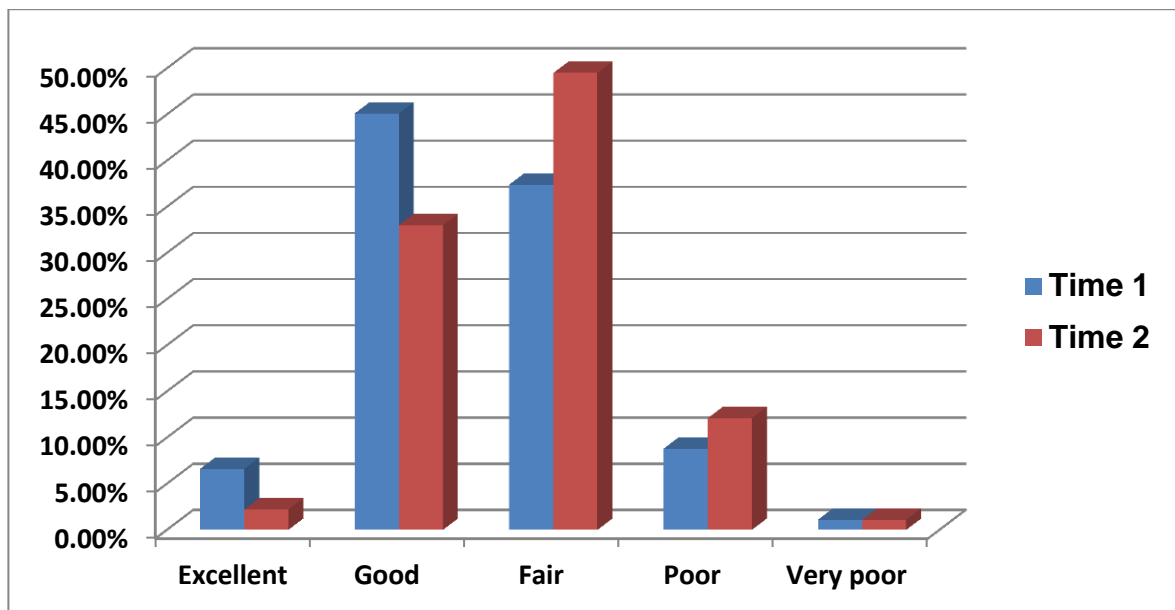
Figure 5.12: Percentage self-rating of dental health at Time1 and Time2

Table 5.15 shows the proportion of self-rating of dental health across the three intervention groups (TAU, DHE and DHE&P) in Time 1 and Time 2. The McNemar-Bowker test of self-reported dental health suggested that there was a significant difference of self-rating of dental health in TAU group (P=0.001). Also there was a significant change in all participants self-rating of their dental health between Time 1 and Time 2 (P=0.001).

Table 5.15: Proportion self-rating dental health in Time 1 and Time 2

Intervention group	Time	Excellent% (n)	Good % (n)	Fair % (n)	Poor % (n)	Very poor% (n)	Total % (n)	P
TAU (N=28)	Time 1	1.1 (1)	12.1 (11)	12.1 (11)	4.4(4)	1.1(1)	30.8 (28)	*0.001
	Time 2	2.2 (2)	9.9 (9)	9.9 (9)	7.7 (7)	1.1 (1)	30.8 (28)	
DHE (N=30)	Time 1	0 (0)	17.6 (16)	13.2 (12)	2.2 (2)	0 (0)	33(30)	0.081
	Time 2	0 (0)	11.0 (10)	17.6 (16)	3.3 (3)	0 (0)	33 (30)	

DHE&P (N=32)	Time 1	5.5 (5)	15.4 (14)	12.1 (11)	2.2 (2)	0 (0)	35 (32)	0.531
	Time 2	0 (0)	12.1 (11)	20.0 (20)	1.1 (1)	0 (0)	35 (32)	
Total	Time 1	6.6 (6)	45.1 (41)	37.4 (34)	8.8 (8)	1.1 (1)	98.9 (90)	*0.001
	Time 2	2.2 (2)	33.0 (30)	49.5 (45)	12.1 (11)	1.1 (1)	98.9 (90)	

*P ≤0.05

b. Self-reported dental hygiene behaviour

i.   Tooth brushing

The questionnaire asked the participants to report their dental health behaviours regarding tooth brushing over the past seven days on six point scales for brushing that included 'not at all', 'once a week', 'every second day', 'once a day', 'twice a day' and 'other.

Most of the participants (76%) reported that they brushed their teeth daily twice per day (38%) or once per day (38%) regardless of the intervention group. At Time 2, more than a half of the participants (57%) reported that they brushed their teeth twice a day and slightly more than a quarter of the women (26%) reported that they brushed their teeth once a day (see Figure 5.13 the percentage of self-reported tooth brushing Time 1 and Time 2). Therefore, all women, regardless of the intervention, had increased their reported brushing.
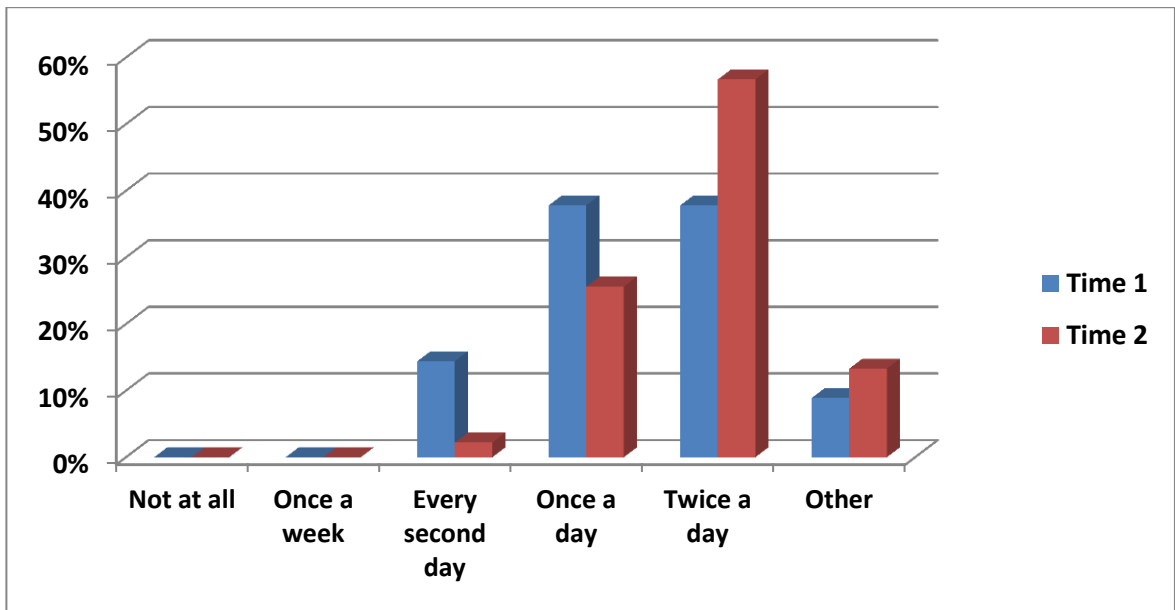
Figure 5.13: Percentage self-reported of tooth brushing Time 1 and Time 2

The McNemar-Bowker test to assess change in self-reported dental health behaviours during the last seven days across the three intervention groups was undertaken. There was a significant difference between Time 1 and Time 2 for self-reported tooth brushing (P=0.003). Pregnant women reported that they brushed their teeth more frequently post intervention. Women in all three groups reported they had increased the frequency of their tooth brushing, though there was no difference between the three groups (see Table 5.16).

Table 5.16: Proportion self-reported tooth brushing over the past seven days in Time 1 and Time 2

Intervention groups	Time	Not at all % (n)	Once a week % (n)	Every second day % (n)	Once a day % (n)	Twice a day % (n)	Other % (n)	Total % (n)	P
TAU (N=28)	Time 1	0 (0)	0 (0)	3.3 (3)	13.3 (12)	11.1 (10)	2.2 (2)	30 (27)	0.422
	Time 2	0 (0)	0 (0)	1.1 (1)	8.9 (8)	14.4 (13)	5.6 (5)	30 (27)	
DHE (N=30)	Time 1	0 (0)	0 (0)	7.8 (7)	7.8 (7)	14.4 (13)	3.3 (3)	33.3 (30)	0.225
	Time 2	0 (0)	0 (0)	1.1 (1)	8.9 (8)	16.7 (15)	5.6 (5)	32.3 (29)	
DHE&P (N=32)	Time 1	0 (0)	0 (0)	3.3 (3)	16.7 (15)	12.2 (11)	3.3 (3)	35.6 (32)	0.251
	Time 2	0 (0)	0 (0)	0 (0)	7.8 (7)	25.6 (23)	2.2 (2)	35.6 (32)	
Total (N=90)	Time 1	0 (0)	0 (0)	14.4 (13)	37.8 (34)	37.8 (34)	8.9 (8)	98.91 (89)	*.003
	Time 2	0 (0)	0 (0)	2.2 (2)	25.6 (23)	56.7 (51)	13.3 (12)	97.8 (88)	

*P ≤0 .05

ii. Dental flossing

The questionnaire asked the participants to report their dental health behaviour regarding dental flossing over the past seven days on five point scales for flossing that included 'not at all', 'once a week', 'every second day', 'once a day', and 'other'.

In pre-intervention most of the participants (62%) reported never using dental floss previously. Only 8% reported that they used dental floss once a day and 16% once a week. At post intervention (regardless of the intervention groups); the percentage of the participants who reported not using dental floss reduced to 33% and almost a quarter (23%) of the pregnant women reported flossing their teeth once a day (see Figure 5.14: Proportion of self-reported tooth brushing Time 1 and Time 2).
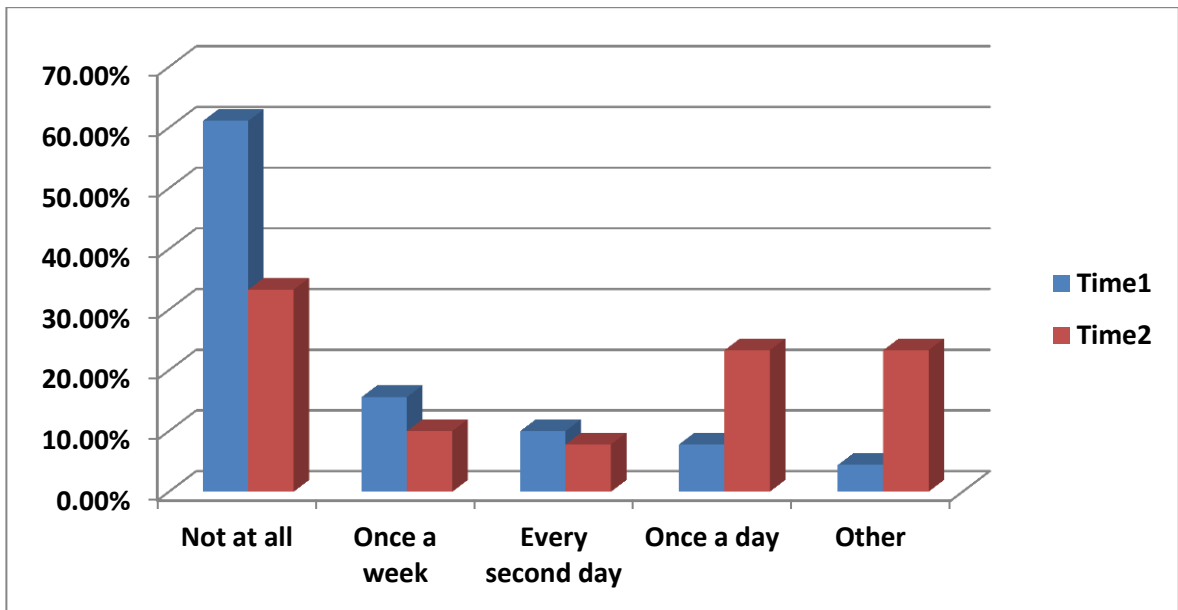
Figure 5.14: Percentage of self-reported dental flossing during the last week Time 1 and Time 2

The McNemar-Bowker test to assess change in self-reported dental flossing over the past seven days was performed. There was a significant difference in self-reporting of dental flossing over the past seven days (P= 0.001). Participants in all three groups reported they had used dental floss to clean their teeth more post intervention; though there was no difference between the three groups (see Table 5.17).

Table 5.17: Proportion self-reported dental flossing over the past seven days

Intervention groups	Time	Not at all % (n)	Once a week % (n)	Every second day % (n)	Once a day % (n)	Other % (n)	Total % (n)	P
TAU (N=28)	Time 1	17.8(16)	3.3(3)	4.4(4)	1.1(1)	3.3(3)	30(27)	0.205
	Time 2	11.1(10)	3.3(3)	1.1(1)	7.8(7)	6.7(7)	30(27)	
DHE (N=30)	Time 1	22.2(20)	5.6(5)	3.3(3)	1.1(1)	1.1(1)	33.3(30)	0.204
	Time 2	13.3(12)	2.2(2)	0(0)	6.7(6)	10.0(9)	32.2(29)	
DHE&P (N=32)	Time 1	21.1(19)	6.7(6)	2.2(2)	5.6(5)	0(0)	35.6(32)	0.467
	Time 2	8.9(8)	4.4(4)	6.7(6)	8.9(8)	6.7(6)	35.6(32)	
Total (N=90)	Time 1	61.1(55)	15.6(14)	10.0(9)	7.8(7)	4.4(4)	98.9(89)	*0.001
	Time 2	33.3(30)	10.0(9)	7.8(7)	23.3(21)	23.3(21)	97.8(88)	

*P ≤0.05

5.5.6 Summary of the inferential analyses

In summary, PI and GI scores improved from Time 1 to Time2 regardless of groups. Scores of knowledge, attitude, subjective norms, tooth brushing barriers, dental flossing barriers, and snack barriers also improved from Time 1 to Time 2 regardless of group. Table 5.18 summarises the clinical measures and SCM constructs findings.

Table 5.18: Summary of the mean standard deviation and mixed factor ANOVA of research outcomes: SCM constructs and clinical outcomes

SCM constructs		TAU (28) Mean(SD)	DHE (30) Mean(SD)	DHE&P (32) Mean(SD)	Total (90) Mean(SD)		Time P value	Time* study group P value	Study group P value
Knowledge	Time 1	8.71 (2.6)	8.67(2.5)	8.97(2.7)	8.79(2.6)		0.0001		
	Time 2	14.04(2.2)	14.53(2.4)	15.19(2.6)	14.61(2.4)				
Attitude	Time 1	2.86(.841)	2.91(.900)	2.96(.817)	2.91(.844)		0.0001		
	Time 2	3.48(.423)	3.59(.674)	3.69(.544)	3.59(.560)				
Subjective norms	Time 1	3.48(1.05)	3.84(1.05)	3.91(0.858)	3.76(0.994)		0.0003		
	Time2	3.89(0.643)	4.08(.483)	4.22(0.718)	4.07(0.632)				
Tooth brushing barriers	Time 1	3.18(.99)	3.48(1.12)	3.48(.80)	3.38(.98)	Mixed factor ANOVA	0.0001		
	Time 2	3.53(1.03)	3.96(.69)	4.04(.80)	3.85(.87)				
Flossing barriers	Time 1	2.09(1.52)	2.17(1.62)	2.30(1.29)	2.19(1.46)		0.0001		
	Time 2	2.86(1.50)	3.35(1.39)	3.35(1.39)	3.21(1.33)				
Attendance barrier	Time 1	2.36(.800)	2.65(.795)	2.21(.616)	2.40(.753)				
	Time 2	2.34(.74)	2.47(.726)	2.39(.635)	2.40(.693)				
Snacks barriers	Time 1	2.00(1.33)	2.37(1.52)	2.38(1.52)	2.26(1.46)		0.002		
	Time 2	2.46(1.39)	2.93(1.01)	3.09(1.37)	2.85(1.28)				
PI	Time 1	1.48(.58)	1.42(.49)	1.46(.46)	1.45(.50)		0.0001		
	Time 2	.95(.74)	.85(.56)	.77(.52)	.85(0.61)				
GI	Time 1	1.64(.59)	1.65(.39)	1.67(.51)	1.66(.50)		0.0001		
	Time 2	1.28(.73)	1.14(.50)	1.06(.54)	1.16(.59)				

5.5.7   Additional analyses

5.5.7.1   Characteristics of respondents based on the three healthcare centres *at baseline* (Time1)

a. Socio demographic characteristics at Time 1 by health centre

Forty-seven pregnant women were enrolled from Al Riqqa Primary Healthcare Centre, 27 from Sabah Al Salem Primary Healthcare Centre and 16 from Al Qurain Primary Healthcare Centre. There were no significant differences between the three healthcare centres regarding participant's age (P=0.13), education level (P=0.15) and current income (P=0.84). However there were significant differences between the three healthcare centres in terms of number of children (P=0.023) and number of previous pregnancies (P=0.026).

It appeared that participants from Sabah Al Salem Primary Healthcare Centre had more children and reported a higher number of previous pregnancies compared to the other two maternity centres.

b. Self-reported concern rating dental health, tooth brushing and dental flossing at Time 1 by health centre

There were no significant differences between the three centres in the self-rating of dental health (P=0.641). There were also no significant differences in the self–reported tooth brushing (P=0.733) and dental flossing (P=0.269) behaviours during the past seven days.

c. SCM constructs at Time 1 by health centre

There were no significant differences between the three centres and the constructs at baseline. The P value for knowledge was .880, attitude (P=0.742), subjective norms (P=0.073), tooth brushing barrier (P=0.216), flossing barrier (P=.870), attendance barrier (P=0.143) healthy snack barrier (P=0.222), tooth

brushing intention (P=0.528), flossing intention (P=0.523), attendance intention (P=0.051) which was very close to statistical significant and healthy snack intention (P=0.514) (see Table 5.19).

Table 5.19: The SCM constructs of respondents based on the three healthcare centres at baseline (Time 1)

SCM construct	Al Riqqa Healthcare Centre Mean (SD) N=47	Sabah Al Salem Healthcare Centre Mean (SD) N=27	Qurain Healthcare Centre Mean (SD) N=16	P value
Knowledge	8.70(2.7)	9.0 (2.6)	.8.79 (2.1)	0.880
Attitude	2.74 (.857)	2.84 (.698)	2.91 (.734)	0.742
Subjective norms	3.27 (.987)	3.77 (.807)	3.35 (.828)	0.073
Brushing barrier	3.28 (.884)	3.33 (1.205)	3.77 (.737)	0.216
Flossing barrier	2.177 (1.422)	2.306 (1.433)	2.062 (1.69)	0.870
Attendance barrier	2.35 (.788)	2.7 (.758)	2.36 (.603)	0.143
Snack barrier	2.08 (1.39)	2.19 (1.65)	2.81 (1.22)	0.222
Brushing intention	4.55 (.544)	4.69 (.471)	4.56(.512)	0.528
Flossing intention	2.72 (1.39)	3.00 (1.59)	2.5(1.265)	0.523
Attendance intention	3.62 (.951)	3.92 (.829)	3.22(.894)	0.051
Snack intention	3.00 (1.33)	3.15 (1.19)	2.69(1.26)	0.514

*P ≤0.05

5.5.8 Socio-demographic characteristics of respondents at Time 1 who did not return at Time 2

The total number of respondents who did not complete Time 2 was N=64 women with a mean age of 26.6 (SD 6.1); their age ranged from 18 to 42 years. The mean number of children was 1.9 (SD 2.1). More than a third of the pregnant women (33% N=21) who participated in Time 1 only, were in their first pregnancy. The mean of the number of previous pregnancies for these participants was 1.8 (SD 1.9).

Most of the pregnant women were educated to high school (31%) or diploma level (33%). The percent of respondents who had no formal education was 8% and only 19% had a bachelor's degree.

More than a quarter of Time 1 participants (27%) were not working; 22% were students, 27% were secretaries and services personnel, 2% were technicians and 13% were teachers.

Twenty-four participants did not respond to the monthly family income question. Almost one-third (30%) of the respondents' income was less than 750 KD (£1500), 14% were between 751 and 1250 KD (£1502 and 2500), 13% of the participants were between 1251 and 1750 KD (£2502 and 3500), and only 6% had more than 1751 KD (£3502) monthly.

In order to identify if there were any differences between the participants who did not complete the intervention and those that did, the means were calculated and compared for participants' age, number of children, number of previous pregnancies, and Time 1 PI and GI.

There were no significant differences between returning participants and non-returning participants in terms of age (P=0.227), number of children (P=0.622), number of pregnancies (P=0.226), PI (P=0.499) and GI (P=0.448). In addition, the Chi square test was used to test if there were differences between the two groups in terms of educational level, current occupation and monthly family allowance. There were no significant differences between the two groups concerning highest level of education (P=0.983), current occupation (P=0.725) and monthly family income (P=.238).

5.6 Discussion

The aim of this study was to assess the efficacy of dental health education with or without planning intervention on adherence with dental health related behaviours amongst pregnant Kuwaiti women. The intervention was designed and informed by a previous qualitative study with the same target group. Attitude, subjective norms and barriers were assessed alongside knowledge. A three arm RCT was designed to test the efficacy of an intervention based on SCM constructs which included knowledge, attitude, subjective norms, intention and barriers. Intention was subsequently eliminated from the analyses because the item measures proved to be unreliable. Planning was included in one arm of the intervention as the literature review had identified the efficacy of using planning in other dental studies to improve oral hygiene behaviour.

The study hypothesised that PI and GI scores would improve from Time 1 to Time 2, and also hypothesised that study groups would improve differently from Time 1 to Time 2. The results showed that there were significant differences between Time 1 and Time 2 in PI and GI; however all three groups improved in similar ways. The DHE&P group improvement was better than the DHE and TAU groups, and the DHE group, although it appeared to have improved more than the TAU group these differences were not statistically significant. This is in contrast to other studies which have demonstrated an effect from using planning in an intervention (Pakpour and Sniehotta, 2012; Suresh et al., 2011; Clarkson et al., 2009; Schüz et al., 2006).

The study hypothesised that SCM constructs would influence adherence with oral health behaviour. The results revealed change and improvements in knowledge, attitude, and subjective norms in relation to oral health. The study

showed a reduction in tooth brushing barriers, dental flossing barriers and snacking barriers. Perceived barriers to dental attendance did not change. There were however no significant differences in SCM or behaviours between groups and by intervention types. In this study an intervention based on SCM and/or planning was no superior to providing information (TAU). The results did show that it was possible and feasible for pregnant Kuwaiti women to improve their oral health behaviours under their individual control, to plan their oral hygiene regimes, and to develop strategies to overcome barriers to tooth brushing and flossing. In contrast behaviours that involved barriers outside their control (such as dental attendance) were less successfully overcome.

Regular oral health preventive visits are partly culturally determined and dependent on health structure and access opportunities to health care (Behbehani and Scheutz, 2004). Pregnant women could not easily take the decision to change their attendance pattern without, in essence being supported by a wider change such as changing the oral health system in Kuwait or changing the attitudes of dentists. Based on the previous qualitative study, pregnant Kuwaiti women reported that state dental clinics did not provide dental treatments to pregnant women and dentists did not encourage pregnant women to have dental treatment. These large cultural and structural barriers were not within the control of the women in the present study so it is not surprising that changes in their dental attendance barrier were not improved post -intervention.

Most of the oral health research conducted in Kuwait previously involved observational studies (mostly cross-sectional) which used single measures with no follow up. With hindsight aiming to conduct an RCT where there is little research support (ethics governance or clinical research network) was perhaps

too ambitious. A feasibility study to pilot study processes, research support and women's reaction to being involved in research might have provided valuable insights before the main study was conducted. Having an understanding of the women's reaction to the research would be important; as it cannot be ruled out that some of the changes in the self-report items could have occurred as a result of a 'Hawthorne' effect. The study did include objective clinical measures to offset this particular weakness, but as discussed later there were some limitations associated with these measures.

The strength of this RCT study was the development of an intervention based on a thorough understanding of the target group of women derived from the previous qualitative study. In this study, there were efforts to design an intervention to be culturally sensitive to the needs of pregnant Kuwaiti women. Attention was paid to understand the target group's needs concerning oral health during pregnancy. The decision to use the flyer and booklet was taken because pregnant women suggested written documents as their most favourite method to receive oral health information. All intervention documents were translated into Arabic language; to be understandable by Kuwaiti women as Arabic is the native language of Kuwait. The questionnaire was piloted to check whether questions were understandable and clear. The booklet and flyer were read by several Kuwaiti women to ensure their simplicity and clarity. Illustrations used in the booklet were of ordinary pregnant Kuwaiti women in order to be culturally appropriate to the target group. The booklet and flyer were designed to address the women's lack of accurate basic oral health information, which was the most important SCM construct noted in the qualitative study.

This approach adopted is to the best of the author's knowledge, the only one in the dental field that has been designed based on an understanding of the target group's needs. The intervention used constructs derived from the qualitative study to inspire, rather than drive, the intervention forward. In contrast most other studies using psychological theory to inform DHE have used one model of health behaviour, though the choice of these models are often not justified (Bonettie et al., 2009) and the evidence for their applicability in non-western settings has never been empirically tested. While this study found that an intervention planned on SCM was not superior to information-giving alone, it did demonstrate that these SCMs were amenable to positive change. The high attrition rates compromises the study and the numbers at T2 are too few to demonstrate an effect from the use of SCMs.

This intervention partially applied some of the MRC complex intervention framework that includes the following three elements: development, evaluation and implementation. The first element development involves understanding the background and context, defining and understanding the problem. This element was applied in this intervention by developing a clear and comprehensive background in relation to pregnancy and oral disease, through conducting a systematic review and the qualitative study. In addition the evidence gathered from these two background studies informed the study design and the theoretical framework used to frame the intervention. The researcher opted to undertake the definitive study rather than a feasibility study, which with hindsight as described earlier, might have been preferable.

The approach of employing a qualitative study before a definitive study has been used in dentistry previously.

Gilinsky and Swanson (2012) also used an a priori qualitative study which explored constructs followed by an intervention study (Gilinsky and Swanson, 2012). While the current study used a qualitative study to shape the intervention based on the SCM constructs identified, Gilinsky and Swanson's study undertook a qualitative study to assess predictors of oral health behaviour and then selected the constructs by using a taxonomy of behaviour change, developed by Abraham and Michie (2008). Both studies designed an intervention based on selected SCM constructs hypothesised to improve dental health behaviour for specific groups. While Gilinsky and Swanson demonstrated an improvement in oral health knowledge, oral health behaviours did not improve. In the present study SCMs changed positively and behaviours also improved (both self-report and objective measures).

The findings from the present study suggest that even simple health education (when knowledge levels are very low), which increases knowledge, might influence oral health behaviour for pregnant women in Kuwait. It seemed that providing basic oral hygiene information with a brief discussion and demonstration of oral hygiene skills, as occurred in the TAU group, might be sufficient to support improvement in dental health behaviours for participants who lacked basic oral health knowledge. The study suggested that in Kuwait, influencing health behaviour might be dependent on the individual's baseline health knowledge levels.

The study findings were inconsistent with several previous studies (Aboud and Singla, 2012; Bonetti et al., 2009; Glaz et al., 2008; Conner and Norman, 2007) that suggested that using psychological models to design an intervention might be more effective in influencing health behaviours than simply increasing health

knowledge by providing educational materials alone. Their samples however, did not demonstrate the very low levels of knowledge the participants demonstrated in the current work, which may be the reason behind this difference. Nevertheless, the findings from the present study suggest there is a role for oral health knowledge.

In contrast to the design used in the present study, many studies in dentistry have used cross-sectional studies to assess the influence of SCMs (Anagnostopoulos et al., 2011; Buglar et al., 2010; Buunk-Werkhoven et al., 2009; Defranc et al., 2008; Rayant and Sheiham, 1980). Cross-sectional approaches may not be that effective in influencing oral health behaviours because they are limited by their design; that is, being single measure only, they fail to capture any long-term effects of time on behaviour change. Time is an important factor in determining how sustained and embedded a new health behaviour may become (Morrison and Bennett, 2006). The same authors argue the importance of longitudinal research to study the association between health behaviour and an individual's health status. The strength of the current study lies in its longitudinal, repeated measures design.

The technique of utilising common psychological models is an evolving field and dental studies which have used SCMs have not produced conclusive results (Bonetti et al., 2009). Most previous work to change oral health behaviour has used traditional SCM theory (utilising models) (Buunk-Werkhoven et al., 2009; Defrance et al., 2008; Kuhner and Raetzke, 1989; Rayant and Sheham, 1980). Studies have expanded the SCM theory by adding one construct from other SCMs (Anagnostopoulos, et al., 2011; Buglar et al., 2009; Baker, 1994). Other studies applied a theory of SCMs and planning (Pakpour and Sniehotta, 2012;

Clarkson et al., 2009; Schuz et al., 2006; Lavin and Groarke, 2005). In contrast to the previous studies' approach, the present study is the only study known that is designed based on a thorough understanding of the target group, and has used SCM constructs known to be relevant and important to the target group. This is in contrast to previous dental studies that have selected the SCM theory on a hypothetical basis and then suggested that it would change and predict oral health behaviours without any background on the needs of the target group being studied (Pakpour and Sniehotta, 2012; Anagnostopoulos et al., 2011; Suresh et al., 2011; Buglar et al., 2010; Clarkson et al., 2009; Defranc et al., 2008; Schüz et al., 2006; Lavin and Groarke, 2005; Baker, 1994; Kuhner and Raetzke, 1989; Beck and Lund, 1981; Rayant and Sheiham, 1980). The present study was designed attempting to be culturally sensitive to the target group. It was designed based on women's needs, an approach which might be more efficient than applying SCMs in a one-size-fits-all way. Previous studies addressing the oral health information needs of pregnant women have been undertaken in Europe, the US and Australia and reflect cultural and social norms (Battancs et al., 2011; Christensen et al., 2003; Detman et al., 2010; Keirse et al., 2010; Martinez-Beneyto et al., 2011; Scambler et al., 2010). The findings from the present study are of course specific to the local, non-Western cultural setting and to women at an early stage of pregnancy and may only generalise to such settings. While the development of SCM occurred in the West, there is little work which suggests that these models have applicability in a Middle Eastern country with different social norms and culture.

The current findings can be explained in terms of recent attempts to understand behaviour change in terms of the COM-B model. This intervention, in focusing predominantly on knowledge, only addressed one of the three COM-B

components that is capability; it considered participants' capability to look after their oral health. Future work should methodically work through all three components of the model (Capability, Opportunity and Motivation) and consider behaviour change techniques that might be appropriate to tackle each of the three components. It could be, for example, that in the current cultural setting, providing pregnant women with opportunities to improve their oral health might be harder than in Western cultures where the health system might be more supportive of oral healthcare delivery to pregnant women. At the same time, increasing these women's motivation will probably be subject to culturally-influenced factors such as *maly khalg* (laziness) and probably be as challenging as it is in the West. The Theoretical Domains Framework (Cane et al., 2012) might be usefully applied in future work.

This study undertook a comparatively short term follow-up period (four weeks) to assess the improvement in women's oral health behaviour. However, the literature has highlighted the importance of long-term follow-ups of six months and over to ensure participants sustained adherence with oral health behaviour (Watt and Marinho, 2007). The four week period was chosen for practical reasons and is not ideal. Therefore, it would be important in future studies of adherence to oral hygiene measures to use longer follow-up periods to test whether the behaviour change was sustained. However this must be balanced against maintaining access to participants and likely higher attrition rates.

This study has shown that designing a culturally-relevant study, providing knowledge-based interventions may bring about change in health behaviour. Further research into this area would be useful in improving oral health behaviour.

5.6.1 Limitations

Although it was feasible to design an RCT intervention to improve oral health behaviour amongst pregnant Kuwaiti women, the attrition rate (participants who failed to complete Time 2) was high (41.5%). There was however no significant differences in demographic characteristics between people who completed the study and those who did not, suggesting that the women who remained in the study were still representative of all the women recruited to the study.

As mentioned earlier, the women's failure to complete Time 2 might be related to the following reasons: the questionnaire was too long, they were not interested to go through the research process again, or participants might have felt that they got the needed information so there was no need to come back. Simply put, the intervention may not have been acceptable to the women. Another reason might be related to Ramadan (the fasting month for Muslims); the intervention was delivered over six months and the last month was Ramadan so women might not have felt able to complete the follow-up visits because of feeling tired during fasting. Accordingly in future studies, it might be important to consider using a shorter questionnaire and staying in touch with the participants between the pre- and post- intervention to minimise the attrition rate. It might also be important to use more than one contacting method, such as home and mobile phone numbers as well as emails. In this way the researcher could be flexible in reaching the participants as well as in collecting the data. However, maintaining contact with participants might itself produce an effect which would need to be factored into the design of a study. It would also be important, if data were collected remotely to check that the participants completed all items included carefully, however in the present study the number of missing items was relatively small. Collecting data should be avoided during

Ramadan as it impacts on women's attendance and energy levels particularly during pregnancy. Future studies should investigate women's views of the interventions post hoc and include an objective assessment of the acceptability of the interventions post hoc.

The findings of this study might not be representative of all pregnant Kuwaiti women, because the sample was recruited from state medical health centres and most of Kuwaiti pregnant women sought health care from private clinics and hospitals. It might be important to consider recruiting women from state and private clinics and hospitals to ensure the representative sample in future work.

A four week gap between pre- and post-intervention seemed practical and a similar time gap was used in several studies such as Barker (1994), Beck and Lund (1981), Buunk-Werkhoven et al. (2009), Pakpour and Sniehotta (2012) and Suresh et al.(2011). It was not sufficient however to measure enhancement to oral health behaviour over a sustained period (Watt and Marinho, 2007). It might be more helpful to increase the time period between the first visit and follow up to ensure measuring long-term adherence to oral health behaviour effectively. Alternatively an additional follow up could be introduced at six months, but this could be seriously affected by attrition.

This study suggested some improvement in oral health behaviour (though group changes were not statically significant), however some of the items were assessed using self-reports. Although popular, such reports come with limitations such as social desirability issues and problems with participants' recall being inaccurate even when using short time frames (Asimakopoulou and Hampson, 2005). It is also possible that given women's unfamiliarity with research as a process, that there was a strong 'Hawthorne effect' associated

with the findings. These two limitations were partially controlled in the study using objective indicators of oral health change, as seen in PI and GI.

Even though clinical assessment scores were improved from Time 1 to Time 2 regardless of the type of intervention, the PI and GI were not applied according to the criteria of using these indices, which might influence the PI and GI validity in this study. This limitation was not under the researcher's control but determined by local research committee requirements as discussed earlier. The measurements might be underestimated concerning the scores 1 for PI and score 2 and 3 for GI. The indices were assessed by the same hygienist so any systematic differences in recording of these would have been similar across the three groups. Nevertheless it is an acknowledged limitation in the study. In future studies where local research ethics committees allow probing of the gingiva during pregnancy, the GI and PI should be used with probing, and supplemented with plaque staining.

It was not feasible to assess intra-examiner variability during the conduct of the study, so there is a danger of lack of consistency in application of diagnostic criteria and measures (PI and GI) over the period of the study.

The study did not ask the participants to reveal whether they received any dental treatment or advice before following up (Time 2). So the improvement in SCM constructs and clinical assessments might be related to additional sources other than the intervention. However, this limitation might not be serious because women reported that they did not receive dental treatment during pregnancy and they also reported that they only visited dentists for emergency dental treatment.

Another possible limitation is that the gingival health of pregnant women might have improved anyway regardless of the intervention as a result of underlying hormonal changes associated with pregnancy. Pregnancy gingivitis can occur at any stage during pregnancy and abates postpartum (Hugoson et al., 1971). It is not however associated with plaque accumulation, though women with excellent oral hygiene do not develop gingivitis (Carrillo-de-Albornoz et al., 2010). While presence of pregnancy hormones might have explained changes in GI, it would not explain changes in PI which would occur as a result of improved plaque control. Women were selected who were in their fourth to seventh month to minimise the influence of hormonal changes. In addition, the reductions in GI and PI were similar and correlated, suggesting they were associated.

It would be useful to re-implement this intervention study in similar groups to assess the effectiveness of the study approach in improving the oral health behaviour. There is a need to increase the time period between pre- and post-intervention and include a control group to generate robust evidence of the efficacy of knowledge in enhancing oral health behaviour amongst pregnant Kuwaiti women and/or culturally similar women. It is also important to investigate perception, cultural and social context amongst pregnant women who seek private maternal clinics and hospitals to assess their needs concerning oral health.

This RCT intervention was almost the first RCT study conducted in oral health (and indeed within the health care sector) in Kuwait, and the learning from this study suggests that an a priori study would have been beneficial to test feasibility and the measures before the main DHE intervention. Factors which

were identified as limitations (attrition rate, timing of data collection) could have been planned for in the definitive study.

This brief study suggests a need for an educational programme that aims to provide and correct the attitude, knowledge and behaviours within pregnant women as well as dental and healthcare providers in Kuwait. A number of conditions would need to operate to enable pregnant women to have regular preventive dental visits: 1) correcting the cultural beliefs concerning the need for and safety of dental treatment during pregnancy and 2) the availability of state dental clinics providing dental care for pregnant women and dentists agreeing to provide dental treatment for women during pregnancy.

5.7 Conclusion

There were improvements in Kuwaiti pregnant women in PI and GI as well as knowledge and other SCM constructs regardless of the intervention groups. The addition of Dental Health Education with or without a planning intervention confers no additional benefit in terms of improving the adherence of pregnant women to oral hygiene behaviours.

Self-reported oral health behaviour including oral health rating, tooth brushing and dental flossing were significantly improved in all pregnant women post-intervention.

The study showed an enhancement in oral health knowledge and behaviour across Kuwaiti pregnant women. It might be beneficial to ensure the effectiveness of this intervention study by re-implementing this study and increasing the time between Time 1 and Time 2 and perhaps using a true control reflecting information given to Kuwaiti women rather than Kuwaiti women attending a dental surgery.

This intervention design would be appropriate for women who have the same cultural contexts as Kuwaiti women.

The intervention study showed an improvement in the oral health behaviour of all Kuwaiti pregnant women participating in the study. It suggests that there might be some benefit to design a study based on correcting knowledge (for participants lacking in knowledge) to improve oral health behaviour. In this study where women had very limited oral health knowledge, information giving was as efficacious as an intervention underpinned by SCMs in influencing behaviour change, but these results must be interpreted with considerable caution given the high attrition rates and possible influence of a Hawthorne effect.

Many of the issues with the measures, conduct of the study, and attrition might have been alleviated or mitigated by use of a lead-in time, and a feasibility study prior to the definitive RCT as recommended by the MRC. This would have allowed women a greater opportunity to ask questions about the study and understand that returning for additional visits was part of the research. A lead-in time would have identified women who were not prepared to return, it would also have afforded the researcher the opportunity to check the validity and timing of the measures, and explore recruitment strategies and retention strategies. These additional qualities of items would have addressed many of the limitations of the present study, but would need to be balanced against the resources available to support research in Kuwait.

Chapter 6

General discussion

6.1 Introduction

The thesis set out to design, implement and evaluate a DHE intervention focusing on adherence to oral hygiene for Kuwaiti pregnant women. In order to design a dental health intervention, it was important first to understand the role of gingivitis and periodontal disease during pregnancy as well as explore the perceptions, beliefs, attitudes and expectations about oral health amongst pregnant Kuwaiti women that have a role in shaping oral health behaviours. This would ensure that the DHE intervention was evidence-based, met the pregnant Kuwaiti women's needs and was relevant to them. Three studies were conducted and reported upon in the previous chapters of this thesis. This final chapter sums up the key findings of this programme of work, evaluates the strengths and limitations of the work and presents some overarching conclusions and areas requiring further research.

6.1.1 Study 1 (Systematic review with meta-analysis) findings and interpretation

In the first study a systematic review with meta-analysis was undertaken to assess the role of PD during pregnancy. The reporting of the review followed PRISMA guidelines and the analyses were planned in a protocol planned a priori (Moher et al., 2009). The specific questions addressed were:

Was there an association between PD and PTB, PD and LBW, and PD and PLBW, and PD and stillbirth? Was there evidence that treating PD (NSPT) could prevent incidence of ABOs? Was provision of NSPT safe during pregnancy?

The majority of individual cohort studies, only two of which were considered to be high quality supported an association between all ABOs and PD, as did the

meta-analyses of cohort studies for the following outcomes: [(PTB n=11: RR1.63 (95% CI: 1.06, 2.50, P=0.03), LBW n=7: RR 2.35 (95% CI: 1.21-4.57, P=0.01) and PLBW n=4: RR 3.53 (95% CI: 1.51 -8.20, P=0.003)]. Only one cohort study investigated stillbirth (Mobeen et al., 2008) and found an association with PD. The meta-analyses were characterised by high levels of heterogeneity which was not diminished by using a random effects model. Sensitivity analyses and subgroup analyses exploring interaction with tobacco use, race/ethnicity and previous history of ABOs were undertaken, but levels of heterogeneity remained high. The level of heterogeneity seen means that the findings from this review of cohort studies must be treated with caution, and there remains uncertainty with respect to the association between PD and ABOs.

The second part of the review considered the efficacy and safety of NSPT during pregnancy. Thirteen studies were included, but only three were considered to be overall at low risk of bias on the Cochrane risk of bias (ROB) assessment tool. Meta-analyses were characterised by high levels of heterogeneity and indicated that NSPT during pregnancy was not associated with reduction in incidence of PTB [RR 0.78 (95% CI: 0.60-1.01, P=0.06)] and PLBW [RR 0.54 (95% CI: 0.28-1.03, P=0.06)], but there was a benefit to receiving treatment to prevent LBW [RR 0.75 (95% CI: 0.56-0.99, P=0.05) and stillbirth [RR 0.48 (95% CI: 0.25-0.90, p=0.02)]. Use of random effects models, sensitivity analysis and subgroup analyses did not markedly reduce the levels of heterogeneity seen. The levels of heterogeneity seen mean that the findings from this review of RCTs studies must also be treated with caution. Uncertainty also exists in relation to NSPT and risk reduction in LBW and stillbirth. It is impossible to predict which ABO a woman might experience, so while there is

cautious evidence that NSPT during pregnancy might reduce the risk of LBW and stillbirth, the evidence suggests the opposite for PTB and PLBW.

There was no explicit evidence for the safety of NSPT during pregnancy. This was because the reporting of adverse outcomes were not planned for a priori in the primary studies included in this review, thus some adverse effects could have been overlooked. There was insufficient evidence in the systematic review of RCTs to state confidently that NSPT was safe during pregnancy, though no adverse event or effects attributable to NSPT were reported in any of the studies at follow-up.

In summary, while the systematic reviews of the cohort studies (association) and RCTs (efficacy and safety) were conducted carefully using published guidance (Moher et al., 2009), the findings should be interpreted with caution given the extent of heterogeneity seen. There remains uncertainty in relation to the association between PD and ABOs and in relation to the efficacy and safety of NSPT to reduce risk of ABOs.

The aim of a systematic review is to collate and synthesise data from studies which meet the inclusion criteria and to use methods which also minimise bias (Higgins et al 2011). The heterogeneity seen in the present systematic reviews was largely attributable to the three areas: 1) the complexity of the phenomena of ABOs and the failure to identify and to control for the shared risk factors with PD 2) the lack of secure case definition of periodontal disease and 3) design limitations associated with the primary studies.

PD and ABOs share similar risk factors such as race, tobacco use, age, income and education, while previous history of ABO is a known risk factor for subsequent ABOs (Goldenberg et al., 2008; Vergnes and Sixou, 2007; Jeffcoat

et al., 2003). In studying the association between PD and ABO in the SR of cohort studies, it was notable that many studies failed to control for these risk factors, or failed to record these risk factors consistently. This is a well-recognised problem with observational studies exploring the association of PD and ABO (Xiong et al., 2011; Wimmer and Pihlstrom, 2008; Egger, 1998). The lack of consistency of reporting of risk factors in the systematic review of RCTs meant that the cause of these risk factor interactions and their impact on effect could not be explored further with meta-regression, which added significant uncertainty to the results of the meta-analyses.

There was also high variability in the study populations in terms of prevalence of ABO for example the PTB and LBW is reported to be between 12% and 13% of all live births in the USA (Polyzos et al., 2009), while in Saudi Arabia it can be as high as 31% (World Health Organization, 2006). Only four cohort studies took account of population prevalence by reporting a power calculation to ensure that the cohort was selected from the same local population (Srinivas et al., 2009; Agueda et al., 2008; Saddiki et al., 2008; Sharma et al 2007). In some of the RCTs included in the review of NSPT interventions, only women at high risk for ABOs were specifically recruited (Offenbacher et al. 2006; Jeffcoat et al. 2003), and thus the external validity of some of these RCTs to the general population of pregnant women are questionable.

It would be important that in future cohort and RCTs studies exploring the association between PD and ABO, and efficacy of interventions, that the prevalence of ABOs in the local population is carefully recorded; that suitably powered samples are recruited and that samples are stratified to take account of the known risk factors for ABO and PD. Robust measures of these risk

factors should be consistently recorded, and analyses planned to control for these covariates and effect modifiers.

A key weakness in both the cohort and RCT studies was the inconsistency in recording the presence of periodontal disease and lack of security in the diagnosis of the presence of periodontal disease. In the present systematic reviews only one cohort study (Marin et al. 2005) and no RCTS used a secure definition of periodontal disease as proposed by Nabili et al (2013) .It is important to use consistent and secure case definitions of PD because different definitions lead to different results and conclusions. For example Manau et al. (2008) in a review of 23 studies found that the prevalence of periodontitis among a sample of women depended on the case definition of periodontitis applied and the statistical significance of the association between periodontitis and ABOs was directly determined by the case definition of periodontitis or the periodontal indicator used in the analysis. While for example Ide and Pappanou (2013) found that the use of continuous or categorical measures impacted the results in their systematic review of the relationship between ABOs and PD. They found that when continuous variables were used the relationship between ABOs and PD was attenuated.

The lack of secure definition of PD is a fundamental weakness in the systematic reviews described in this thesis. In order to overcome this weakness, future primary studies should use a secure definition of PD as set out by Nabili et al. (2013). It is also recommended that a combination of continuous and categorical data be used, and that partial recordings should be avoided (Ide and Pappanou, 2013). Moreover, Sanz and Korman (2013) reporting upon a consensus conference on PD and ABO (EPI) suggest that additional measures

should also be recorded because clinical measures do not adequately reflect the inflammatory burden present in pregnant women. They suggest that these should include assessment of the microbial composition of oral biofilm and measures of host inflammatory response. The authors also recommend that more than one time point be used to reflect different exposures during gestation (Sanz and Korman, 2013).

The final major contributor to heterogeneity in the present reviews was the methodological flaws associated with the design of the cohort and RCT studies. Only two studies in the systematic review of cohort studies were assessed as being of high quality (Newcastle-Ottawa assessment tool), and only three RCT studies were assessed as being at low risk of bias (according to the Cochrane risk of bias tool). The major flaws were related to how women were recruited, how risk factors and covariates were assessed and the way in which periodontal disease was assessed, which have been discussed earlier.

There is considerable uncertainty remaining as to the association between PD and ABOs, particularly given the poor quality of studies in existence, and the lack of robust evidence from Non-Westernised settings where the underlying population prevalence is high. There is also considerable uncertainty as to the safety and efficacy of NSPT, again because evidence is flawed, mostly derived from Westernised settings, and adverse events are poorly recorded. There is merit to continue to study the association between ABOs and PD but using robust study designs and secure definitions of periodontal disease. Once the pathophysiology is better understood, then it may be feasible to consider interventions to mitigate risk attributable to PD.

Systematic reviews are seen as the top of the hierarchy of evidence, but they are only as good as the included primary studies. Until more primary studies are published using a secure definition of periodontal disease and employing robust study designs, there is little merit to conducting further systematic reviews.

In terms of DHE, while there is evidence of an association between PD and ABOs, there is considerable uncertainty in receiving NSPT during pregnancy to prevent ABOs. The safety of NSPT interventions has been poorly studied, though no adverse events have been noted. On this basis, it would be unethical to raise women's concerns about the relationship between ABOs and PD, when there was no effective treatment currently that could be recommended to prevent or reduce their risk of ABOs. However, it would be reasonable to encourage women to maintain optimal oral hygiene during pregnancy to reduce inflammatory loading.

6.1.2   Study 2 (Qualitative study) findings and interpretation

The second study was a qualitative study. This was undertaken in order to understand the perceptions, beliefs, attitudes and expectations surrounding oral health amongst pregnant Kuwaiti women in which oral health behaviours are undertaken and to map the data derived in the interviews against social cognitions with the aim to identify those that might be helpful to understanding oral health in this group of women.

The qualitative study showed that pregnant Kuwaiti women lacked basic oral health knowledge and information e.g. how to choose a tooth brush or tooth paste, tooth brushing techniques, symptoms and causes of gingival and periodontal disease. Women did not have any knowledge about the relationship between pregnancy and periodontal disease. Most of the women reported that

they stopped brushing their teeth during the first trimester due to pregnancy sickness. Women believed that pregnancy might have a long term negative effect on their oral health i.e. losing a tooth with each pregnancy or having dental pain during pregnancy. Women also believed that receiving dental treatment during pregnancy might put their unborn babies at risk. A small number of women believed that receiving dental treatment during pregnancy would not harm the unborn baby; however these women were unmotivated to seek required dental treatment during pregnancy. Several individual barriers (e.g. knowledge) and lack of dental health care access (e.g. dentist refused to provide any dental treatment or advice for pregnant women) were identified. It would appear also that the medical teams looking after pregnant women had poor oral health knowledge and in one case mistreated dental pain as a result. Five social cognitions constructs could be identified from the qualitative data, which were: oral health knowledge, attitude, subjective norms, barriers and intention.

The study demonstrated that there was a rich and important social and cultural context to oral health behaviours. Subjective norms in particular were very powerful and women derived much of their information from family and friends, which perpetuated a considerable amount of misinformation. Kuwaiti women are not alone in this, as other studies have highlighted a number of commonly held erroneous views about oral health (Hashim et al., 2011; Ozen et al., 2011; Detman et al., 2010; Keirse and Plutze, 2010; Scambler et al., 2010). There is no counterbalance to this misinformation in Kuwait, as women reported that dentists were reluctant to both treat them and provide information. This lack of access to information was further compounded by the way in which oral health care is delivered in Kuwait (treatment-orientated) and a lack of faith in state

funded dental care services. This would suggest that there is a need for some reorientation in the care philosophy in delivery of dental care in Kuwait. Moreover, this study highlights the need for dentists to work more closely with medical teams providing care to pregnant women in order to raise awareness of oral health issues.

The oral health behaviour amongst pregnant Kuwaiti women could be improved and corrected through assisting them to change their oral health behaviours. A social cognition approach is most frequently used to explore and understand health behaviours (Conner and Norman, 2007) and to this end its usefulness was explored in this thesis.

Several constructs such as seriousness, susceptibility, and self-efficacy which have been found to be important in oral health behaviours in Western studies (Conner and Norman, 2007) did not emerge, as might have been expected, from the qualitative study. This may have been attributable to the lack of dental health knowledge concerning dental diseases and PD amongst pregnant Kuwaiti women. Associated with this was the women's lack of knowledge of the benefit of maintaining good oral health during pregnancy. It could not be expected that pregnant Kuwaiti women would consider PD serious or themselves susceptible while they did not have the correct or appropriate information and knowledge concerning dental diseases and PD.

Few SCMs have been used in Middle Eastern countries. The qualitative study suggested at least at this stage, that some SCM constructs reported in the literature were not important influences on behaviour in this group of women with such low baseline dental knowledge. Using the constructs that were identified as helpful in the qualitative study to improve dental behaviour was

deemed appropriate in meeting the needs of pregnant Kuwaiti women who lacked basic dental health information and knowledge. Underpinning a DHE intervention with constructs known to affect oral health behaviour positively might be more appropriate than applying one theory of SCMs that might not fit Kuwaiti women's needs to improve their dental health behaviour.

Deriving SCMs from the qualitative study was novel, particularly in a non-Westernised setting, where women are not familiar with research, or indeed as it emerged, familiar with oral health information. The utility of the SCMs to underpin the intervention was then tested in the third study.

6.1.3 Study 3 (RCT) findings and interpretation

It was concluded from study 1, that while there was evidence that there is an association with PD and ABOs, it would not be ethical to raise women's concerns about the issue, when there was no obvious effective and safe intervention available which would either reduce or prevent risk of ABOs. However, it would be reasonable to encourage women to improve oral hygiene to reduce their risk of dental disease, pregnancy related gingivitis, and overall contribution to inflammatory loading.

The qualitative study provided comprehensive insight and understanding of the needs of pregnant Kuwaiti women concerning their oral health before and during pregnancy. In the qualitative study it was clear that the major oral health issue was the lack of basic oral health knowledge amongst women. It was decided in this intervention to focus primarily on knowledge as a logical first step as levels were so low but it was also important to ground the intervention on the four additional SCM constructs that were identified in the qualitative study as important within the cultural oral health context of these women.

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In addition to the constructs that emerged from Study 2, we also sought to explore the efficacy of planning (in the form of implementation intentions) as previous work has shown that use of implementation intention increases the likelihood of adherence with oral hygiene behaviour (Pakpour and Sniehotta, 2012; Suresh et al., 2011; Clarkson et al., 2009; Schüz et al., 2006). Additionally, developing action plans has been shown to encourage regular tooth brushing behaviour (Pakpour and Sniehotta, 2012; Clarkson et al. 2009) and flossing behaviour (Schüz et al., 2006). As such, planning was considered a useful variable to explore here in line with previous work (Pakpour and Sniehotta, 2012; Suresh et al., 2011; Clarkson et al., 2009; Schüz et al., 2006).

Thus, the aim of the RCT was to assess the efficacy of DHE, the primary construct these women seemed to be low on, with or without planning to enhance health behaviour amongst pregnant Kuwaiti women. The DHE intervention was designed based on constructs found in the previous qualitative study including knowledge, attitudes, subjective norms, intentions and barriers.

All three groups completing the study improved between T1 and T2 in terms of PI, GI, knowledge, attitude, subjective norms, tooth brushing barriers, dental flossing barriers, and snacks barriers regardless of the intervention groups. There was no significant improvement across time regarding barriers to attendance. The three groups demonstrated improvements in the GI and PI and self-reported behaviours but between group differences were not statistically significant. These overall findings must be treated with caution and interpreted carefully because the study was compromised by high attrition rates. It must also be considered that the change in objective and self-report of behaviours

could have been attributed to a Hawthorne effect, to hormonal effects and to problems with the validity of the clinical indices.

The RCT results showed no advantage to the DHE intervention over TAU. But it must be noted that the TAU group were provided with a simple oral hygiene leaflet with a dental hygiene demonstration. However, in reality most 'standard care' in Kuwait does not offer consistently a DHE leaflet to dental patients. It might have been better to assess the outcomes of the RCT intervention by adding a fourth group who received no information which is closer to the actual standard care in Kuwait. It is likely in this study that the TAU arm received more information than would be typical of the normal clinical encounter in Kuwait. However given the levels of attrition seen in the study, adding a fourth arm might have further compromised the trial and the TAU arm showed that in situations where women have next to no knowledge, a simple leaflet can be effective.

The findings suggested that knowledge might be considered as the most basic stage to change or improve health behaviours amongst this group of pregnant Kuwaiti women. But another explanation must be considered. There is little research conducted in Kuwait, and it is highly likely that simply being asked to participate in this trial raised women's' awareness of being studied and in a desire to conform and to please the researcher, the participants changed their oral hygiene and self-reported behaviours. Thus the improvements seen could have been explained by a Hawthorne effect, rather than simply receiving the information leaflet. Although the women would have needed some knowledge to change behaviour in the correct direction. There is much controversy about the size of the Hawthorne effect, and the mechanisms and conditions under which

they operate (McCambridge et al., 2014) and but it could make some contribution to the changes in the behaviour seen in the present study.

The improvement in PI and GI in all post intervention groups suggested that women adhered to the given dental health instructions. The PI improvement suggested that women were brushing and flossing effectively in the previous 24 hours. In addition, the improvement in gingival health suggested that this sample of women adhered to effective tooth brushing and dental flossing during the period between Time 1 and Time 2. It was possible that the findings in relation to PI and GI could have been confounded by pregnancy hormone levels. The hormonal levels during pregnancy increase until the eight month of pregnancy which could play a role in raising the severity of gingivitis during pregnancy (Adriaens et al., 2009). However pregnancy gingivitis is not always associated with plaque accumulation and women with optimal oral hygiene do not experience pregnancy gingivitis (Carillo-de-Albornoz et al., 2010). In this RCT we planned recruitment to include women in second trimester to make sure that any improvement in gingival health would not related to the hormonal fluctuation. The improvement in PI and GI were well correlated suggesting that improvement in PI was reflected in decreasing GI.

An additional explanation relates to the validity of the measurement of the PI and GI. As explained in Chapter 5, the research ethics committee in Kuwait required that no invasive procedures be conducted, which meant that the PI and GI were undertaken without probing. Thus for the PI the presence of plaque for score 1 may have been underestimated and for GI the presence of bleeding in score 2 and 3 would have been underestimated, however, the visible signs of score 2 and 3 would be visible in good light. As the same calibrated hygienist

examined all women in all conditions, any systematic variations in recording of these would have been similar across the three groups. In this case it was not feasible to conduct assessments of intra-examiner variability as the study progressed which may have impacted on the consistency of measuring GI and PI between patients and at pre- and post-intervention. Future work might do this to ensure that the outcomes are reliably recorded.

6.2 Learning from the thesis

The overall approach to conducing this research took place in three phases: a comprehensive literature review including two systematic reviews, a qualitative study to understand the cultural context in which oral health behaviours occur, and an intervention informed by the work undertaken in the two preliminary phases. The thesis followed the outline suggested by the MRC guidance on complex interventions, though it had not been designed to adhere to this guidance a priori. This evolution of understanding from phase 1 and phase 2, allowed the researcher to base the intervention on the best available information on the relationship between ABOs and PD, the best available evidence on SCM models promoting adherence with oral hygiene behaviour, and a good understanding of the cultural context in which behaviours take place. With hindsight, the researcher should have then planned a feasibility pilot study, rather than go directly to undertake an RCT. A feasibility and pilot study might have helped in planning strategies to minimise high attrition rates seen in the completed RCT, it would have enabled the validity and reliability of the proposed measures to be checked, and allowed the researcher the chance to explore the feasibility of conducting a trial in a real world setting.

It was clear as the planning and approval processes for the RCT progressed that there was little infrastructure in Kuwait to support clinical research. While the RCT was planned based on CONSORT principles and had UK and Kuwaiti ethical approval, many problems emerged during implementation. A key problem was the high attrition rates. The study did not achieve the target sample size (N=198); it only achieved 77.7% (N=154) in Time 1 and only 58.4 % completed Time 2. It is quite possible that the attrition rate affected the findings of the study and a larger sample would have been more capable of detecting a difference between the three groups, if one existed. As the study progressed it became apparent that women found the questionnaire too long or were reluctant to attend for follow-up during the religious festival of Ramadan. It also became clear that Kuwaiti women's lack of familiarity with research meant they did not understand the need to return for follow-up. The receipt of the bounty pack at Time 1, might have acted as a disincentive to return at Time 2, as there was no obvious incentive then. A lead-in period to the trial might have removed this issue, and would have given more time for women to understand what was involved in a trial, such as giving women experience of having to come back to complete screening questionnaires etc. This could have identified women who were unlikely to return to take part in the main study; however this might lead to other biases. Recruiting women who were 'more motivated to return' and wanted to be part of a trial might impact on the generalisability of the results and exacerbated a Hawthorne effect. Women in Kuwait are not used to the concept of being involved in research and retention could have been improved by for example, talking to the women and explaining to them the importance of follow–up. These unexpected and unforeseen issues point to the importance of undertaking research within the cultural parameters that a study

is framed in here, a feasibility study as proposed by MRC guidance would have helped iron out these apparent threats to retention rates.

The second problem was the short term follow-up period (four weeks). Despite the fact many studies chose four weeks as a follow up period the literature emphasises the importance of a long-term period (Watt and Marinho, 2007). It is important to choose a long follow-up period to better measure the participants' adherence to the oral health behaviour under investigation (Watt and Marinho, 2007) and to ensure the improvements are sustained. Thus, it is essential to consider expanding the follow-up period in the post-intervention period to confirm the women's' adherence to oral health behaviour was sustained. However, as with any piece of research, there needs to be a balance between what is academically recommended and what is practically possible and in this case, the four week window was in line with previous work in the area and practically possible.

To sum up, future studies planning interventions of this kind in Kuwait should consider a feasibility study to ensure the instruments, measures and recruitment and retention rates are explored and tested. This would allow the processes and conduct of the study to be piloted and might help identify and offer solutions for some of the problems with recruitment that was noted in the present study. Following a feasibility study pathway would insure that the reliability and validity of the instruments, and the processes would be optimal in the definitive RCT. Of course, balanced against this are the few resources available for researchers in Kuwait and the limited infrastructure to support research in Kuwait.

Despite the limitations associated with implementation, the RCT trialled a novel approach, by drawing on SCMs identified in the qualitative study. The technique

of utilising common psychological models is an evolving field and studies that have used SCMs have not produced conclusive results (Bonetti et al., 2009). Most previous work to change oral health behaviour has used traditional models in different ways (Buunk-Werkhoven et al., 2009; Defrance et al., 2008; Kuhner and Raetzke, 1989; Rayant and Sheham, 1980). For example, studies have expanded SCM models by adding constructs from other SCMs (Anagnostopoulos et al., 2011; Buglar et al., 2009; Baker, 1994). Other studies have applied SCMs and combined them with planning (Pakpour and Sniehotta, 2012; Clarkson et al., 2009; Schuz et al., 2006; Lavin and Groarke, 2005). The results of all these studies have been inconclusive. In contrast to the previous studies' approach, the present RCT is the only study known that is designed based on a thorough understanding of the target group, and used SCM constructs which have emerged as candidates for shaping the behaviour in the group. This is in contrast with the approach employed in previous dental studies, where the choice of model and hypothesised mode of action was theorized without any understanding of the target population's needs (Pakpour and Sniehotta, 2012; Anagnostopoulos et al., 2011; Suresh et al., 2011; Buglar et al., 2010; Clarkson et al., 2009; Defranc et al., 2008; Schüz et al., 2006; Lavin and Groarke, 2005; Baker, 1994; Kuhner and Raetzke, 1989; Beck and Lund, 1981; Rayant and Sheiham, 1980) .

The present study was designed attempting to be culturally sensitive to the target group. It was designed based on women's needs, an approach which might be more efficient than applying SCMs in a one-size-fits-all way. The findings from the present study are of course specific to the local, non-Western cultural setting and to women at an early stage of pregnancy and may only generalise to such settings. While the development of SCM occurred in the

West, there is little work which suggests that these models have applicability in a Middle Eastern country with different social norms and culture.

The current findings can be explained in terms of recent attempts to understand behaviour change in terms of the COM-B model. This intervention, in focusing predominantly on knowledge, only addressed one of the three COM-B components that is capability; it considered participants' capability to look after their oral health. Future work should methodically work through all three components of the model (Capability, Opportunity and Motivation) and consider behaviour change techniques that might be appropriate to tackle each of the three components. It could be, for example, that in the current cultural setting, providing pregnant women with opportunities to improve their oral health might be harder than in Western cultures where the health system might be more supportive of oral healthcare delivery to pregnant women. At the same time, increasing these women's motivation will probably be subject to culturally-influenced factors such as *maly khalg* (laziness and lack of motivation) and probably be as challenging as it is in the West. The Theoretical Domains Framework (Cane et al., 2012) might be usefully applied in future work.

6.3 Strengths of the intervention

This study is the first of its kind in Kuwait aiming to improve the oral health of pregnant women and addresses a key dental public health problem for women in Kuwait (Honkala, Al-Ansari, 2005). It is the first study in Kuwait to base the design of the intervention on a comprehensive understanding of Kuwaiti pregnant woman's current knowledge, beliefs, attitudes and social status. Undertaking the qualitative study before designing the intervention assisted in understanding and identifying Kuwaiti pregnant women's particular needs. Poor

baseline oral health knowledge was a key area to target in this group. The intervention was designed mainly to correct and improve Kuwaiti pregnant woman's oral health knowledge and secondly to improve attitude, subjective norms and reduce barriers. The qualitative study is the first study to explore the social cognitions which shape oral behaviours in a Middle Eastern country. Some of the accepted cognitions such as 'relevance' and 'seriousness' did not emerge in the qualitative study, largely because knowledge was so low. This suggests that SCMs which have been tested in Western settings may not be appropriate to simply transplant into an intervention in a Middle Eastern setting. This suggests that a one-size-fits-all model should be avoided, and rather more work should be done identifying social cognitions that are important in shaping oral behaviours. The intervention study was also the first study in Kuwait that attempted to understand the oral health behaviour by using the one component (capability) of the COM-B model.

6.4 Limitations of the intervention

This thesis had a number of limitations which might be considered when designing future studies to improve oral health amongst Kuwaiti pregnant women. Uncertainty and caution in relation to interpretation of findings relating to the Hawthorne effect, high attrition rates, validity of clinical indices and timing of follow-up have been dealt with in earlier sections.

An additional limitation was that the participants in this research might not be a representative sample of Kuwaiti pregnant women. The researcher recruited women who attended government maternity clinics only. The qualitative study found that most Kuwaiti women sought maternal care from private maternity clinics and only small numbers sought maternal care from government

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maternity clinics. So the intervention reported in the third study was applied and designed for pregnant women who attended government maternity clinics, however it might not be generalisable to the wider population of Kuwaiti women who are pregnant.

Also, it would be important to identify whether the participants sought dental care or advice between pre- and post-intervention to ensure that the intervention was the only basis for any improvements in oral health behaviours.

6.5 Implications of the findings

The findings from this thesis demonstrate that while there is evidence for an association between ABOs and PD, the evidence is flawed by the clinical and methodical diversity in studies attributable to the complexity and shared risk factors for ABO and PD, the insecurity of definition of PD, and the design flaws manifest in the cohort studies. Much of the clinical uncertainty could be overcome through use of secure definitions of PD (e.g. Nabili et al 2013) and more robust cohort design. There remains a gap in knowledge with respect to the association between ABOs and PD in countries with a high prevalence of ABOs in the population and future research should be directed at these populations. Careful attention needs to be paid to using categorical and continuous assessments of periodontal status, assisted by microbial assessment and host inflammatory responses. More than one time point for recording is recommended. The findings in relation to the efficacy and safety of NSPT to reduce risk of ABOs are also marred by clinical and methodological diversity, for similar reasons to those cited for cohort studies. There remains a gap in knowledge in relation to the efficacy of NSPT, particularly in women with high levels of periodontal disease, and where prevalence of ABOs is high in the

local population. There is merit in studying these phenomena further, but using robust study design and secure definitions of periodontal disease. Future studies exploring the effectiveness of interventions need to control for other factors associated with ABO. In terms of safety, there is no robust evidence currently to suggest NSPT is safe, but equally no study has reported adverse outcomes attributed to NSPT. The gap in knowledge here requires that the reporting of adverse events be planned for a priori in future intervention studies.

It is reasonable to recommend women maintain optimal oral hygiene during pregnancy, and should attend for oral health assessment and treatment as required. Women with periodontal treatment who are contemplating pregnancy may want to consider timing periodontal care prior to conception.

The findings in this thesis in relation to the second and third studies have demonstrated the low level of oral health knowledge amongst pregnant women in Kuwait. This is compounded by the absence of the medical and dental health providers who have the correct information and are willing to provide DHE and dental treatment during pregnancy. The findings have also shown that pregnant women, who knew that dental treatment did not harm the unborn baby, were not motivated to seek dental treatment during pregnancy which might be due to the lack of oral health knowledge about the importance of having optimal oral health during pregnancy.

The intervention reported in study 3 has also shown that providing simple oral health information such as providing a simple DHE leaflet and oral hygiene demonstration could be effective in improving the oral health behaviours amongst a population with baseline low level oral health knowledge such as

pregnant Kuwaiti women. But it is important to interpret this finding cautiously as there may have been an associated Hawthorne effect operating.

The thesis illustrates the importance of understanding the target group before designing an intervention to improve oral health behaviour. In contrast to health psychologists who suggest that increasing health knowledge by providing educational materials alone would not improve health behaviour (Aboud and Singla, 2012; Bonetti et al., 2009; Glaz et al., 2008; Conner and Norman, 2007), this study found that targeting the knowledge gaps could change and improve oral health behaviour. It appeared that influencing health behaviour might be dependent first on the individual's health knowledge baseline levels before moving on to address other SCM constructs.

The findings of this thesis should be highlighted to the Public Health Ministry in Kuwait which currently does not routinely offer dental health preventive services or education for adults (Behbehani and Scheutz, 2004). Rather, the current mode of service provision looks to offer treatment for pain relief and dental emergencies (Behbehani and Scheutz, 2004). Given that expectant mothers lacked basic oral health knowledge (the findings of this thesis) and have oral health problems and little awareness of the importance of oral health during pregnancy (Honkala and and Al-Ansari, 2005) this places the Kuwaiti health authorities in a position of needing to look at this issue carefully; this thesis has provided an evidence base to show that the erroneous beliefs of pregnant women in Kuwait may well be a national issue in Kuwait that needs addressing.

Therefore, the findings of this thesis should be considered by the Public Health Ministry in Kuwait and dental services in Kuwait should have a greater role in providing DHE and preventive services for women before and during pregnancy

to encourage oral health awareness amongst the women. The Kuwaiti government should also ensure that prevention of oral diseases and their relationships with systemic disease and conditions should form a part of the training of medical and dental care teams. This would ensure a workforce which is qualified and willing to provide dental health education and treatment for pregnant women in Kuwait.

6.6 Conclusions

1. The systematic review of cohort studies supported the association between ABOs and PD, and meta-analyses of the cohort studies supported the association but were characterised by high heterogeneity levels.

2. Meta-analyses of RCTs (n=3) did not support a benefit in providing NSPT during pregnancy to prevent PTB and PLBW respectively. There was some evidence to support a benefit in reducing LBW and stillbirth. As these meta-analyses were characterised by high levels of heterogeneity these findings should be treated with caution.

3. It is reasonable to encourge women to maintain good oral hygiene during pregnancy to reduce the effect of pregnancy on periodontal health status and reduce inflammatory loading.

4. There was no robust evidence supporting the safety of NSPT during pregnancy as safety aspects were poorly and inconsistently measured in the primary studies. Equally no study reported any adverse event attributable to NSPT.

5. Pregnant Kuwaiti women had low levels of oral health knowledge and information. They were unaware of the effect of pregnancy on oral health. Pregnant women lacked motivation to seek dental care even when they considered dental treatment safe during pregnancy. Dentists, negative cultural beliefs, and lack of motivation were identified as barriers to accessing oral health care and seeking oral health knowledge. The erroneous beliefs of pregnant women in Kuwait may well be a national issue in Kuwait that needs addressing.

6. An RCT intervention was designed to improve and correct pregnant Kuwaiti women's knowledge, as well as change pregnant women's attitudes, beliefs and behaviours towards oral health. The RCT study used an approach which was hoped to be appropriate and sensitive to pregnant Kuwaiti women. There were improvements in PI, GI, knowledge, attitude, subjective norms, tooth brushing barriers, flossing barriers and snack barriers regardless of the intervention groups. Also there were improvements in self-reported oral health behaviours. The findings for the RCT should be interpreted with caution because of the high attrition rate and the influence of the Hawthorne effect

7. The understanding and insight into the target group is important in terms of attempting to enhance their oral health behaviours.

8. Providing a simple oral health leaflet and simple dental hygiene demonstration on plastic mouth model might influence the oral health behaviours amongst a population with low levels of oral health knowledge. While the improvements seen could be attributed to simply increasing knowledge through the use of a leaflet and hygiene

demonstration, this finding must be interpreted with caution given the possibility of a Hawthorne effect.

9. Designing a DHE intervention based on SCM constructs that emerged from the target group's need might help in designing an intervention that is appropriate and relevant to women's information needs and so improve their oral health behavior.

10. COM-B model components (Capability, Opportunity and Motivation) might help in understanding the intervention study findings. In the present study only capability was explored. Future work should methodically work through all three components of the model (Capability, Opportunity and Motivation) and consider behaviour change techniques that might be appropriate to tackle each of the three components.

6.7   Future research

1. Given the need to understand better the pathophysiology of the association between adverse birth outcomes and PD, dental researchers should continue to study the phenomena using a prospective cohort design based on the STROBE criteria (Sharp et al., 2014) suitably controlled for the known risk factors for ABO and which adhere to contemporary quality standards of reporting as set out in the Newcastle-Ottawa scale. As host response and inflammatory loading is a key aspect of this pathophysiology, measures of gingivitis and PD should use a combination of continuous and categorical variables, assessment of microbial composition of oral biofilm and measures of host response. Once the pathophysiology is better understood, then it may be feasible to consider interventions to mitigate risk attributable to PD.

2. The qualitative study highlighted the importance of understanding the target group before designing an intervention to improve oral health behaviour. The present research was confined to a small group of pregnant women using maternal health centres, and may not be generalisable to other pregnant women or other adults in Kuwait. Previous research in Kuwait has highlighted poor oral health knowledge and information. Prior to developing DHE programmes with these groups, exploratory qualitative research should be undertaken to understand the particular information needs of these groups

3. The qualitative study also suggested that the dental profession in Kuwait were reluctant to treat pregnant women, and did not routinely provide DHE as part of the clinical encounter. However these data are based on self-reports from the women; future research should test this finding with the dental profession and explore dentists' sense of confidence and competence in providing dental care to pregnant women. Additionally future research could explore how much the clinical encounter involves prevention and the factors that explain the proportion of care devoted to prevention and assigned by dentists.

4. The qualitative study also suggested that the medical teams caring for pregnant women were largely unaware of the importance of dental health. Future research should explore the information needs of these medical teams and how key dental health messages might be incorporated into medical consultations with pregnant women.

5. Future research could involve implementation of a similar study with pregnant women who are not using the state medical centre. The design

of the study should build on the learning from the present study in relation to sampling, lead-in times, piloting of measures and follow-up. It would also need to be suitably adapted to ensure it was addressing the target groups' information needs. The acceptability of the study to the women could also be explored post hoc.

6. A future intervention study could be designed based the Theoretical Domains Framework (Cane et al., 2012) which involves the model and theories to change behaviour based on the three components of COM-B model (Capability, Opportunity and Motivation) and the appropriate SCM constructs.

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APPENDICES

Appendix A

Health care provision for expectant mothers in Kuwait

In Kuwait, Government maternity healthcare is available for all Kuwaiti citizens and migrant workers through 28 healthcare centres across the five medical regions of Kuwait. There are 90 obstetricians serving a population of 3,442,823 person, 1,087,000 Kuwaiti and 2,354,261 non-Kuwaiti (Central Statistical Office, 2008). The total number of women is 1,290,481; out of that figure 554,985 are Kuwaiti women. The total fertility rate is 2.97 children born/woman (Central Statistical Office, 2008). Maternity healthcare centres are open three days per week and provide pregnant women with monthly checks during their pregnancy (Ministry Of Public Health, 2006). Women who have medical problems during pregnancy transfer to maternity hospitals. During 2006, there were 206,290 visits to the government maternity healthcare centres (Ministry Of Public Health, 2006). The Government maternity healthcare centres are distributed across five medical regions:

- AL Asimah medical region: includes 4 healthcare centres served by 20 obstetricians

- Hawalli medical region: includes 5 healthcare centres served by 23 obstetricians

- Al Farwaniyah medical region: includes 6 healthcare centres served by 17 obstetricians

- Al Ahmadi medical region: includes 6 healthcare centres served by 15 obstetricians

- Al Jahra medical centre: includes 7 healthcare centres served by 15 obstetricians

Ninety nine% (99%) of pregnant mothers give birth in hospitals either government or private hospitals. Al Sabaah maternity hospital in the Al Asimah medical region is the only government-funded maternity hospital and serves two medical regions (AL Asimah and Hawalli). In addition, three government-funded maternity units in government hospitals are available in Al Addaan (in Al Farwaniyah medical region), Al Jahra (Al Jahra medical region) and Al Farwaniyah (in Al Farwaniyah medical region) serving the population of each medical region (Ministry Of Public Health, 2006)

Appendix B

Search strategies

Medline search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

----
1   exp Gingivitis/ (10217)
2   exp Periodontitis/ (24097)
3   exp Periodontal Diseases/ (72535)
4   1 or 2 or 3 (72535)
5   (gingivitis or periodontalitis or periodontal disease).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (11798)
6   4 or 5 (73818)
7   exp Dental Scaling/ (3479)
8   exp Dental Polishing/ (2238)
9   7 or 8 (5677)
10   (dental scaling or dental polishing).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (2252)
11   9 or 10 (5689)
12   6 or 11 (76787)
13   exp Premature Birth/ (7374)
14   exp Infant, Low Birth Weight/ (27512)
15   13 or 14 (33435)
16   (preterm birth or low birth weight).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (39519)
17   15 or 16 (46689)
18   12 and 17 (421)

Database: Embase <1980 to 2014 Week 47>
Search Strategy:

----
1   exp gingivitis/ (12943)
2   exp periodontal disease/ (79715)
3   exp periodontitis/ (31245)
4   1 or 2 or 3 (79715)
5   (gingivitis or periodontitis or periodontal disease).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] (67431)

6   4 or 5 (83804)
7   dental scaling.mp. or exp preventive dentistry/ (40059)
8   dental polishing.mp. (21)
9   (dental scaling or dental polishing).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] (21)
10   7 or 8 or 9 (40067)
11   6 or 10 (113701)
12   (preterm birth or low birth weight).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] (48937)
13   exp low birth weight/ (39829)
14   exp premature labor/ (29438)
15   13 or 14 (64502)
16   12 or 15 (73107)
17   11 and 16 (606)
****

Cochrane search strategy:

Date Run: 22/11/14 16:08:53.98

Description:

ID	Search	Hits
#1	MeSH descriptor: [Gingivitis] explode all trees	928
#2	MeSH descriptor: [Periodontitis] explode all trees	1772
#3	MeSH descriptor: [Periodontal Diseases] explode all trees	3868
#4	#1 or #2 or #3	3868
#5	gingivitis or periodontitis or periodontal diseases	4662
#6	#4 or #5	5837
#7	dental scaling or dental polishing	3272
#8	MeSH descriptor: [Dental Scaling] explode all trees	873
#9	MeSH descriptor: [Dental Polishing] explode all trees	176
#10	#8 or #9	1045
#11	#7 or #10	3319
#12	#6 or #11	7868
#13	preterm birth or low birth weight	7998
#14	MeSH descriptor: [Premature Birth] explode all trees	403
#15	MeSH descriptor: [Infant, Low Birth Weight] explode all trees	1818

#16   #14 or #15   2148

#17   #13 or #16   8164

#18   #12 and #17 153

Tuesday, November 25, 2014 2:45:35 AM

#	Query	Limiters/Expenders	Last Run Via	Results
S39	S31 AND S37	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	200
S38	S31 AND S37	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S37	S34 OR S35	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S36	S34 OR S35	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S35	preterm birth or low birth weight	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S34	S32 OR S33	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	9,853
S33	(MH "Infant, Low Birth Weight+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S32				Display

		(MH "Childbirth, Premature")	Search modes – Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	
	S31	S25 OR S30	Search modes – Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
	S30	S28 OR S29	Search modes – Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
	S29	dental scaling or dental polishing	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
	S28	S26 OR S27	Search modes – Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
	S27	(MH "Dental Polishing")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
	S26	(MH "Dental Scaling+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
	S25	S23 OR S24	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database – CINAHL	Display
	S24		Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases	Display

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			gingivitis or periodontitis or periodontal diseases		Search Screen - Advanced Search Database - CINAHL	
S23	S20 OR S21 OR S22	Search modes - Boolean/Phrase		Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL		Display
S22	(MH "Periodontal Diseases+")	Search modes - Boolean/Phrase		Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL		Display
S21	(MH "Periodontitis+")	Search modes - Boolean/Phrase		Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL		Display
S20	(MH "Gingivitis+")	Search modes - Boolean/Phrase		Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL		Display
S19	S12 AND S18	Search modes - Boolean/Phrase		Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL		Display
S18	S15 OR S16	Search modes - Boolean/Phrase		Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL		Display
S17	S15 OR S16	Search modes - Boolean/Phrase		Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL		Display
S16	preterm birth or low birth weight	Search modes - Boolean/Phrase		Interface - EBSCOhost Research Databases Search Screen - Advanced		Display

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			Search Database - CINAHL	
S15	S13 OR S14	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S14	(MH "Infant, Low Birth Weight+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S13	(MH "Childbirth, Premature")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S12	S6 OR S11	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S11	S9 OR S10	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S10	dental scaling or dental polishing	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S9	S7 OR S8	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S8	(MH "Dental Polishing")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display

S7	(MH "Dental Scaling+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S6	S4 OR S5	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S5	gingivitis or periodontitis or periodontal diseases	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S4	S1 OR S2 OR S3	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S3	(MH "Periodontal Diseases+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S2	(MH "Periodontitis+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S1	(MH "Gingivitis+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display

Appendix C

Excluded Studies of Part 1 (Cohort studies)

Name of Review	Reason for Exclusion
Boggess et al., (2006)	Secondary analysis of cohort study
Farrell et al., 2006	It was a sub-analysis of Moore 2004 prospective study.
Deppe et al.2010	Clinical prospective study
(Ercan et al., 2013)	Pathogenic analysis
(Blereau, 2003)	Note
(Boggess, 2003)	pictorial
(Dasanayake et al., 2003)	review
(Davenport, 2004)	commentary
(Jeffcoat, 2000)	Not related to study aim
(Jeffcoat et al., 2001d)	review
(Matthews, 2003)	Commentary.
(Holbrook et al., 2004)	Not related to study aims
(McGaw, 2002)	review
(Radnai et al., 2008b)	Hungarian language
(Gazolla et al., 2007)	Case-Control Studiy
(Harper et al., 2012)	Assessed bacterial vaginosis (BV) is synergistic
Lin et al., : 2007	
	Assessed microbial and antibody responses
Adams B	Exploring the link between oral health and systemic health
YR: 2011	
Matula K YR: 2012	Not related to Sr objectives
Deppe H	observational study provide NSPT
YR: 2010	
: Jeffcoat M	Conference abstract
YR: 2002	
Reddy BVR	Assessed t IgM and IgG antibodies status in cord blood during delivery
YR: 2014	
(Abrahamowicz et al., 2012)	review
(Al Habashneh et al., 2013)	Evaluation study
(Albert et al., 2011)	retrospective cohort study,
(Moothedath et al., 2014)	Editorial
(Leader, 2014)	Critical summary
(Santa Cruz et al., 2013)	Assess periodontal pathogens

(Dasanayake, 2013)	comments
(Slim, 2012)	Question and answer
(Rastogi et al., 2012)	Not related to study aim
(Lauren et al., 2012)	retrospective study
(Horton and Boggess, 2012)	review
(Dasanayake, 2012)	editorial
(Das and Das, 2012)	Conference abstract
(Xiong et al., 2011)	review
(Arteaga-Guerra et al., 2010)	Spanish
(Betleja-Gromada et al., 2008)	Polish language
(Bilinska and Osmola, 2014)	Polish language
(Boutigny et al., 2005)	French and review
(Castaldi et al., 2006a)	Spanish
(Castaldi et al., 2006b)	[Portuguese]
(Ceylantekin et al., 2011)	Turkish
(Chen et al., 2012)	Chinese
(Condylis et al., 2013)	Review and French
(Costa, 2006)	Letter and Portuguese, English]
(Dahmane and Petelin, 2011)	Slovene Language
(Kadowaki et al., 2003)	Japanese
(Kazmierczak et al., 2004)	Polish
(Kazmierczak et al., 2005)	Polish
(Konopka, 2004)	Polish
(Konopka et al., 2004)	Polish
(Landa Goni, 2011)	Spanish and note
(Kurnatowska and Stankiewicz, 2006)	Polish
(Le Borgne et al., 2011)	French
(Li et al., 2004)	Chinese and review
(Li et al., 2006)	Chinese
(Malinova, 2013)	Bulgarian
(Mayer et al., 2008)	Hebrew
(Moghadam et al., 2013)	Perisan
(Nesse et al., 2006)	Dutch

(Novak et al., 2005)	Hungarian
(Panknin and Trautmann, 2014)	German
(Radnai and Gorzo, 2002)	Hungarian
(Radnai et al., 2008a)	Hungarian
(Rodriguez Nunez et al., 2004)	Spanish
(Schweig, 2011)	German and short survey
(Seixas da Cruz et al., 2005)	Portuguese]
(Sembene et al., 2000)	French
(Sezer, 2007)	Turkish
(Sha et al., 2009)	Chinese
(Stankiewicz-Szalapska et al., 2010)	Polish

Appendix D

Excluded Studies of Part 2 (RCTs)

Name of Review	Reason for Exclusion
(Blereau, 2003)	note
(Boggess, 2003)	pictorial
(Dasanayake et al., 2003)	review
(Davenport, 2004)	Commentary
(Jeffcoat, 2000)	Not related to study aim
(Jeffcoat et al., 2001d)	Review
(Matthews, 2003)	Commentary.
(Offenbacher and Beck, 2001)	Study bugs
(McGaw, 2002)	review
(Fiorini et al., 2013)	Incluiding clinical data Clinical data, and samples of blood and gingival crevicular fluid
(Radnai et al., 2008b)	Hungarian language
(Novak et al., 2008)	Study of bacteria
(Michalowicz et al., 2009b)	Clinical analysis
(Barnes, 2007)	It is not RCT
(Jeffcoat et al., 2011)	spontaneous preterm birth before 35 weeks
(Sant'Ana et al., 2011)	Only controlled trail no randomization
Adams B YR: 2011	Exploring the link between oral health and systemic health
AU: Jeffcoat M YR: 2011	Assess the efficacy of an alcohol-free antimicrobial mouth rinse containing cetylpyridinium chloride on the the incidence of preterm birth (PTB) in a high-risk populatio
Matula K YR: 2012	Not related to Sr objectives
Novák T YR: 2009	prospective study
Cruz SS YR: 2010	A nonrandomized intervention study
: Jeffcoat M YR: 2002	Conference abstract
Reddy BVR YR: 2014	Assessed t IgM and IgG antibodies status in cord blood during delivery
AU: Macones G 2008	Not RCT
(Offenbacher et al., 2006b)	I think it should excluded because it included biological parameter and assssing the eight oral pathogens, levels of gingival crevicular fluid (GCF)

	interleukin-1b (IL-1b), prostaglandin E2
	(PGE2), 8-isoprostane (8-iso), and IL-6, and serum levels of IL-6, soluble intercellular adhesion molecule
	1 (sICAM1), 8-isoprostane, soluble glycoprotein 130 (sGP130), IL-6 soluble receptor (IL-6sr), and C-reac-
	tive protein (CRP). L
(Abrahamowicz et al., 2012)	review
(Moothedath et al., 2014)	Editorial
(Leader, 2014)	Critical summary
(Geisinger et al., 2014)	Not related to study aim
(Santa Cruz et al., 2013)	Assess periodontal pathogens
(Horton and Boggess, 2012)	review
(Dasanayake, 2012)	editorial
(Das and Das, 2012)	Conference abstract
(Xiong et al., 2011)	review
(Jiang et al., 2013)	Recruited women who planned to get pregnancy
(Sant'anaPassanezi et al., 2011)	Not randomized and assess
(Mayer et al., 2008)	Hebrew
(Sembene et al., 2000)	French

Appendix E

Newcastle-Ottawa quality assessment scale: Cohort studies (Author assessment)

<u>Note</u>: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

	Criteria	(Jeffcoat et al., 2001b)	(Offenbacher et al., 2001)	Moore et al., 2004)	Rajapakse et al.,2005	Marin et al.2005	Offenbacher et al.2006	Sharma el at., (2007)	Agueda et al., (2008)	Mobeen et al., (2008)	Pitiphat el at., (2008)	Saddki et al., (2008)
Selection	1)Representativeness of the exposed cohort a) truly representative of the average _____ (describe) in the community ▯ b) somewhat representative of the average _____ in the community ▯ c) selected group of users eg nurses, volunteers d) no description of the derivation of the cohort	* pregnant woman and have reached 21 to 24 weeks' gestation.	* Pregnant women (no includion criteria were reported)	* Pregnant women attending an ultrasound scan at approximately 12 weeks of pregnancy.	* Pregnant women in late third trimester	* singleton gestation, Any weeks' gestation	* before 26 weeks of gestation.	* pregnant women Mean age was 25.8 13 had PTB	* pregnant women, age between 18 and 40 years, pregnancy duration of 20–24 weeks	* 20-26 weeks of gestation	* the 2nd trimester of gestation	* Pregnant women in the second trimester of pregnancy
	2) Selection of the non-	*From the same	*From the	*From the	*From the	*From the	*From m	*From the same	*From the	*From the	*From the same	*From the

384

	Col1	Col2	Col3	Col4	Col5	Col6	Col7	Col8	Col9	Col10	Col11
exposed cohort a) drawn from the same community as the exposed cohort ☐ b) drawn from a different source c) no description of the derivation of the non-exposed cohort	community	same community	same community	same community	same community	the same community	community	same community	same community	community	same community
3) Ascertainment of exposure a) secure record (eg surgical records) ☐ b) structured interview ☐ c) written self report d) no description	* medical records and perio assessment	* Interview and perio assessment	* Questionnaire and perio assessment	* Questionnaire and perio assessment	* medical records and perio assessment	* Questionnaire and perio assessment	* Interview and perio assessment	* Interview and perio assessment	* Questionnaire and perio assessment	* medical records and perio assessment	* medical records and perio assessment
4) Demonstration that outcome of interest was not present at start of study a) yes ☐ b) no	*yes	*yes	*yes	*yes	*yes	*yes	*yes	*yes	*yes	*yes	*yes
Comparability 1) Comparability of cohorts on the basis of the design or analysis a) study controls for _____ (select the	No controls reported	No controls reported	No controls reported	No controls reported	No controls reported	No controls reported	No controls reported	No controls reported	No controls reported	No controls reported	* Without periodontal disease

<table>
<tbody>
<tr><td colspan="2">most important factor)

b) study controls for any additional factor   (This criteria could be modified to indicate specific
control for a second important factor.)</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</tbody>
</table>

Outcome	1) Assessment of outcome a) independent blind assessment b) record linkage c) self report d) no description	*Record likage of periodontal disease and PT	*Record linkage	*Record linkage	*Record linkage	*Record linkage	*Record linkage	*Record linkage	*Record linkage	*Record linkage	*Record linkage	*Record linkage
	2) Was follow-up long enough for outcomes to occur a) yes (select an adequate follow up period for outcome of interest) b) no	Yes*	Yes*	Yes*	Yes*	Yes*	Yes*	Yes*	Yes*	Yes*	Yes*	Yes*
	3)Adequacy of follow up of cohorts a) complete follow up - all subjects accounted for b) subjects lost to follow up unlikely to introduce bias - small number lost - > _____ % (select an adequate %) follow up, or description provided of those	Not reported	Not reported	*description provided of those lost	Not reported	Not reported	*description provided of those lost	Not reported	*description provided of those lost	*description provided of those lost	Not reported	*description provided of those lost

lost) ☐
    c) follow up rate < ____%
(select an adequate %) and
no description of those lost
    d) no statement

Cont. of quality assessment of cohort studies

	Criteria	Srinivas et al., (2009)	Rakoto-Alson et al., (2010)	Vogt et al., (2010)	Ali and Abidin (2012)	Habashneh et al., 2013

Selection	1)Representativeness of the exposed cohort
	    a) truly representative of the average _____ (describe) in the community ☐
	    b) somewhat representative of the average _____ in the community ☐
	    c) selected group of users eg nurses, volunteers
	    d) no description of the derivation of the cohort
		*
		Pregnant women who were 6-20 weeks' gestation
			*
			pregnant women with a gestational age between 20 and 34.
				*
				pregnant women with gestational age ≤ 32 weeks
					*
					pregnant women between 28 to 36 gestation weeks
						*
						pregnant with a gestational age of 20 weeks or less

	2) Selection of the non-exposed cohort
	    a) drawn from the same community as the exposed cohort ☐
	    b) drawn from a different source
	    c) no description of the derivation of the non-exposed
		*From the same community	*From the same community	*From the same community	*From the same community	*From the same community

	cohort					

	3) Ascertainment of exposure
	    a) secure record (eg surgical records) □
	    b) structured interview □
	    c) written self report
	    d) no description
		*
		Interview and perio assessment
			* medical records and perio assessment	*questionnaire and perio assessment	*interview, questionnaire and perio assessment	* medical records and perio assessment

	4) Demonstration that outcome of interest was not present at start of study
	    a) yes □
	    b) no
		*yes	*yes	*yes	*yes	*yes

Comparability	1) Comparability of cohorts on the basis of the design or analysis
	    a) study controls for _____ (select the most important factor) □
	    b) study controls for any additional factor □ (This criteria could be modified to indicate specific control for a second important factor.)
		No controls reported	No controls reported	*
				Women without Periodontal disease
					No controls reported	No controls reported

	1) Assessment of outcome
	    a) independent blind assessment □
	    b) record linkage □
	    c) self report
	    d) no description
		*Record linkage	*Record likage of periodontal disease and PT	*Record likage	*Record likage	*Record likage

Outcome	2) Was follow-up long enough for outcomes to occur a) yes (select an adequate follow up period for outcome of interest) □	Yes*	*Record linkage	Yes*	Yes*	Yes*

	b) no					

	3)Adequacy of follow up of cohorts
	    a) complete follow up - all subjects accounted for ☐
	    b) subjects lost to follow up unlikely to introduce bias - small number lost - > _____ % (select an adequate %) follow up, or description provided of those lost) ☐
	    c) follow up rate < _____% (select an adequate %) and no description of those lost
	    d) no statement
		Not reported	Not reported	Not reported	Not reported	Not reported

Criteria		Rakoto-Alson et al., (2010)	Vogt et al., (2010)	Ali and Abidin (2012)	Habashneh et al., 2013

Selection	1)Representativeness of the exposed cohort
	    a) truly representative of the average _____ (describe) in the community ☐
	    b) somewhat representative of the average _____ in the community ☐
	    c) selected group of users eg nurses, volunteers
	    d) no description of the derivation of the cohort
		*
		pregnant women with a gestational age between 20 and 34.
			*
			pregnant women with gestational age ≤ 32 weeks
				*
				pregnant women between 28 to 36 gestation weeks
					*
					pregnant with a gestational age of 20 weeks or less

	2) Selection of the non-exposed cohort	*From the same	*From the same	*From the same	*From the same

		community		community	community	community
	a) drawn from the same community as the exposed cohort ☐ b) drawn from a different source c) no description of the derivation of the non-exposed cohort					
	3) <u>Ascertainment of exposure</u> a) secure record (eg surgical records) ☐ b) structured interview ☐ c) written self report d) no description	* medical records and perio assessment		*questionnaire and perio assessment	*interview, questionnaire and perio assessment	* medical records and perio assessment
	4) <u>Demonstration that outcome of interest was not present at start of study</u> a) yes ☐ b) no	*yes		*yes	*yes	*yes
Comparability	1) <u>Comparability of cohorts on the basis of the design or analysis</u> a) study controls for _____ (select the most important factor) ☐ b) study controls for any additional factor ☐ (This criteria could be modified to indicate specific control for a second important factor.)	No controls reported		* Women without Periodontal disease	No controls reported	No controls reported
Outcome	1) <u>Assessment of outcome</u> a) independent blind assessment ☐ b) record linkage ☐ c) self report	*Record likage of periodontal disease and PT		*Record likage	*Record likage	*Record likage

d) no description

2) <u>Was follow-up long enough for outcomes to occur</u>
  a) yes (select an adequate follow up period for outcome of interest) ☐
  b) no
	Yes*	Yes*	Yes*	Yes*

3)<u>Adequacy of follow up of cohorts</u>
  a) complete follow up - all subjects accounted for ☐
  b) subjects lost to follow up unlikely to introduce bias - small number lost - > _____ % (select an adequate %) follow up, or description provided of those lost) ☐
  c) follow up rate < _____% (select an adequate %) and no description of those lost
  d) no statement
	Not reported	Not reported	Not reported	Not reported

Appendix F

The forest plot of the subgroup meta-analyses of cohort studies

Race/ethnicity

PTB

All Representation (PTB)

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	31	338	54	958	11.7%	1.63 [1.06, 2.49]
Marine 2005	6	114	2	38	4.9%	1.00 [0.21, 4.75]
Moore et al., 2004	268	3461	20	277	11.7%	1.07 [0.69, 1.66]
Offenbacher et al., 2001	150	611	38	201	12.3%	1.30 [0.94, 1.79]
Offenbacher et al.2006	154	735	32	285	12.2%	1.87 [1.31, 2.66]
Pitiphat el at., 2008	5	62	100	1573	8.7%	1.27 [0.54, 3.00]
Rakotoalson et al., 2010	33	47	9	157	10.1%	12.25 [6.32, 23.72]
Saddki et al., 2008	16	232	3	240	6.5%	5.52 [1.63, 18.68]
Srinivas et al., 2009	37	311	72	475	12.1%	0.78 [0.54, 1.14]
Vogt et al., (2010)	19	156	11	171	9.8%	1.89 [0.93, 3.85]
Total (95% CI)		6067		4375	100.0%	1.81 [1.17, 2.79]
Total events	719		341			

Heterogeneity: Tau² = 0.37; Chi² = 60.48, df = 9 (P < 0.00001); I² = 85%
Test for overall effect: Z = 2.67 (P = 0.008)

Low Representation (PTB)

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Agueda et al., 2008	31	338	54	958	38.7%	1.63 [1.06, 2.49]
Moore et al., 2004	268	3461	20	277	50.9%	1.07 [0.69, 1.66]
Pitiphat el at., 2008	5	62	100	1573	10.4%	1.27 [0.54, 3.00]
Total (95% CI)		3861		2808	100.0%	1.31 [0.98, 1.74]
Total events	304		174			

Heterogeneity: Chi² = 1.82, df = 2 (P = 0.40); I² = 0%
Test for overall effect: Z = 1.84 (P = 0.07)

Moderate Representation (PTB)

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Offenbacher et al., 2001	150	611	38	201	47.0%	1.30 [0.94, 1.79]
Offenbacher et al.2006	154	735	32	285	40.3%	1.87 [1.31, 2.66]
Vogt et al., (2010)	19	156	11	171	12.7%	1.89 [0.93, 3.85]
Total (95% CI)		1502		657	100.0%	1.58 [1.21, 2.06]
Total events	323		81			

Heterogeneity: Tau² = 0.01; Chi² = 2.56, df = 2 (P = 0.28); I² = 22%
Test for overall effect: Z = 3.36 (P = 0.0008)

Extensive Representation (PTB)

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Marine 2005	6	114	2	38	22.3%	1.00 [0.21, 4.75]
Rakotoalson et al., 2010	33	47	9	157	26.4%	12.25 [6.32, 23.72]
Saddki et al., 2008	16	232	3	240	24.1%	5.52 [1.63, 18.68]
Srinivas et al., 2009	37	311	72	475	27.2%	0.78 [0.54, 1.14]
Total (95% CI)		**704**		**910**	**100.0%**	**2.74 [0.51, 14.60]**
Total events	92		86			

Heterogeneity: Tau² = 2.64; Chi² = 55.11, df = 3 (P < 0.00001); I² = 95%
Test for overall effect: Z = 1.18 (P = 0.24)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — women without PD women with PD

LBW and Race/ethnicity

All representation

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	28	338	50	958	20.8%	1.59 [1.02, 2.48]
Marine 2005	7	114	0	38	5.0%	5.09 [0.30, 87.03]
Moore et al., 2004	246	3461	22	277	21.0%	0.89 [0.59, 1.36]
Rakotoalson et al., 2010	17	47	5	157	16.3%	11.36 [4.43, 29.14]
Saddki et al., 2008	33	232	8	240	18.2%	4.27 [2.01, 9.04]
Vogt et al., (2010)	18	156	12	171	18.7%	1.64 [0.82, 3.30]
Total (95% CI)		**4348**		**1841**	**100.0%**	**2.47 [1.21, 5.07]**
Total events	349		97			

Heterogeneity: Tau² = 0.59; Chi² = 31.32, df = 5 (P < 0.00001); I² = 84%
Test for overall effect: Z = 2.48 (P = 0.01)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — women without PD women with PD

Low representation

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	28	338	50	958	49.1%	1.59 [1.02, 2.48]
Moore et al., 2004	246	3461	22	277	50.9%	0.89 [0.59, 1.36]
Total (95% CI)		**3799**		**1235**	**100.0%**	**1.19 [0.68, 2.08]**
Total events	274		72			

Heterogeneity: Tau² = 0.12; Chi² = 3.37, df = 1 (P = 0.07); I² = 70%
Test for overall effect: Z = 0.59 (P = 0.55)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — women without PD women with PD

High representation

Study or Subgroup	women with PD Events	Total	woman without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Marine2005	7	114	0	38	6.0%	5.09 [0.30, 87.03]
Rokotoalson 2010	17	47	5	157	40.1%	11.36 [4.43, 29.14]
Saddki 2008	33	232	8	240	53.8%	4.27 [2.01, 9.04]
Total (95% CI)		**393**		**435**	**100.0%**	**6.39 [3.13, 13.05]**
Total events	57		13			

Heterogeneity: Tau² = 0.10; Chi² = 2.60, df = 2 (P = 0.27); I² = 23%
Test for overall effect: Z = 5.09 (P < 0.00001)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — woman without PD woman with PD

PLBW

All

	women with PD		women without PD			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
Agueda et al., 2008	16	338	27	958	32.3%	1.68 [0.92, 3.08]	
Rajapakse et al.,2005	8	66	9	161	26.8%	2.17 [0.87, 5.38]	
Rakotoalson et al., 2010	7	47	2	157	17.0%	11.69 [2.51, 54.39]	
Sharma el at., 2007	7	95	6	575	23.9%	7.06 [2.43, 20.56]	
Total (95% CI)		546		1851	100.0%	3.53 [1.51, 8.20]	
Total events	38		44				

Heterogeneity: Tau² = 0.48; Chi² = 9.18, df = 3 (P = 0.03); I² = 67%
Test for overall effect: Z = 2.92 (P = 0.003)

0.01 0.1 1 10 100
women without PD   women with PD

Extensive

	women with PD		women without PD			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
Rajapakse et al.,2005	8	66	9	161	39.8%	2.17 [0.87, 5.38]	
Rakotoalson et al., 2010	7	47	2	157	24.8%	11.69 [2.51, 54.39]	
Sharma el at., 2007	7	95	6	575	35.4%	7.06 [2.43, 20.56]	
Total (95% CI)		208		893	100.0%	5.00 [1.83, 13.63]	
Total events	22		17				

Heterogeneity: Tau² = 0.44; Chi² = 4.64, df = 2 (P = 0.10); I² = 57%
Test for overall effect: Z = 3.14 (P = 0.002)

0.01 0.1 1 10 100
women without PD   women with PD

ABOs History

PTB

All

	women with PD		women without PD			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
Agueda et al., 2008	31	338	54	958	12.9%	1.63 [1.06, 2.49]	
Marine 2005	6	114	2	38	5.6%	1.00 [0.21, 4.75]	
Moore et al., 2004	268	3461	20	277	12.9%	1.07 [0.69, 1.66]	
Offenbacher et al., 2001	150	611	38	201	13.6%	1.30 [0.94, 1.79]	
Offenbacher et al.2006	154	735	32	285	13.4%	1.87 [1.31, 2.66]	
Pitiphat el at., 2008	5	62	100	1573	9.8%	1.27 [0.54, 3.00]	
Rakotoalson et al., 2010	33	47	9	157	11.3%	12.25 [6.32, 23.72]	
Saddki et al., 2008	16	232	3	240	7.4%	5.52 [1.63, 18.68]	
Srinivas et al., 2009	37	311	72	475	13.3%	0.78 [0.54, 1.14]	
Total (95% CI)		5911		4204	100.0%	1.80 [1.12, 2.89]	
Total events	700		330				

Heterogeneity: Tau² = 0.40; Chi² = 60.06, df = 8 (P < 0.00001); I² = 87%
Test for overall effect: Z = 2.45 (P = 0.01)

0.01 0.1 1 10 100
women without PD   women with PD

Low

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	31	338	54	958	27.8%	1.63 [1.06, 2.49]
Marine 2005	6	114	2	38	18.1%	1.00 [0.21, 4.75]
Moore et al., 2004	268	3461	20	277	27.8%	1.07 [0.69, 1.66]
Rakotoalson et al., 2010	33	47	9	157	26.2%	12.25 [6.32, 23.72]
Total (95% CI)		**3960**		**1430**	**100.0%**	**2.25 [0.76, 6.64]**
Total events	338		85			

Heterogeneity: Tau² = 1.05; Chi² = 38.25, df = 3 (P < 0.00001); I² = 92%
Test for overall effect: Z = 1.47 (P = 0.14)

Extensive

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Offenbacher et al., 2001	150	611	38	201	26.2%	1.30 [0.94, 1.79]
Offenbacher et al.2006	154	735	32	285	25.3%	1.87 [1.31, 2.66]
Pitiphat el at., 2008	5	62	100	1573	14.2%	1.27 [0.54, 3.00]
Saddki el al., 2008	16	232	3	240	9.3%	5.52 [1.63, 18.68]
Srinivas et al., 2009	37	311	72	475	25.0%	0.78 [0.54, 1.14]
Total (95% CI)		**1951**		**2774**	**100.0%**	**1.43 [0.92, 2.24]**
Total events	362		245			

Heterogeneity: Tau² = 0.17; Chi² = 16.65, df = 4 (P = 0.002); I² = 76%
Test for overall effect: Z = 1.57 (P = 0.12)

LBW

All

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	28	338	50	958	24.9%	1.59 [1.02, 2.48]
Marine 2005	7	114	0	38	7.1%	5.09 [0.30, 87.03]
Moore et al., 2004	246	3461	22	277	25.1%	0.89 [0.59, 1.36]
Rakotoalson et al., 2010	17	47	5	157	20.5%	11.36 [4.43, 29.14]
Saddki et al., 2008	33	232	8	240	22.3%	4.27 [2.01, 9.04]
Total (95% CI)		**4192**		**1670**	**100.0%**	**2.79 [1.15, 6.77]**
Total events	331		85			

Heterogeneity: Tau² = 0.77; Chi² = 31.35, df = 4 (P < 0.00001); I² = 87%
Test for overall effect: Z = 2.26 (P = 0.02)

Low

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	28	338	50	958	32.0%	1.59 [1.02, 2.48]
Marine 2005	7	114	0	38	9.3%	5.09 [0.30, 87.03]
Mobeen et al., 2008	246	3461	22	277	32.3%	0.89 [0.59, 1.36]
Rakotoalson et al., 2010	17	47	5	157	26.4%	11.36 [4.43, 29.14]
Total (95% CI)		**3960**		**1430**	**100.0%**	**2.47 [0.89, 6.84]**
Total events	298		77			

Heterogeneity: Tau² = 0.79; Chi² = 24.43, df = 3 (P < 0.0001); I² = 88%
Test for overall effect: Z = 1.74 (P = 0.08)

PLBW

All and low

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	16	338	27	958	56.9%	1.68 [0.92, 3.08]
Rakotoalson et al., 2010	7	47	2	157	43.1%	11.69 [2.51, 54.39]
Total (95% CI)		385		1115	100.0%	3.88 [0.59, 25.65]
Total events	23		29			

Heterogeneity: Tau² = 1.54; Chi² = 5.33, df = 1 (P = 0.02); I² = 81%
Test for overall effect: Z = 1.41 (P = 0.16)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — women without PD / women with PD

History of smoking

PTB

All

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	31	338	54	958	16.2%	1.63 [1.06, 2.49]
Marine 2005	6	114	2	38	2.7%	1.00 [0.21, 4.75]
Moore et al., 2004	268	3461	20	277	15.8%	1.07 [0.69, 1.66]
Offenbacher et al., 2001	150	611	38	201	19.7%	1.30 [0.94, 1.79]
Offenbacher et al.2006	154	735	32	285	18.4%	1.87 [1.31, 2.66]
Srinivas et al., 2009	37	311	72	475	17.9%	0.78 [0.54, 1.14]
Vogt et al., (2010)	19	156	11	171	9.3%	1.89 [0.93, 3.85]
Total (95% CI)		5726		2405	100.0%	1.31 [1.00, 1.72]
Total events	665		229			

Heterogeneity: Tau² = 0.07; Chi² = 14.14, df = 6 (P = 0.03); I² = 58%
Test for overall effect: Z = 2.00 (P = 0.05)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — women without PD / women with PD

Low

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Marine 2005	6	114	2	38	7.5%	1.00 [0.21, 4.75]
Moore et al., 2004	268	3461	20	277	42.8%	1.07 [0.69, 1.66]
Offenbacher et al.2006	154	735	32	285	49.6%	1.87 [1.31, 2.66]
Total (95% CI)		4310		600	100.0%	1.40 [0.89, 2.21]
Total events	428		54			

Heterogeneity: Tau² = 0.07; Chi² = 3.97, df = 2 (P = 0.14); I² = 50%
Test for overall effect: Z = 1.47 (P = 0.14)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — women without PD / women with PD

High

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	31	338	54	958	25.8%	1.63 [1.06, 2.49]
Offenbacher et al., 2001	150	611	38	201	30.3%	1.30 [0.94, 1.79]
Srinivas et al., 2009	37	311	72	475	28.1%	0.78 [0.54, 1.14]
Vogt et al., (2010)	19	156	11	171	15.9%	1.89 [0.93, 3.85]
Total (95% CI)		1416		1805	100.0%	1.27 [0.88, 1.83]
Total events	237		175			

Heterogeneity: Tau² = 0.09; Chi² = 8.86, df = 3 (P = 0.03); I² = 66%
Test for overall effect: Z = 1.27 (P = 0.20)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — women without PD / women with PD

LBW

All

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Agueda et al., 2008	28	338	50	958	36.7%	1.59 [1.02, 2.48]	
Marine 2005	7	114	0	38	2.0%	5.09 [0.30, 87.03]	
Moore et al., 2004	246	3461	22	277	38.7%	0.89 [0.59, 1.36]	
Vogt et al., (2010)	18	156	12	171	22.5%	1.64 [0.82, 3.30]	
Total (95% CI)		**4069**		**1444**	**100.0%**	**1.31 [0.87, 1.98]**	
Total events	299		84				

Heterogeneity: Tau² = 0.07; Chi² = 5.09, df = 3 (P = 0.17); I² = 41%
Test for overall effect: Z = 1.30 (P = 0.19)

0.01 0.1 1 10 100
women without PD   women with PD

Low

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Marine 2005	7	114	0	38	17.0%	5.09 [0.30, 87.03]	
Moore et al., 2004	246	3461	22	277	83.0%	0.89 [0.59, 1.36]	
Total (95% CI)		**3575**		**315**	**100.0%**	**1.20 [0.33, 4.41]**	
Total events	253		22				

Heterogeneity: Tau² = 0.48; Chi² = 1.45, df = 1 (P = 0.23); I² = 31%
Test for overall effect: Z = 0.28 (P = 0.78)

0.01 0.1 1 10 100
women with PD   women without PD

High

Study or Subgroup	women with PD Events	Total	women without PD Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Agueda et al., 2008	28	338	50	958	69.5%	1.59 [1.02, 2.48]	
Vogt et al., (2010)	18	156	12	171	30.5%	1.64 [0.82, 3.30]	
Total (95% CI)		**494**		**1129**	**100.0%**	**1.60 [1.10, 2.34]**	
Total events	46		62				

Heterogeneity: Chi² = 0.01, df = 1 (P = 0.93); I² = 0%
Test for overall effect: Z = 2.47 (P = 0.01)

0.01 0.1 1 10 100
women without PD   women with PD

Appendix G

The forest plot of the subgroup meta-analyses of RCTs

Race/ethnicity

PTB

All

Low

Moderate

High

LBW

All

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Macones 2010	49	359	35	361	15.0%	1.41 [0.94, 2.12]
Michalowicz 2006	40	406	43	403	15.1%	0.92 [0.61, 1.39]
Newnham 2009	53	99	68	89	18.9%	0.70 [0.56, 0.87]
Offenbacher 2009	72	872	71	866	17.0%	1.01 [0.74, 1.38]
Oliveira 2011	23	113	31	112	13.7%	0.74 [0.46, 1.18]
Tarannum and Faizuddin (2007	19	91	48	89	14.3%	0.39 [0.25, 0.60]
Weidlich 2012	8	145	6	154	6.0%	1.42 [0.50, 3.98]
Total (95% CI)		2085		2074	100.0%	0.83 [0.62, 1.12]
Total events	264		302			

Heterogeneity: $Tau^2 = 0.11$; $Chi^2 = 23.60$, df = 6 (P = 0.0006); $I^2 = 75\%$
Test for overall effect: $Z = 1.21$ (P = 0.23)

Risk Ratio M-H, Random, 95% CI — Favours [experimental] Favours [control]

Low

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Michalowicz et al., 2006)	40	406	43	403	35.4%	0.91 [0.58, 1.44]
Offenbacher 2009	72	872	71	866	59.5%	1.01 [0.72, 1.42]
Weidlich et al., 2012	8	145	6	154	5.0%	1.44 [0.49, 4.26]
Total (95% CI)		1423		1423	100.0%	1.00 [0.76, 1.30]
Total events	120		120			

Heterogeneity: $Chi^2 = 0.58$, df = 2 (P = 0.75); $I^2 = 0\%$
Test for overall effect: $Z = 0.03$ (P = 0.98)

Odds Ratio M-H, Fixed, 95% CI — Favours experimental Favours control

High

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Macones 2010	49	359	35	361	32.4%	1.41 [0.94, 2.12]
Newnham 2009	53	99	68	89	36.1%	0.70 [0.56, 0.87]
Tarannum and Faizuddin (2007	19	91	48	89	31.5%	0.39 [0.25, 0.60]
Total (95% CI)		549		539	100.0%	0.73 [0.40, 1.34]
Total events	121		151			

Heterogeneity: $Tau^2 = 0.26$; $Chi^2 = 18.20$, df = 2 (P = 0.0001); $I^2 = 89\%$
Test for overall effect: $Z = 1.02$ (P = 0.31)

Risk Ratio M-H, Random, 95% CI — Favours [experimental] Favours [control]

PLBW

All

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Macones 2010	11	357	8	357	18.6%	1.38 [0.56, 3.38]
Oliveira 2011	29	113	31	112	72.4%	0.93 [0.60, 1.43]
Weidlich 2012	6	145	4	154	9.0%	1.59 [0.46, 5.53]
Total (95% CI)		615		623	100.0%	1.07 [0.74, 1.56]
Total events	46		43			

Heterogeneity: $Chi^2 = 1.11$, df = 2 (P = 0.57); $I^2 = 0\%$
Test for overall effect: $Z = 0.36$ (P = 0.72)

Risk Ratio M-H, Fixed, 95% CI — Favours [experimental] Favours [control]

High

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Macones 2010	11	357	8	357	20.4%	1.38 [0.56, 3.38]
Oliveira 2011	29	113	31	112	79.6%	0.93 [0.60, 1.43]
Total (95% CI)		470		469	100.0%	1.02 [0.69, 1.51]
Total events	40		39			

Heterogeneity: $Chi^2 = 0.61$, df = 1 (P = 0.44); $I^2 = 0\%$
Test for overall effect: $Z = 0.09$ (P = 0.93)

Risk Ratio M-H, Fixed, 95% CI — Favours [experimental] Favours [control]

399

Stillbirth

All

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
(Macones et al., 2010)	7	359	8	361	28.0%	0.88 [0.32, 2.40]	
Michalowicz et al., 2006)	5	407	14	405	49.3%	0.36 [0.13, 0.98]	
Newnham 2009	0	538	4	540	15.8%	0.11 [0.01, 2.07]	
Weidlich et al., 2012	1	145	2	154	6.8%	0.53 [0.05, 5.79]	
Total (95% CI)		1449		1460	100.0%	0.48 [0.25, 0.90]	
Total events	13		28				

Heterogeneity: Chi² = 2.72, df = 3 (P = 0.44); I² = 0%
Test for overall effect: Z = 2.27 (P = 0.02)

0.01 0.1 1 10 100
Favours experimental Favours control

Low

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Michalowicz et al., 2006	5	407	14	405	87.9%	0.36 [0.13, 0.98]	
Weidlich et al., 2012	1	145	2	154	12.1%	0.53 [0.05, 5.79]	
Total (95% CI)		552		559	100.0%	0.38 [0.15, 0.95]	
Total events	6		16				

Heterogeneity: Chi² = 0.09, df = 1 (P = 0.76); I² = 0%
Test for overall effect: Z = 2.06 (P = 0.04)

0.01 0.1 1 10 100
Favours experimental Favours control

High

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
(Macones et al., 2010)	7	359	8	361	71.6%	0.88 [0.32, 2.40]	
Newnham 2009	0	538	4	540	28.4%	0.11 [0.01, 2.07]	
Total (95% CI)		897		901	100.0%	0.49 [0.07, 3.21]	
Total events	7		12				

Heterogeneity: Tau² = 1.03; Chi² = 1.83, df = 1 (P = 0.18); I² = 45%
Test for overall effect: Z = 0.74 (P = 0.46)

0.01 0.1 1 10 100
Favours experimental Favours control

Smoking RCT

PTB

All

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	2	163	12	188	6.0%	0.19 [0.04, 0.85]	
(López et al., 2005)	8	560	16	283	11.8%	0.25 [0.11, 0.58]	
Jeffcoat et al., 2003)	16	246	92	723	16.4%	0.51 [0.31, 0.85]	
Newnham 2009	52	538	50	540	18.4%	1.04 [0.72, 1.51]	
Offenbacher 2009	97	882	81	880	19.6%	1.19 [0.90, 1.58]	
Offenbacher et al., 2006)	9	35	14	32	13.8%	0.59 [0.30, 1.17]	
Weidlich et al., 2012	17	145	14	154	14.0%	1.29 [0.66, 2.52]	
Total (95% CI)		2569		2800	100.0%	0.69 [0.45, 1.06]	
Total events	201		279				

Heterogeneity: Tau² = 0.22; Chi² = 25.02, df = 6 (P = 0.0003); I² = 76%
Test for overall effect: Z = 1.67 (P = 0.09)

0.01 0.1 1 10 100
Favours experimental Favours control

Low

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Jeffcoat et al., 2003)	16	246	92	723	33.0%	0.51 [0.31, 0.85]
Offenbacher 2009	97	882	81	880	39.1%	1.19 [0.90, 1.58]
Offenbacher et al., 2006)	9	35	14	32	27.9%	0.59 [0.30, 1.17]
Total (95% CI)		1163		1635	100.0%	0.74 [0.40, 1.38]
Total events	122		187			

Heterogeneity: Tau² = 0.23; Chi² = 10.10, df = 2 (P = 0.006); I² = 80%
Test for overall effect: Z = 0.95 (P = 0.34)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — Favours experimental Favours control

High

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	2	163	12	188	15.9%	0.19 [0.04, 0.85]
(López et al., 2005)	8	560	16	283	24.9%	0.25 [0.11, 0.58]
Newnham 2009	52	538	50	540	31.7%	1.04 [0.72, 1.51]
Weidlich et al., 2012	17	145	14	154	27.5%	1.29 [0.66, 2.52]
Total (95% CI)		1406		1165	100.0%	0.59 [0.26, 1.33]
Total events	79		92			

Heterogeneity: Tau² = 0.50; Chi² = 14.76, df = 3 (P = 0.002); I² = 80%
Test for overall effect: Z = 1.26 (P = 0.21)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — Favours experimental Favours control

LBW

All

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	1	163	7	188	2.6%	0.16 [0.02, 1.33]
(López et al., 2005)	4	560	3	283	4.8%	0.67 [0.15, 2.99]
Newnham 2009	53	99	68	89	45.5%	0.70 [0.56, 0.87]
Offenbacher 2009	72	872	71	866	37.9%	1.01 [0.74, 1.38]
Weidlich et al., 2012	8	145	6	154	9.2%	1.42 [0.50, 3.98]
Total (95% CI)		1839		1580	100.0%	0.82 [0.59, 1.16]
Total events	138		155			

Heterogeneity: Tau² = 0.05; Chi² = 7.41, df = 4 (P = 0.12); I² = 46%
Test for overall effect: Z = 1.10 (P = 0.27)

Risk Ratio M-H, Random, 95% CI — 0.01 0.1 1 10 100 — Favours experimental Favours control

High

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
(Lopez et al., 2002)	1	163	7	188	13.1%	0.16 [0.02, 1.31]	
(López et al., 2005)	4	560	3	283	8.0%	0.67 [0.15, 3.02]	
Newnham 2009	53	99	68	89	67.6%	0.36 [0.19, 0.67]	
Weidlich et al., 2012	8	145	6	154	11.2%	1.44 [0.49, 4.26]	
Total (95% CI)		967		714	100.0%	0.48 [0.30, 0.77]	
Total events	66		84				

Heterogeneity: Chi² = 6.07, df = 3 (P = 0.11); I² = 51%
Test for overall effect: Z = 3.03 (P = 0.002)

0.01   0.1   1   10   100
Favours experimental   Favours control

PLBW

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	3	163	19	188	30.5%	0.18 [0.05, 0.60]	
(López et al., 2005)	12	560	19	283	39.8%	0.32 [0.16, 0.65]	
Weidlich et al., 2012	6	145	4	154	29.7%	1.59 [0.46, 5.53]	
Total (95% CI)		868		625	100.0%	0.43 [0.14, 1.31]	
Total events	21		42				

Heterogeneity: Tau² = 0.67; Chi² = 6.79, df = 2 (P = 0.03); I² = 71%
Test for overall effect: Z = 1.48 (P = 0.14)

0.01   0.1   1   10   100
Favours experimental   Favours control

Stillbirth

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Newnham 2009	0	538	4	540	70.0%	0.11 [0.01, 2.06]	
Weidlich et al., 2012	1	145	2	154	30.0%	0.53 [0.05, 5.88]	
Total (95% CI)		683		694	100.0%	0.24 [0.04, 1.39]	
Total events	1		6				

Heterogeneity: Chi² = 0.69, df = 1 (P = 0.41); I² = 0%
Test for overall effect: Z = 1.59 (P = 0.11)

0.01   0.1   1   10   100
Favours experimental   Favours control

ABOs History

PTB

All

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	2	163	12	188	3.7%	0.19 [0.04, 0.85]	
(López et al., 2005)	8	560	16	283	7.9%	0.25 [0.11, 0.58]	
(Macones et al., 2010)	58	359	47	361	14.0%	1.24 [0.87, 1.77]	
Jeffcoat et al., 2003	16	246	92	723	11.8%	0.51 [0.31, 0.85]	
Michalowicz et al., 2006)	52	402	38	391	13.4%	1.33 [0.90, 1.97]	
Newnham 2009	52	538	50	540	13.8%	1.04 [0.72, 1.51]	
Offenbacher 2009	97	882	81	880	15.0%	1.19 [0.90, 1.58]	
Offenbacher et al., 2006)	9	35	14	32	9.5%	0.59 [0.30, 1.17]	
Sadatmansouri 2006	0	15	3	15	1.2%	0.14 [0.01, 2.55]	
Weidlich et al., 2012	17	145	14	154	9.7%	1.29 [0.66, 2.52]	
Total (95% CI)		3345		3567	100.0%	0.82 [0.60, 1.13]	
Total events	311		367				

Heterogeneity: Tau² = 0.16; Chi² = 31.62, df = 9 (P = 0.0002); I² = 72%
Test for overall effect: Z = 1.19 (P = 0.23)

0.01   0.1   1   10   100
Favours experimental   Favours control

Low

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
(López et al., 2005)	8	560	16	283	15.0%	0.25 [0.11, 0.58]
Jeffcoat et al., 2003)	16	246	92	723	20.2%	0.51 [0.31, 0.85]
Michalowicz et al., 2006)	52	402	38	391	22.1%	1.33 [0.90, 1.97]
Newnham 2009	52	538	50	540	22.4%	1.04 [0.72, 1.51]
Sadatmansouri 2006	0	15	3	15	2.7%	0.14 [0.01, 2.55]
Weidlich et al., 2012	17	145	14	154	17.6%	1.29 [0.66, 2.52]
Total (95% CI)		**1906**		**2106**	**100.0%**	**0.76 [0.46, 1.25]**
Total events	145		213			

Heterogeneity: Tau² = 0.26; Chi² = 20.80, df = 5 (P = 0.0009); I² = 76%
Test for overall effect: Z = 1.08 (P = 0.28)

High

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	2	163	12	188	10.0%	0.18 [0.04, 0.83]
(Macones et al., 2010)	58	359	47	361	34.8%	1.29 [0.85, 1.95]
Offenbacher 2009	97	882	81	880	38.2%	1.22 [0.89, 1.66]
Offenbacher et al., 2006	9	35	14	32	17.0%	0.45 [0.16, 1.25]
Total (95% CI)		**1439**		**1461**	**100.0%**	**0.87 [0.50, 1.49]**
Total events	166		154			

Heterogeneity: Tau² = 0.18; Chi² = 9.39, df = 3 (P = 0.02); I² = 68%
Test for overall effect: Z = 0.52 (P = 0.60)

LBW

All

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	1	163	7	188	1.7%	0.16 [0.02, 1.33]
(López et al., 2005)	4	560	3	283	3.2%	0.67 [0.15, 2.99]
(Macones et al., 2010)	49	359	35	361	19.2%	1.41 [0.94, 2.12]
Michalowicz et al., 2006)	40	406	43	403	19.2%	0.92 [0.61, 1.39]
Newnham 2009	53	99	68	89	26.9%	0.70 [0.56, 0.87]
Offenbacher 2009	72	872	71	866	22.9%	1.01 [0.74, 1.38]
Sadatmansouri 2006	0	15	1	15	0.8%	0.33 [0.01, 7.58]
Weidlich et al., 2012	8	145	6	154	6.1%	1.42 [0.50, 3.98]
Total (95% CI)		**2619**		**2359**	**100.0%**	**0.93 [0.70, 1.23]**
Total events	227		234			

Heterogeneity: Tau² = 0.06; Chi² = 14.79, df = 7 (P = 0.04); I² = 53%
Test for overall effect: Z = 0.52 (P = 0.60)

Low

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
López et al. (2005)	4	560	3	283	3.2%	0.67 [0.15, 2.99]
Michalowicz 2006	40	406	43	403	34.2%	0.92 [0.61, 1.39]
Newnham 2009	53	99	68	89	56.8%	0.70 [0.56, 0.87]
Sadatmansouri et al. (2006)	0	15	1	15	1.2%	0.33 [0.01, 7.58]
Weidlich 2012	8	145	6	154	4.6%	1.42 [0.50, 3.98]
Total (95% CI)		**1225**		**944**	**100.0%**	**0.80 [0.66, 0.99]**
Total events	105		121			

Heterogeneity: Chi² = 3.51, df = 4 (P = 0.48); I² = 0%
Test for overall effect: Z = 2.08 (P = 0.04)

403

High

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
(Lopez et al., 2002)	1	163	7	188	5.0%	0.16 [0.02, 1.33]
(Macones et al., 2010)	49	359	35	361	44.3%	1.41 [0.94, 2.12]
Offenbacher 2009	72	872	71	866	50.7%	1.01 [0.74, 1.38]
Total (95% CI)		1394		1415	100.0%	1.07 [0.65, 1.74]
Total events	122		113			

Heterogeneity: Tau² = 0.10; Chi² = 4.92, df = 2 (P = 0.09); I² = 59%
Test for overall effect: Z = 0.26 (P = 0.80)

Risk Ratio M-H, Random, 95% CI — Favours experimental Favours control

PLBW

All

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Lopez et al. (2002)	3	163	19	188	20.8%	0.18 [0.05, 0.60]
López et al. (2005)	12	560	19	283	26.5%	0.32 [0.16, 0.65]
Macones 2010	11	357	8	357	24.3%	1.38 [0.56, 3.38]
Sadatmansouri et al. (2006)	0	15	4	15	8.2%	0.11 [0.01, 1.90]
Weidlich 2012	6	145	4	154	20.2%	1.59 [0.46, 5.53]
Total (95% CI)		1240		997	100.0%	0.51 [0.20, 1.33]
Total events	32		54			

Heterogeneity: Tau² = 0.75; Chi² = 13.59, df = 4 (P = 0.009); I² = 71%
Test for overall effect: Z = 1.38 (P = 0.17)

Risk Ratio M-H, Random, 95% CI — Favours [experimental] Favours [control]

Low

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
(López et al., 2005)	12	560	19	283	47.3%	0.32 [0.16, 0.65]
Sadatmansouri 2006	0	15	4	15	15.7%	0.11 [0.01, 1.90]
Weidlich et al., 2012	6	145	4	154	37.0%	1.59 [0.46, 5.53]
Total (95% CI)		720		452	100.0%	0.49 [0.13, 1.86]
Total events	18		27			

Heterogeneity: Tau² = 0.85; Chi² = 5.80, df = 2 (P = 0.06); I² = 66%
Test for overall effect: Z = 1.05 (P = 0.29)

Risk Ratio M-H, Random, 95% CI — Favours experimental Favours control

High

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Lopez et al. (2002)	3	163	19	188	48.1%	0.18 [0.05, 0.60]
Macones 2010	11	357	8	357	51.9%	1.38 [0.56, 3.38]
Total (95% CI)		520		545	100.0%	0.52 [0.07, 3.90]
Total events	14		27			

Heterogeneity: Tau² = 1.82; Chi² = 7.23, df = 1 (P = 0.007); I² = 86%
Test for overall effect: Z = 0.64 (P = 0.53)

Risk Ratio M-H, Random, 95% CI — Favours [experimental] Favours [control]

Stillbirth

All

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
(Macones et al., 2010)	7	359	8	361	28.0%	0.88 [0.32, 2.40]
Michalowicz et al., 2006)	5	407	14	405	49.3%	0.36 [0.13, 0.98]
Newnham 2009	0	538	4	540	15.8%	0.11 [0.01, 2.07]
Weidlich et al., 2012	1	145	2	154	6.8%	0.53 [0.05, 5.79]
Total (95% CI)		1449		1460	100.0%	0.48 [0.25, 0.90]
Total events	13		28			

Heterogeneity: Chi² = 2.72, df = 3 (P = 0.44); I² = 0%
Test for overall effect: Z = 2.27 (P = 0.02)

Risk Ratio M-H, Fixed, 95% CI — Favours experimental Favours control

404

Low

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Michalowicz et al., 2006)	5	407	14	405	68.6%	0.36 [0.13, 0.98]
Newnham 2009	0	538	4	540	21.9%	0.11 [0.01, 2.07]
Weidlich et al., 2012	1	145	2	154	9.5%	0.53 [0.05, 5.79]
Total (95% CI)		**1090**		**1099**	**100.0%**	**0.32 [0.13, 0.76]**
Total events	6		20			

Heterogeneity: Chi² = 0.72, df = 2 (P = 0.70); I² = 0%
Test for overall effect: Z = 2.56 (P = 0.01)

Risk Ratio
M-H, Fixed, 95% CI

0.01 0.1 1 10 100
Favours experimental   Favours control

Appendix H

Table A: An overview of the systematic review assessed the effect of NSPT and ABOs.

Review title	Date of search (date assessed as up to date) Databases searched	No. of studies included (No. of patients included)	Inclusion criteria for types of participants	Periodontal disease: Case definition used C=continuous CaT=categorical	Comparison intervention (no of studies and no of participants)	Outcomes for which data were reported that could be included in the analysis	Summary of quality of evidence in reviews
Chambrone et a 2011 Evidence grade associating periodontitis with preterm birth and/or low birth weight: II. A systematic review of randomized trials evaluating the effects of periodontal treatment	No early limit to October 2010 Cochrane Central Register of Controlled Trials, MEDLINE and EMBASE without language restriction. Also grey literature accessed and hand searching of relevant journals. More detailed report in Chambrone 2011a	14 RCTs in countries (Australia, Brazil, Chile, Hungary, India, Iran and USA) 11 RCTS included in Met analysis (Radnai 2009 & Oliveira 2010 excluded) 5964pregnant women For all 11 studies in metaanlysi intervention 3,039 women included. Interventions 1) Scaling and root planing (SRP) versus no treatment; (2) SRP versus supragingival debridement/tooth polish- ing; or	Only studies comparing data from pregnant women with slight/mild CAL 1-2mm; moderate 3-4mm; severe >or =5mm. Armitage 1999,2004 All RCTs appraised patients with periodontitis, except for the study by Lopez et al. (2002), who evaluated a sample of pregnant women with gingivitis.	All RCTs reported an 'adequate' method for the assessment of periodontal conditions, except for the study by Macones et al. (2010), which was classified as inadequate level-1 (diagnosis based on partial-mouth recording). CaT defx based on 1) Analyses by PD and CAL definition 2) Analyses by CAL alone 3) Analyses by PD alone Out of 12 studies seven used a Secure definition of periodontal disease and remaining 5 used Insecure definition based on Nabili et al 2013	14 studies but only 11 included in meta-analysis For control 2,935 women from 11 studies No active comparator for control group	Primary: PTB, LBW and a combination of both outcomes, i.e. PB/LBW. Secondary: Occurrence of adverse effects/complications associated with MPDT. Three time periods for PTB assessed <37 wks <35 wks <32 wks	Only five out of 13 trials (38%) were considered to be at low risk of bias, while the remainder (62%) were considered at unclear or high risk of bias The influence of specific aspects that were not investigated (disease diagnosis, extension and severity and the success of MPDT) should be evaluated by future RCTs p 902 There was significant heterogeneity for comparisons (eg PTB p = 0.002; I^2

| | | (3) SRP plus systemic antibiotics versus supragingival debridement/tooth polishing | Included gingivitis and periodontitis | | | | = 76%). Analyses were then undertaken for high quality trials only . Similar to the overall results, there were no statistically significant differences between groups, but no significant het- erogeneity was found

Bottom Line

While 2/3 of included studies found that PD could decrease ABO, on the other-hand none of the metanalyses supported

Only 38% low risk bias
Only 38% secure Defx PD
69& good defx ABOs
Heterogeneity due to PD dex explored using regression. Other casues not fuly explored in primary studies
Amstar score 11/11 |

							No grade score presentation
De Olivera 2010 Effect of periodontal treatment on the incidence of preterm delivery: a systematic review.	Medline PUBMED (from November 1998 to November 2009)	7 RCTs in 6 countries(Brazil, Chile, Hungary, India, Iran and USA) 2536 pregnant women Intervention 1,313 group Treatment group received: plaque control, scaling and root planning, OHI, rinse with 0.12%chlorohexidine	Pregnant women between <20 and <32 gestational weeks with periodontal disease. Included studies had to evaluate periodontal status after non surgical dental treatment using PPD, CAL and BOP Studies using antibiotics excluded	Included studies that evaluated periodontal disease after treatment by periodontal pocket depth (PPD), CAL and BOP Definition of periodontal disease not standardized. Authors devised a categorization called: Mild, moderate, severe but not clear how this was assessed, though PPD >4 teeth and CAL .7mm at same site was classed as severe. Participants with periodontitis or gingivitis(BOP> 25% of sites and no sites with CAL> 2mm) dFx varied including 1. >2 sites with PD>5 mm and CAL 1-2 mm at one site, 2. ≥ 4 teeth with >1 site with PD >4 mm and CAL> 3mm 3. ≥ 4 teeth with >1 site with PD >4 mm and CAL>2 mm and POB> 35% of sites 4. PD1(≥ 4 teeth with PD 4-5 mm and CALof 3-5mm at the	7 RCTs 2536 women Control 957 4 studies No active comparator for control group, but in one OHI received, one received OHI and prophylaxis and one received supragingival calculus removal	Primary : PTB (gestation time ≤ 37 weeks LBW (≤2500 gram) Combination of PTLBW , One time period for PTB assessed <37 wks Secondary outcomes Periodontal disease post treatment	Bottom line Not a well conducted review by Amstar standards Provides narrative review supporting MDT during pregnancy to prevent ABOs, but individual outcomes not supported. No comprehensive assessment of risk of bias, nor are we clear that there was a secure definition of ABO. But most studies had a secure definition of PD

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				same site), PD2(≥ 4 teeth with PD and CAL of 5-7mm at the same site); PD3(≥ 4 teeth with PD and CAL>7mm at the same site) 5. CAL >2 mm at >50% of examined sites ≥4mm PD at ≥1 site, and BOP≥50% of teeth			
(Kim et al., 2012) Scaling and root planning treatment for periodontitis to reduce preterm birth and low birth weight: a systematic review and meta-analysis of randomized controlled trails	Final search update was on September 19, 2011. MEDLINE from 1950 to September 2011 Cochrane Library from 1990 to September 2011 CINAHL Nursing data-base from 1980 to September 2011 University of Michigan School of Dentistry "Dentistry and Oral Sciences" database (EBSCO host) from 1990 to September	12 RCTs in countries (Australia, Brazil, Chile, Hungary, India, Iran and USA) 14 RCTs in 11 RCTS included in Met analysis (Jeffcoat et al.2011 excluded) 5935 pregnant women For all 11 studies in meta-analysis intervention 2875 women included. Study intervention was defined as:	RCTs that reported PTB risk <37 weeks (except of Jeffcoat <35) reported PTB outcomes Periodontal disease in pregnant women with singleton pregnancies in any trimester PD ≥4mm or CAL ≥2mm for ≥1 site) Treated with SRP Outcome of preterm birth	Outcome of preterm birth <37 weeks All RCTs reported an 'adequate' method for the assessment of periodontal conditions, except for the study by Macones et al. (2010), which was classified as inadequate level-1 (diagnosis based on partial-mouth recording). CaT defx based on 1) Analyses by PD and CAL definition 2) Analyses by CAL alone 3) Analyses by PD alone	12 studies but only 11 included in meta-analysis (Jeffcoat et al.2011 excluded) 2992 women in TR group and 2,943 in control group from 12 studies	Primary: PTB< 37 weeks And/or secondary: LBW< 2500g. And/or mean birth weight Two time periods for PTB assessed <37 wks <35 wks	Only two out of 11 trials (18.2%) were considered to be at low risk of bias, while the remainder (81.8%) were considered at unclear. (Oliveria 2010 was not included in this assessment) AMSTAR 9/11 (no exclusion study table and no conflict of interest) The results indicate statistically significant effect in reducing risk of preterm birth for SRP in pregnant women with periodontitis for

	2011. No limitations in the search were used. Hand search and of the references were included. ClinicalTrials.gov and abstracts of scientific conferences were searched for unpublished trails.	1) Including SRP during the pregnancy 2) Control groups could not receive periodontitis treatment before delivery. 3) Control and intervention groups could both receive routine dental treatment and education. 4) Studies followed all participants through delivery or loss of pregnancy. 5) Infant gestational age was a required outcome	<37 weeks Study intervention was defined as including SRP during the pregnancy Control groups could not receive periodontitis treatment before delivery. Control and intervention groups could both receive routine dental treatment and education. Studies followed all participants through delivery or loss of pregnancy. Infant gestational age was a required outcome	Out of 12 studies seven used a secure definition of periodontal disease and remaining 5 used Insecure definition based on Nabili et al 2013 Periodontal disease in pregnant women with singleton pregnancies in any trimester PD ≥4mm or CAL ≥2mm for ≥1 site Periodontitis definitions varied according to: affected sites (≥1to ≥20 teeth), PD (not assessed to ≥5 mm), And CAL (not assessed to ≥5mm). Two studies additionally used criteria for bleeding on probing(BOP) (35%33 or 50%38 of sites assessed)			groups with high risks of preterm birth only. Heterogeneity was high for PTB, LBW, Mean birth weight , LBW as high risk group Risk of bias assessment didn't include Oliveira 2010

(George et al., 2011) Periodontal treatment during pregnancy and birth outcomes: a meta-analysis of randomised trials.	MEDLINE(1966–present) EMBASE (1980–present) CINAHL (1982–present) and, the Cochrane library up to and including 2010 Issue 10. Manual search of the references of all possible books and journals was performed. Unpublished trials were also sought from experts in the field. Relevant conference proceedings and grey literature were reviewed Internet searching was conducted.	10 RCTs in countries (Australia, Chile, Hungary, India, Iran, USA) The 10 studies included in meta-analysis 5645 pregnant women Intervention: RCTs compared periodontal treatment with scaling and/or root planning and/or oral hygiene education versus no treatment in pregnant women with periodontitis.	Included all published and ongoing RCTs compared pregnancy outcomes for pregnant women who received periodontal treatment during the prenatal period RCTs considered eligible regardless of the severity of the periodontal disease. All single-arm studies, non-randomised and pseudo-randomised trials, and trials published in meeting abstracts were excluded from the review.	Including periodontal disease (periodontitis or gingivitis) Included studies that evaluated periodontal disease after treatment by periodontal pocket depth (PPD), CAL and BOP No concerned about the severity of periodontal disease and included RCTs assessed gingivitis and periodontitis dFx varied including 1. ≥4 teeth with ≥1 site with PD ≥ 4 mm and CAL ≥3mm 2. >3 sites with CAL≥ 3 mm 3. BOP ≥ 25% of sites and no sites with CAL ≥ 2mm 4. ≥4 teeth with PD ≥ 4mm and CAL ≥ 2 mm and BOP ≥ 35% of tooth sites 5. ≥2 sites with PD ≥ 5mm and CAL 1–2 mm at ≥1 site with PD≥ 5mm 6. ≥2 mm CAL at ≥ 50% of examined sites 7. PD≥ 4mm at≥12 probing sites 8. ≥3 sites≥3 mm CAL 9. PD ≥ 4mm at ≥1 site	10 studies included in meta analysis 5496 pregnant women IG: 2888 CG:2608	Primary outcome was PTB (PTB < 37 weeks), LBW (LBW < 2500 g) and stillbirth. Secondary outcome included periodontal measures: • Bleeding on probing (BOP) • Probing depth (PD) • Clinical attachment loss (CAL)	NO Grade Score was reported Publication bias did not reported Authors used the Joanna Briggs Quality Assessment tool for experimental studies to assess the studies' quality The cumulative evidence suggests that periodontal treatment during pregnancy may reduce preterm birth and low birth weight incidence Moderate heterogeneity was found between the studies for two of the primary outcomes, the results show that periodontal treatment involving scaling and root planning can reduce the incidence of PTBs and LBW

				and BOP ≥ 50%			
(Polyzos et al., 2010) Obstetric outcomes after treatment of periodontal disease during pregnancy: systematic review and meta-analysis**.**	Up to July 2010 Cochrane Central Trials Registry, ISI Web of Science, Medline, and reference lists of relevant studies to July 2010; hand searches in key journals.	11 RCTs in countries (Australia, Brazil, Chile, India, Iran and USA) The 11 RCTS included in meta analysis (analysis included high quality or low quality trails) 6558 pregnant women(I:3438 and C: 3120) Interventions: 1) Scaling and root planing (SRP) versus no treatment or prophylaxis	Eligible studies included patients with documented periodontal disease (periodontitis or gingivitis), as defined by the International Workshop for a Classification of Periodontal Diseases and Conditions. All trials were eligible regardless of the depth and the severity of periodontal disease. Further classification of the severity of periodontal disease based on the conclusions of the working group by the Centres for Disease Control and Prevention and the American Association of Periodontology	periodontitis or gingivitis defined by the International Workshop for a Classification of Periodontal Diseases and Conditions. Classification of the severity of periodontal disease based on the conclusions of the working group by the Centres for Disease Control and Prevention and the American Association of Periodontology in 2003. Moderate and severe periodontitis were defined according to the classification, in terms of: probing depth and clinical attachment loss. CaT defx based on 1. probing depth 2. CAL dFx including: Gingivitis(BOP≥25%of sites and no sites with CAL>2mm) Mild periodontitis ≥3 sites with CAL≥3mm. ≥12 probing sites with PD≥4. 4 or more teeth with	11 RCTS included in meta analysis (analysis included high quality or low quality trails) 6558 pregnant women(I:3438 and C: 3120)	Primary outcome: preterm births (<37 weeks). Secondary outcomes: low birth-weight infants(< 2500g), spontaneous abortions/stillbirths, and The overall rate of adverse outcomes of pregnancy (PTB and stillbirth). The rate of spontaneous preterm births, (<35 weeks) and very low birth weight (<1500 g).	One study included gingivitis(Lopez 2005)and one moderate periodontitis (Offenbacher 2006) 9studies included mild periodontitis. Grade score did not recorded. Only five trials with a low risk of bias. One study had an unclear risk of bias, whereas the five remaining studies had a high risk of bias. The authors conclusion: Treatment of periodontitis with scaling and root planing in pregnant women has no significant effect on the incidence of preterm birth. treatment does not seem to have a significant effect on the incidence of low birth weight or spontaneous abortions/stillbirths or on the overall

			in 2003 were adopted. RCTs included patients with threatened preterm delivery who received tocolyticagents, non-randomised trials, and pseudo-randomised trials were excluded.	PD≥4mm and CAL≥2mm and BOP>35%of sites. ≥4 teeth with≥1sites with PD≥4mm and CAL≥3mm. CAL≥2mmat ≥50% of examined Sites. ≥12 probing sites with PD≥4. CAL≥3mmon ≥3 teeth. ≥1 sites with PD≥4mmand CAL≥3mm. Moderate periodontitis ≥2 sites with PD≥5mmand CAL 1-2mmat ≥1 sites with PD≥5mm.			rate of adverse outcomes of pregnancy
(Fogacci et al., 2011) The effect of periodontal therapy on preterm low birth weight: a meta-analysis	searched to May 2010 Pub Med, Bireme, LILACS/VHL (Virtual Health Library), and Cochrane database no language restriction	10 RCTs included 5450 women	clinical trials, randomized clinical trials, or controlled clinical trials that considered the treatment of destructive periodontal disease or periodontitis as the intervention of interest and preterm birth, LBW, or both preterm birth and LBW as the outcome	Only articles that used probing depth and attachment loss measurements as the criteria for the periodontitis definition. Articles that used only attachment loss for the definition of maternal periodontal disease were excluded. Randomized clinical trials that used probing depth as the unique parameter for periodontal disease definition were excluded. Definition varied : CAL ≥3 mm on at	14 clinical studies. Ten articles met the inclusion criteria for preterm birth 4r for LBW. 5 meta analyses on preterm birth were performed according to different criteria: 1) use of probing depth and attachment loss for periodontitis definition,	the first analysis would include only those articles that used probing depth and attachment loss measurements as the criteria for the periodontitis definition. Second analysis performed for randomized clinical trials that controlled for the confounding effect of multiparty Third analysis, only randomized clinical trials that adjusted for previous preterm birth were	The quality assessment of selected studies was performed according to the Consolidated Standards of Reporting Trials (CONSORT) statement28 and the Cochrane "risk of bias" table. studies were excluded if they did not mention information about the confounder or if they did not find a

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						relative risk	considered.	significant
					least 3 teeth.(SP) Participants who met this requirement were eligible for random assignment. Moderate-severe periodontal disease was defined as CAl ≥ 5 mm on at	relative risk 5450 women I:2818 C:2632	considered. The fourth criterion included randomized clinical trials that controlled for genitourinary infection, an important risk factor for preterm birth. The fifth analysis included RCTs that fulfilled all the previous criteria: probing depth and attachment loss measurements as the criteria for the periodontitis definition and control for the following confounders: multiparty, previous preterm birth, and genitourinary infection.	significant difference between control and treatment groups for that variable, with a P>.05 but <.20, and did not carry out a multivariate analysis Homogeneity among studies was tested by Cochran's Q test All participants of the intervention group received instructions for dental plaque control, supragingival scaling, scaling, and root planning. Other procedures such as dental prophylaxis and 0.12% chlorhexidine mouth rinse twice daily were offered to the intervention group in some studies. For the control group, the majority of studies did not offer
					Least 3 teeth. PD ≥4 mm at 12 or more probing sites in fully erupted teeth (ISP) At least 3 periodontal sites with ≥3 mm of CAL.(SP) PD ≥ 4 mm at one site or more, and BOP for 50% or more (ISP) At least 20 completely erupted teeth, excluding the third molars; and subjects with 2 mm or more CAL at 50% of examined sites or more(ISP) 2 or more sites measuring at least 5 mm PD plus CAL of 1to2mm at one or more sites with PD of at least 5 mm(ISP) ≥4 teeth with			

				a PD of ≥4mm and CAL≥2 mm, BOP at 35% or more of tooth sites(SP) ≥4 teeth with at least one site with PD of at least 4 mm and CAL of 3 mm or more(SP) At least three sites with CAL of 3 mm or more(SP) Four or more teeth with one or more sites with PD of at least 4 mm and with CAL of at least 3 mm at the same site(SP)			periodontal treatment at all, but dental plaque instruction, prophylaxis, and supragingival scaling were performed in a few of the studies.
(Uppal et al., 2010) The effectiveness of periodontal disease treatment during pregnancy in reducing the risk of experiencing preterm birth and low birth weight: a meta-analysis	two database aggregators OvidSP (12 databases) and EBSCOhost (11 databases) Manually scanning the reference lists of the relevant articles and published systematic reviews and meta-analyses.

Not reported gray literatures Or date of search | 11 RCTs were eligible but one was excluded ((Sadatmansouri et al., 2006) because in a previous meta-analysis which was included and had a low weight in that meta-analysis (2 percent). 10 RCTs included in meta analysis with 6,142 women

Intervention: Scaling and root planing with polishing) or a control arm no treatment or only prophylaxis. In studies with a separate arm for antibiotic treatment | studies in which investigators randomly assigned pregnant women with periodontal disease to a treatment arm (scaling and root planing with polishing) or a control arm (no treatment or only prophylaxis).

In studies with a separate arm for antibiotic treatment alone or in combination | Periodontal disease was categorized based on severity as follows:

mild to moderate: bleeding on probing may be present, CAL of zero to 2 to 5mm at more than three sites (considering each tooth as six sites)

moderate to severe: BOP is present, PD of 4 mm or more are measured at more than one site (one to 12 sites) with or without measurement of CAL at more than one site TR Definition varied PD4 (> 1 site)Cal 3 (> 2 sits)BOP in 6 sites (SP)

CAL≥3 (>3 SITES)(SP) | 10 RCTs included in meta analysis with 6,142 women I: 3199 C:2943 | PTB LBW covariates (smoking, education, previous PTB and gestational age at the start of treatment) | Only 6 studies compared the effectiveness of periodontal disease treatment before and after treatment found significant heterogeneity in the pooled results (I2 Heterogeneity and subgroup = 0.758; Cochran Q = 37.208; P < .001) (Figure 2). To explain the reason for this high level of heterogeneity, we performed several subgroup analyses. However, except for the quality of |

		alone or in combination with any other dental treatment strategies included only the data from the treatment and control arms.	with any other dental treatment strategies, we included only the data from the treatment and control arms.	BOP in 6 sites.(ISP) PD 5mm (> 2 site)CAL 1-2mm(> 1 sits) and BOP.(SP) PD4mm (> 4site) CAL> 2 mm, and BOP. (SP) CAL >2mm. (ISP) PD≥ 4mm in >12 sites and BOP in 4 sites PD≥ 4mm in >12 sites and BOP. (ISP) CAL ≥ 3-5mm in 6 sites.(SP)			the study, none of the variables accounted for the high level of heterogeneity. Two studies had unclear overall bias, and four studies had low bias.
(Rosa et al., 2012) **Periodontal disease treatment and risk of preterm birth: a systematic review and meta-analysis.**	between 1980 and March 2012 MEDLINE, Embase, BIOSIS, LILACS, Scopus, the Cochrane Central Register of Controlled Trials, the ISI Web of Science and IBECS. Manually scanned the reference lists of all identified articles. No restrictions were placed on the language of the publications.	Studies had to examine specific treatments for periodontal disease during pregnancy, compare the results of usual care ("intensified") and specific treatment ("less intensified") and report on at least one outcome of interest (PT, LBW, and/or PTLBW). Included only RCTs with the following criteria: women over the age of 18 with a single gestation at 22 weeks or less. Had gingival inflammation with ≥ 25% of sites BOP with CAL > 2mm. Exclusion criteria:	13 RCTs (Australia, Brazil, Chile, India, Iran and USA) 6,988 women (I: 3,576 and C: 3,412).	gingival inflammation with ≥ 25% of sites BOP with CAL > 2mm. periodontitis or gingivitis were defined as the International Workshop for Classification of Periodontal Diseases and Conditions in 1999. All trials were eligible regardless of the depth and the severity of the periodontal disease. classification of severity of periodontal disease based on the conclusions of the 2003 working group of the Centres for Disease Control and Prevention and the American Academy of Periodontology. moderate and severe periodontitis defind in terms of PD and CAL .	PT (< 37 weeks), LBW (<2,500g).	13 RCTs 6,988 women (I: 3,576 C: 3,412)	The PRISMA guidelines were followed for the meta-analysis of randomized trial The authors reported Sadatmansouri as study from Iraq instead of Iran Bleeding index treatment group (%): 81.54 and Bleeding index control group (%): 83.63 was the definition of periodontal disease of Tarannum 2007as ROSA reported which is not consistent with Uppal who reported that PD

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		having fewer than 18 natural teeth., indication of prophylactic antibiotics for invasive procedures, occurrence of diabetes prior to pregnancy, and the intention of giving birth at a hospital outside this study.		Definition of periodontal disease 4 or more teeth with PD > 4mm. women separated into 2 categories: < 2.5mm and > 2.5mm depth(IS) 4 or more teeth with 1 or more sites with PD > 4mm (IS) gingivitis in ≥ 25% of sites with BOP and no sites with CAL > 2mm(IS) ≥ 4 teeth with PD≥2mm and BOP ≥ 35% of tooth sites.(IS) ≥ 2 sites with PD≥5mm and CALof 1 to 2mm at one or more depth ≥ 5mm(SP) ≥ 4 teeth with ≥ 1 site with PD ≥ 4mm. Bleeding index treatment group (%): 81.54 and Bleeding index control group (%): 83.63(IS) PD ≥ 4mm at ≥ 12 probing sites in fully erupted teeth(IS) ≥ 2 sites with > 5mm probing depths CAL ≥ 3mm in ≥ 3 teeth(SP) ≥ 4 teeth with ≥ 1 site with probing depth > 4mm(IS)			was assessed by CAL >2 (should check) Inter-rater agreement of assessments of methodological quality ranged from 0.58 to 1.00 for the eight categories, with an overall agreement of 0.75. perfect agreement was achieved in the areas of adequate sequence generation and allocation concealment

				4 or more teeth with one or more sites with PD≥ 4mm (IS)			
				Full-mouth, excluding third molars, six sites per tooth, periodontal examination was carried out. Unclear how periodontal disease was defined (Weidlich 2012)(IS)			
(Shah et al., 2013) Effect of nonsurgical periodontal therapy during gestation period on adverse pregnancy outcome: a systematic review	From January 2000 to October 2012. MEDLINE, CINAHL and EMBASE Limits used were humans and English language. Hand searched references.	13 RCTs (Australia, Brazil, Chile, India, Iran and USA) 7195 women Intervention given to test group included SRP, CHX (chlorhexidine) with or without maintenance therapy till delivery while control group was not given any active periodontal treatment,	Studies Which measured incidence of either PT, LBW or both were included.	Periodontal status was defined by probing depth, loss of attachment and/or bleeding on probing. Definition reported: ≥4mm PD at ≥4 teeth, ≥3mm CAL at same site (SP) ≥3 site with CAL ≥3mm(SP) ≥25% of sites with BOP and no sites with CAL>2mm.(IS) PD ≥4mm and CAL ≥2mm, and BOP at ≥35% of tooth sites.(IS) ≥4mm PD at ≥4 teeth ≥3mm CAL at same site(SP) P1=≥4 teeth PD of 4 to 5mm and CAL of 3 to 5mm at same site(SP) P2=≥4 teeth with PD and CALof 5 to 7mm at the same site;(SP) P3=≥4 teeth with PD and	13 RCTs 7195 women I: 3850 C:3345	PTB LBW PTLBW	Could not pool data for meta analysis because of heterogeneity due to dissimilar severity of periodontal diseases, different treatment protocol and varying time of treatment across studies. Five studies had low risk of bias. Conclusive results could not be obtained for incidence of PTL or LBW because of heterogeneity in results due to various reasons, but all studies which assessed PTL and LBW combined showed significant

				CAL>7mm at the same site(SP) ≥2mm CAL at ≥50% of examined sites.(IS) ≥4mm PD at least at one site(IS) BOP for ≥50% of teeth. Three periodontal sites with at least 3mm of CAL(SP) PD ≥4mm at ≥12 sites(IS) CAL≥3mm on ≥3 teeth, Moderate CAL of ≥5mm on≥3 teeth(SP) 4 teeth with one or more sites with PD ≥4mm and CAL ≥3m(SP)			difference in incidence of same in group which received non surgical periodontal treatment. Only two studies were identified to be having high risk of bias. None of the study included in this systematic review reported any adverse effect on participants after non surgical periodontal therapy.
(Michalowicz et al., 2013) Should consider as secondary analysis They only have one study and all analysis based on other SR	From January 2011 through July 2012 to identify RCTs published since the latest reviews. PubMed, ISI Web of Science and the Cochrane Library did not search non-peer reviewed materials (e.g. government reports or	Only one RCT(Brazil) 303 women Randomization was stratified on Smoking. Intervention All women, regardless of their periodontal status, received comprehensive non-surgical treatment (test group: oral hygiene instruction, scaling and root planing, and at least monthly follow-up visits) or supragingival scaling	RCTs comparing periodontal treatment to either no treatment, oral hygiene instruction alone or superficial debridement (prophylaxis). focused on preterm birth and low birth weight as trial outcomes and considered pre-eclampsia as a pregnancy	BOP No other information reported concerning periodontal examination (except improving periodontal status such as BOP in post intervention)			do not report neonatal outcomes because many of these (e.g. neonatal intensive care admissions, neonatal deaths, AP-GAR scores) are strongly correlated with gestational age at delivery or birth weight and were not reported in most RCTs.

	unpublished theses or dissertations).	and oral hygiene instruction (control group).	complication rather than an outcome.				

Table B: AMSTAR rating for each systematic review

Amstar Criteria	Author date Oliviera et al 2010	Author date Chambrone et al 2011	Author date (Kim et al., 2012)	Author date (George et al., 2011)	Author date Polyzos et al., 2010)	Author date (Fogacci et al., 2011)	Author date (Uppal et al., 2010)	Author date (Rosa et al., 2012)	Author date (Shah et al., 2013)	Author date
A priori design	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	
Duplicate selection & extraction	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Comprehensive literature search performed	No- only one database searched from 1998 Only English studies	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Was the status of publication used as a quality criterion?	No grey literature did not reviewed	Yes	Yes	Yes	Yes	Yes	NO grey literature did not reviewed	NO, grey literature did not reviewed	NO, grey literature did not reviewed	
Was a list of studies included and excluded provided	Yes	Yes, though one Moreu 2005 not fully referenced	NO(only provided included studies but not excluded)	Yes	Only included studies	Yes (exclusion criteria reported)	Only included studies	Only included studies	Only included studies	
Where the characteristics of the included studies	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	

provided?										
Was the scientific quality of the included studies used assessed and documented	**No,** there was no formal structured assessment	**Yes,** the Cochrane ROB tool an overall assessment given	**Yes,** the Cochrane ROB tool an overall assessment	**Yes, The Joanna Briggs Quality Assessment tool for experimental studies was used**	**Yes,** the Cochrane ROB tool an overall assessment	Yes	**Yes**	**Yes**	**Yes**	
Quality used appropriately in forming conclusions	**No**	**Yes**	**Yes**	**Yes**	**Yes**	Yes	**Yes**	**Yes**	**Yes**	
Methods used to combine studies appropriate	**Not clear**	**Yes** it was decided to enter the trials into meta-analyses in subgroups conforming to the PD definition,	**Yes,** it was decided to enter the trials into meta-analyses in subgroups conforming the PTB definitions (<37,PTB <35 weeks and LBW definition),	**Yes** it was decided to enter the trials into meta-analyses in subgroups Previous PTB/LBW (%): comparison of studies with ☐5% and >5% of participants with history of PTB/LBW; • <12 years of education: comparison of studies with ≥50% and >50% of participants with education <12 years.	**Yes,** it was decided to enter the trials into meta-analyses in subgroups based on studies' quality.	Yes it was decided to enter the trials into meta-analyses in subgroups	**Yes** it was decided to enter the trials into meta-analyses in subgroups	**Yes,** included meta analysis no subgroup analysis provided	**no (meta analysis did not conducted due to high hetroginity but OR was reported for PT LBW and PTLBW**	

Publication bias assessed	No	Yes	Yes	No	Yes	Author stated that publication bias tested for using the rank correlation of Begg's test33 and the Egger test.34	No	Yes	No	
Conflict of interest stated	No	Yes	No	Yes	Yes	No	No	No	yes	
Total score (out of a maximum of 11)	2/11	11/11	9/11	10/11	10/11	10/11	7/11	7/11	6/11	

Table C: Results by individual review

Title of Review/Author/Date	Outcome	No of studies (no of women)	Results	Comment
Chambrone et a 2011 Evidence grade associating periodontitis with preterm birth and/or low birth weight: II. A systematic review of randomized trials evaluating the effects of periodontal treatment	PTB 8/14 studies suggest MPDT may reduce risk of PTB. Metaanalyses PTB<37mm RR 0.88 (0.72, 1.09) I^2=61% p=0.25 PD defined by CAL&PD RR 0.74(0.45,1.19) I^2=52% p=0.21 PD defined by CAL alone RR 0.90(0.67, 1.22) i^2=76% p=0.51 PD defined by PPD alone RR 1.03 (0.71, 1.50) I^2=NA p=0.86 Metaanalyses PTB<35mm RR 0.98(0.73,1.31) I^2=42% p=0.90 PD defined by CAL&PD RR 0.84(0.49,1.46) I^2=NA p=0.54 PD defined by CAL alone RR 1.02(0.70,1.49) I^2=56% p=0.90 To add PTB , 32 weeks To add PTB using only	14 studies and 5975 women: I=3039; C=2935 11 studies and 5752 women: I=2873; C=2879 5 studies and 1,466 women: I=728 ; C=738 5 studies and 3,213 women: I=1607 ; C=1606 1 study and 1,073 women: I=538 ; C=535 5 studies and 3,845 women: I=1923 ; C=1922 1 study and 812 women: I=407 ; C=405 4 studies and 3,033 studies I=1516 ; C=1517	Conflicting evidence was found when the results were evaluated in terms of studies' individual outcomes, but 2/3 of the included trials found that PD treatment could decrease the number of adverse outcomes. On the other hand, all meta-analyses failed to demonstrate such an association). Significant heterogeneity was also observed for comparisons between PTB <37 months gestation by three categories of PD: PPD &CAL; PPD alone and CAL alone. Therefore, a metaregression analysis was performed for comparison in order to estimate whether heterogeneity could be explained by the criteria used to define PD, but no significant differences were found. Moreover, sensitivity analysis excluding studies identified as non-homogeneous did not lead to statistically significant differences	Jeffcoat 2003 described as blinded. Newnham 2009 allocation concealment described as inadequate. They included Lopez 2002 who had 18% in treatment group with aggressive PD (they needed metroniadozole) possible bias. Heterogeneity high and used randoms effects and regression to counteract. Influence of Smoking not assessed in all trials Publication bias not assessed Lack of other prognostic factors No details on success of MPDT except Jeffcoat et al 2009 who found 'intractable PD greater risk of ABO No gold standard for definition of PD in individual studies High quality studies suggest no advantage for PTB prevention regardless of three time frames used and regardless of definition of PD used

	studies at low risk of bias (5) Also add a new row for LBW		between the test and the control groups. Also, meta-analyses excluding studies considered to be at an unclear/high risk of bias showed the same result.	
DeOliviera 2010 Effect of periodontal treatment on the incidence of preterm delivery: a systematic review.		7 RCTs in 6 countries (Brazil, Chile, Hungary, India, Iran and USA) 2456 pregnant women 1= 1530 ; C=926	Most of the RCts concluded that non-surgical periodontal treatment reduces the PTB and LBW rate(PTB reduction was between 0.8% to 28%.01; LBW reduction was from 0.44%to 33% and PTLBW reduction from 4.57% to 71.5%	No rating of quality of studies, but authors suggest papers suggest a benefit to PTB, however when broken down by individual outcome majority of studies do not support This does not meet quality criteria of Amstar. No meta analyses because of heterogeneity attributed to sample size, different social characteristics, diffferning defx of PD. Originally metaanalyses were planned.

(Kim et al., 2012) Scaling and root planning treatment for periodontitis to reduce preterm birth and low birth weight: a systematic review and meta-analysis of randomized controlled trails	PTB Meta-analyses: Primary outcome PTB <37 weeks(11 studies) RR 0.81 (95% CI = 0.64, 1.02) I^2=59%P = 0.07 Secondary outcomes PTB <35 weeks(3 studies) RR 0.89(95%CI=0.74, 1.09) I^2=0% P = 0.29 LBW<2,500 g(8 Studies) RR 0.72 (95% CI = 0.48, 1.07) I^2=75% P = 0.11 . mean birth weight (6 studies) mean difference =68.29 g (95% CI =-22.11, 158.69) I^2=80% P = 0.14 Subgroup analysis subgroup analysis for PT high risk group <37 (4 studies RR 0.66 (95% CI = 0.54, 0.80; P <0.0001 I 2 =3%; 7 studies with more moderate risks of prematurity RR 0.97 (95% CI = 0.75,1.24; P = 0.79) I 2 = 37% LBW< 2,500 g high risk(3	12 studies and 5935 women: I=2992; C=2943 11 studies and 5655 women: I=2875; C=2780 3studies and 2896 women: I=1449 ; C=1447 8 studies and 4136 women: I=2057 ; C=2079 6 study and 3921 women: I=1948 ; C=1973 4 studies and 555 women: I=280 ; C=275 7 study and 5100 women: I=2595 ; C=2505 3 studies and 488 studies	The results indicates statistically significant effect in reducing risk of preterm birth for SRP in pregnant women with periodontitis for groups with high risks of preterm birth only.	Heterogeneity was high for PTB, LBW, Mean birth weight , LBW as high risk group Risk of bias assessment didn't include Oliveira 2010 The results of SR did not stated The studies included were the same studies included in Chambrone's SR. Included PTB<37 and 35

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	studies) RR=0.48,CI=0.30,0.78),P=0.003;I2=75% moderate risk: RR= 1.08, CI=0.83, 1.42) and P = 0.02) I2=81% High risk group(2 studies) Mean differences 282,15 CI=-51.71, 616.01) and P = 0.56) I2=37% moderate risk:(4 studies) Mean differences -12.40 CI=-69.10,44.30) and P = 0.12) I2=48%	I=245 ; C=243 5 studies and 3648 studies I=1812; C=1836 2 studies and 263 studies I=132 ; C=131 4 studies and 8358 studies I=1816; C=1842		
(George et al., 2011) Periodontal treatment during pregnancy and birth outcomes: a meta-analysis of randomised trials.	A total of 316 (11.1%) and 341 (13.2%) PTBs were observed in the intervention and control group, 6 RCTs reported higher number of PTB in the control group compared with the intervention group. spontaneous abortion/stillbirths (8 trials) 2 studies were excluded because no stillbirth cases reported (Jeffcoat et al,2003, Lopez et. al., 2005)	10 RCTs and 5496 women I=2888; C=2608	The cumulative evidence suggests that periodontal treatment during pregnancy may reduce preterm birth and low birth weight incidence	moderate heterogeneity was found between the studies for two of the primary outcomes, the results show that periodontal treatment involving scaling and root planning can reduce the incidence of PTBs and LBW infants. PDTR reduce ABO Might be: 1.treatment can reduce the concentration of oral

	Meta analysis PTB (10 studies) OR 0.65 (95% CI, 0.45–0.93; = 66%) I^2=66%	10 RCTs and 5496 women I=2888; C=2608		bacteria thereby minimising the risk of bacteraemia and seeding of the genital tract with pathogens that can cause infection
	Low birth weight (7 studies) OR 0.53; 95% CI, 0.31–0.92; P = 0.02) I^2=69%	7 RCTs and 4105 women I=2192; C=1913		2. the reduction in oral bacteria concentration will reduce the production of inflammatory mediators such as cytokines and prostaglandins, which are known to be associated with the onset of labour and PTB.
	spontaneous abortion/stillbirths OR 0.71; 95% CI, 0.43–1.16; P = 0.17, I^2=14%	8 RCTs and 5070 women I=2674; C=2396		
	spontaneous abortion/stillbirths only a large sample size (>500) OR 0.55; CI 0.31–0.99; P = 0.05) I^2= 19%	8 RCTs and 4506 women I=2397; C=2109		The analysis showed that periodontal treatment was more effective in reducing PTB in patients with less severe periodontal disease (defined as PD < 4 mm).
	Subgroup analysis Previous PTB or LBW Low rate (<5% of participants)(2 studies) OR 0.35 (0.17–0.70) P=0.003)	2 RCTs and 329 women I=164; C=165		Although gingivitis is the most common oral disease in pregnancy affecting up to 75% women11,48 most of the relevant trials have only targeted pregnant women with periodontitis.
	High rate (>5% of participants) OR 0.87 (0.64–1.44) P=0.38	7 RCTs and 4975 women I=2623; C=2352		
	Level of education Low level (>50% participants with education <12 years) OR0.81 (0.56–1.16) P=0.25	6 RCTs and 4656 women I=2473; C= 2183		
		2 RCTs and 402 women I=191; C= 211		
	High rate(≤50% participants			

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	with education <12 years OR 0.47 (0.19–1.15) P=0.10	4 RCTs and 2974 women I=1480; C= 1494		
	Severity of Periodontal disease PD>4mm in >20% of examined sites OR 1.02 (0.71–1.46) P=0.92 PD > 4mm in ≤20% of examined sites OR 0.49 (0.28–0.87) P=0.01	3 RCTs and 923women I=605; C= 318 5 RCTs and 2064 women I=1176; C= 888 2 RCTs and 402 women I=191; C= 211		
	LBW according of education level Low level (>50% participants with education <12 years) OR 0.75 (0.46–1.23) P= 0.26 High rate(≤50% participants with education <12 years OR 0.19 (0.03–1.11) P=0.07			
(Polyzos et al., 2010) Obstetric outcomes after treatment of periodontal disease during pregnancy: systematic review and meta-analysis.	PTB(<37 weeks) OR 0.93 (0.79 to 1.10) P=0.39, I^2=61% Low quality OR 0.52 (0.38 to 0.72) P=0.001, , I^2=0% High quality OR 1.15 (0.95 to 1.40) P=0.15, I^2=1% LBW(<2500g.)	11 RCTs and 6314 women I= 3299; C=3015 6 RCTs and 1721 women I= 996; C=725 5 RCTs and 4593 women I= 2303; C=2290 8 RCTs and 4929 women	Treatment of periodontitis with scaling and root planing in pregnant women has no significant effect on the incidence of preterm birth. Furthermore, treatment does not seem to have a significant effect on the incidence of low birthweight infants or spontaneous abortions/stillbirths or on the	Treatment of periodontal disease with scaling and root planing during pregnancy does not reduce the risk of pretermbirth and should not be routinely recommended as a measure to prevent pretermbirth Randomised trials of lowmethodological quality tend to overestimate the effect of treatment,

	OR 0.85 (0.70 to 1.04) P=0.11, I^2=65% Low quality OR 0.44 (0.30 to 0.66) P=0.001, I^2=16% High quality OR 1.07 (0.85 to 1.36) P= 0.55, I^2=11% Spontaneous abortion /stillbirth OR 0.84 (0.58 to 1.22) P=0.37, I^2=0% Low quality OR 1.00 (0.51 to 1.97) P= 1.00, I^2=0% High quality 0.79 (0.51 to 1.22) P= 0.28, I^2=35% Adverse pregnancy outcomes OR 0.90 (0.77 to 1.04) P= 0.15, I^2=62% Low quality OR 0.55 (0.41 to 0.73) P= 0.0001, I^2=12% High quality OR1.09 (0.91 to 1.30) P= 0.34, I^2=21% Secondary analysis Spontaneous preterm birth <37weeks OR 0.66 (0.37 to 1.17) P= 0.15, I^2=71%	I= 2603; C=32326 5 RCTs and 1655 women I= 961; C=694 8RCTs and 1655 women I= 1642; C=1632 11 RCTs and 6367 women I= 3320; C=3047 6 RCTs and 1756 women I= 1015; C=741 5 RCTs and 4611 women I= 2305; C=2306 11 RCTs and 6558 women I= 3438; C=3120 6 RCTs and 1840 women I= 1077; C=763 5 RCTs and 4718 women I= 2361; C=2357 5 RCTs and 2949 women I= 1608; C=1341	overall rate of adverse outcomes of pregnancy (pre-term births and spontaneous abortions/stillbirths).	whereas high quality trials provide strong evidence that no significant effect of treatment exists

	Low quality 0.38 (0.13 to 1.13) P= 0.08, I^2=75%	3 RCTs and 1436 women I= 847; C=589		
	High quality OR 1.05 (0.74 to 1.50) P= 0.77, I^2=0%	2 RCTs and 1513 women I= 761; C=752		
	<u>Preterm birth <35 weeks</u> High quality OR 1.22 (0.88 to 1.68) P= 0.23, I^2=38% <u>Low birth weight <1500 g</u> <u>High quality</u> OR 0.99 (0.61 to 1.60) P=0.97, I^2=49%	4 RCTs and 3520 women I= 1765; C=1755 3 RCTs and 3274 women I= 1642; C=1632		
(Fogacci et al., 2011) The effect of periodontal therapy on preterm low birth weight: a meta-analysis	<u>Preterm</u> studies used both pocket depth and attachment loss as the criteria to define Periodontitis. RR 0.58 (0.29–1.12)P= 0.86, controlled for multiparity. RR 0.92 (0.72–1.17)P=.009 studies controlled for previous preterm birth RR 0.75 (0.51–1.10)P=.065 studies controlled for previous genitourinary infections. RR 0.75 (0.57–1.05) P=.083 Studies used both pocket depth and attachment loss as the criteria to define	4 RCts (number of women is not reported) 8 RCts (number of women is not reported) 7 RCts (number of women is not reported) 6 RCts (number of women is not reported) 3 RCts (number of women is not reported)	In all meta-analyses, the effect of periodontal treatment on preterm birth and LBW was not statistically significant. second preterm birth meta-analyses, for mul-tiparity control found a significant hetero-geneity among studies (P=009). A meta-regression was performed to identify which factors could explain the lack of homogeneity. Differences in the control for confounders smoking and alcohol consumption explained the heterogeneity (P=.03). In contrast, different methods in the assessment of	Results of this meta-analysis do not sup-port the hypothesis that periodontal therapy reduces No evidence of heterogeneity was detected in the majority of preterm birth and LBW meta-analyses there was no evidence of publication bias (P of bias >.05) total number of women=5450(I: 2818 C: 2632)

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	periodontitis and controlled for multiparity, previous preterm birth, and genitourinary infections. 0.63 (0.32–1.22) P=078 LBW studies controlled for multiparity. RR 1.03 (0.76–1.40)P= .144 studies controlled for previous preterm birth RR 0.92 (0.66–1.30) P=.214 studies used both pocket depth and attachment loss as the criteria to define periodontitis and controlled for multiparity, previous preterm birth, andand genitourinary infections. RR 0.52 (0.10–2.60)P=.102	4 RCts (number of women is not reported) 3 RCts (number of women is not reported) 2 RCts (number of women is not reported)	educational level (P=.83) and in the classification of periodontal disease (P=.25) were not statistically associated with the heterogeneity.	
(Uppal et al., 2010) The effectiveness of periodontal disease treatment during pregnancy in reducing the risk of experiencing preterm birth and low birth weight: a meta-analysis	PTB (>37weeks) OR 0.589 (0.396-0.875) P=.001, I^2=0.758 LBW(>2500g) OR 0.717 (0.440-1.169) P=.001, I^2= 0.799 Subgroub analysis PTB ased on bias assessment Unclear OR 0.302(0.154-0.594) P=.414, I^2=0.00 High OR 0.309(0.197-0.484) P=.809, I^2=0.00	10 RCTS and 6,142 women I : 3199 C: 2943 8 RCTs and 5829 women I : 3041 C: 2788 2 RCTs and 1089 women I : 6831 C: 406 4RCTs and 681 women I : 330 C: 351	Pooled results from the selected RCTs did not support our hypothesis that there would be a reduction of PTB or LBW in women who were treated for periodontal disease during pregnancy. Pooled results from the high-quality RCTs with low bias do not support the continued treat-ment of periodontal disease in preg-nancy to prevent PTB,	It is possible that the timing of periodontal treatment during pregnancy may play a role in defining the outcomes found significant heterogeneity in the pooled results Sensitivity analysis was conducted and found no significant change in the estimated ORs in one-study-excluded sensitivity analysis of the low bias subgroup

		4 RCTs and 4372 women I : 2186 C: 2186	LBW or both.	
	Low OR 1.082 (0.891-1.314) P=.764, I^2=0.000 Overall OR .589 (0.396-.875) P=.001, I^2=0.758			more valid conclusion could be inferred from the pooled estimates of high-quality studies, which include about 70 percent of all participants and have no heterogeneity (I2=0)
	LBW based on bias assessment Unclear OR 0.671 (0.149-3.021) P=.025, I^2=NA High	1 RCT and 843 women I : 560 C: 283		The plausible biological explanation that the mechanism of PTB in periodontal disease is an increase in both circulating pathogens and inflammatory markers might appeal to clinicians' common sense and be difficult to avoid.
	OR 0.221 (0.129-.379) P=.952, I^2=0.000	3 RCT and 614 women I : 295 C: 319		
	Low OR 1.181 (0.960-1.452) P=.552, I^2=0.000 Overall OR 0.717 (0.440-1.169) P=.001, I^2=0.799	3 RCT and 4372 women I : 2186 C: 2186		scientists, dentists might have asked the wrong question about whether treating periodontal disease with scaling and root planning during pregnancy is effective in preventing PTB, LBW or both.
	Previous Preterm Birth (%) ≤ 10 OR 0.736 (0.452-1.200) P=.852, $I^{2\ high}$ > 10 0.682 (0.359-1.296)P.852 I^2_{high}	5 RCT and 4846 women 3 RCT and 1033 women		the timing of the intervention during pregnancy might play a role in the effectiveness of therapy (the timing of periodontal treatment during pregnancy and that treatment during pregnancy may be too late)
	Level of Education (50% of Population) ≤ 12 years 0.182 (0.040-0.827)P=.076, $I^{2\ high}$ > 12 years	7RCT and 5365 women		

	0.747 (0.512-1.090)P=.076 , $I^{2 \text{ high}}$	1 RCT and 351 women		
	Severity of Disease Mild to moderate 0.566 (0.291-1.100) P=.001 $I^{2 \text{ high}}$	5RCT and 3753 women		
	Moderate to severe 0.608 (0.356-1.039) P=.001 $I^{2 \text{ high}}$	5RCT and 2391 women		
	Diagnosis Gingivitis 0.242 (0.102-0.572) P=.037 $I^{2 \text{ high}}$	1 RCT and 843 women		
	Periodontitis Diagnosis 0.657 (0.449-0.962) P=.037 $I^{2 \text{ high}}$ Gestational Age at the Start of Treatment ≤ 14 weeks 0.596 (0.296-1.200) P=.861 $I^{2 \text{ high}}$	9 RCT and 5299 women 4 RCT and 2392 women		
	> 14 weeks 0.542 (0.248-1.186) P=.0.861 $I^{2 \text{ high}}$	3 RCT and 1141 women		
(Rosa et al., 2012) Periodontal disease treatment and risk of preterm birth: a systematic review and meta-analysis	PTB (< 37 weeks) RR 0.90(0.68-1.19) P =0.45; I2= 74% LBW (< 2,500g) (RR 0.92(0.71-1.20)P=0.55 I2: 56%	13 RCTs with 6988 women I: 3576 C: 3412 9 RCTs with 6484 women I: 3382 C: 3102	periodontal disease treatment during pregnancy had no significant effect on the overall rate of pre-term birth a weak association between periodontal disease treatment during pregnancy and decreases in LBW	Heterogeneity was confirmed by the χ² test, which produced a p-value of 0.00001 and 0.02 for preterm birth and low birth weigh
(Shah et al., 2013) Effect of nonsurgical	PLBW In IG incidence ranged	7 RCTS with 1962 women I:1229 C:733		

| periodontal therapy during gestation period on adverse pregnancy outcome: a systematic review | from 1.6% to 25.66% , in control group range was 4.15% to 79%.
All studies found statistically significant difference in incidence of PTLBW (p<.05) except two [
Three studies (LPez 2002, Lopez 2005 and Radnai 2009))OR 6.67(1.89–23.52), 3.26 (CI 1.56–6.83) and 4.6 (CI1.3–15.5), respectively, with a statistically significant p value.

<u>LBW</u>
 In IG incidence ranged from 0.55% to 26.3% while in C range was 1.15% to 53.9%.
Two trials (Tarannum 2007 and Radnai 2009) found significant difference in incidence of LBW in I and Cl groups.
 One study (Offenbacher 2009) had reported mean birth weight in both group which was not significantly different (P=0.117)
<u>PTB</u>
IG incidence ranged from 1.10% to 53.5% while in CG range was 5.65% to 74.4%.#
4studies found statistically significant difference in test and control group (P<05).
2 studies reported incidence | 9 RCTS with 5664 women
 I:2842   C:2822

11 RCTS with 6837 women
 I:3569   C:3268 | | |

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	of birth before 35 weeks, but significant difference was not found. One trial [also reported incidence of spontaneous abortion/stillbirth which was 5% in IG as compared to 14% in. CG.			

Appendix I

Study topic guide for qualitative study

Looking after your dental health during pregnancy

<u>**Interview Guide**</u>

1. Introduction

- Interviewer introduces themselves
- Background information about the study
- Confidentiality and tape recorder

2. Warm up

- May I ask your Name
- May I ask your Age
- Where do you live?
- Ask about Education
- Nature of work (in the home, outside the home)
- Have children? Ages

3. Pregnancy

- Tell me about your current pregnancy? Pregnancy weeks? Is it your first?
- Do you have any pregnancy complications?
- Have the things you usually do changed since being pregnant?
- In what way/ tell me more about that (if more than one issue arise make sure to explore in detail)

4. Oral Health

- How would you rate your oral health (very good, good, average, poor?)
- Tell me how do you look after (take care) your teeth and gum? Allow participant to expand in detail here
- Do you have any concerns about the health of your teeth and gums?
- Do you have any pain on eating or drinking…?
- What is your daily dental hygiene routine?
- What kinds of things do you think can affect your teeth and gum?
- Do you go to the dentist regularly, any problems with that?

5. Oral Health and pregnancy

- Tell me about your teeth and gum during pregnancy?
- Tell me how do you look after your teeth and gum during pregnancy? Any special care during pregnancy?
- What do you know about oral health during pregnancy?
- What kind of things affects your teeth and gum health during pregnancy?
- What can you do about your own teeth and gum health during pregnancy?
- Do you as pregnant women feel under pressure to have healthy teeth and gum? How? Why?
- Have you been to the dentist while you have been pregnant? Tell me about that experience? Allow participant to expand?

6. Oral Health Education

- What do you think about having information about looking after your mouth during pregnancy?
- What would be the best for you for getting information, seeing a video, have someone talk to you, getting material to read like booklets?
- What things influence a pregnant woman to have healthy teeth and gums? How?

KING'S
College
LONDON

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

REC Reference Number: BDM/09/10-36

Looking after your dental health during pregnancy

We would like to invite you to participate in this postgraduate research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Women sometimes get problems with their gums during pregnancy but these can be prevented by some simple changes in oral hygiene routine. In this study we want to find out about how women look after their mouths in pregnancy and describe any mouth problems they may have experienced during pregnancy. We will use this information to help us design appropriate information and education materials on mouth care for expectant and new mothers in Kuwait. In this study would like to ask you questions about how you currently look after your teeth mouth and gums, whether pregnancy has changed your mouth care routine and whether you would be interested in further information on mouth-care for yourself or for your baby and young children. We would like to recruit women like you who are attending the governmental maternal healthcare centres at Al Asimah, Hawalli, Al Ahmadi, Al Frawaniyah and Al Jahra, either first time mothers or women who have already had children. We shall be conducting interviews so we shall be recruiting pregnant women who can speak Arabic or English fluently.

We will not be doing dental examinations or dental treatment and we do not need to look in your mouth. Participation in the study is voluntary and you have the right to refuse.

Should you agree to take part; the researcher Mrs Suad Al Khamis will interview you here at the health centre after your appointment today. The interview should take no longer than 30-45 minutes. We would like to tape the interviews so we can record accurately what you say. We shall write up the tapes after the interviews and recordings of the interviews will be deleted after the transcriptions have been verified. You will not be identified by name on the

tapes or on any reports we write. The only personal information we will require will be your name, age whether you live in an urban or rural area and whether you are a Kuwaiti national. Only the researcher will have access to the limited personal information about you and this will not be linked to your interview or disclosed to a third party. We shall only retain your name up until the data analysis stage. You may withdraw from the study at any time up until the analysis stage. There are no risks to taking part in this study. You will not benefit directly from this study, but your participation will help us design information and education on mouth care for pregnant women in Kuwait.

Mrs. Suad Al Khamis will have access to the tape to write the transcripts. The research supervisors (Dr. Blanaid Daly, Dr. Koula Asimakopoulou, Prof Tim Newton and Dr Sasha Scambler) will have access to the transcripts. You will be able to withdraw from the study at any time up until the data analysis stage. The transcripts and computer records will be securely retained in a locked cabinet in the Dept of Oral Health Services Research & Dental Public Health, KCLDI, SE5 9RW.

Mrs Suad Al Khamis will be pleased to discuss any aspect of the study by email suad.alkhamis@kcl.ac.uk or by appointment at the day centre where she first met you. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Should you wish to receive a report regarding the findings of this study please give your contact details to Mrs Suad AlKhamis.

If this study has harmed you in any way you can contact King's College London using the details below for further advice and information:

Mrs Suad Al Khamis/ Dr Blanaid Daly

Dept of Oral health Services Research & Dental Public Health

King's College London Dental Institute

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Email: suad.alkhamis@kcl.ac.uk ; blanaid.daly@kcl.ac.

دراسة عن صحة الفم والأسنان للمرأة الحامل

(Information sheet in Arabic language)

الإرشادات العامة للمشاركات في البحث

نود ان ندعوك للمشاركة في هذه الدراسة المتخصصة في صحة الفم والأسنان للمرأه الحامل. الرجاء قراءة المعلومات التالية بدقه ومناقشتها إذا أردت, ونحن على أتم استعداد للاجابه على جميع الاستفسارات الخاصة بالدراسة.

هل تعلمين إن المرأة الحامل معرضة للاصابه بأمراض اللثة خلال فتره الحمل, ومن الممكن تجنب هذه الالتهابات بطريقه بسيطة من خلال العناية اليومية الصحيحة بالفم والأسنان.

في هذه الدراسة نريد معرفه إذا كانت المرأة الحامل في الكويت تعاني من أمراض اللثة خلال الحمل وإذا كان هناك طرق وأساليب متبعه خاصة خلال فتره الحمل للعناية بصحة الفم والأسنان. مشاركتك القيمة سوف تساعدنا بتصميم دراسة توعوويه إرشاديه للوقاية من أمراض الفم والأسنان خاصة بالمرأة الحامل في الكويت.

هذه الدراسة عبارة عن مقابله شخصيه مع الباحثة أ. سعاد الخميس تتم فيها بالاستفسار عن التالي:

- الاستفسار عن الرعاية اليومية في صحة الفم والأسنان
- وما إذا كان الحمل أثر سلبا على الفم والأسنان
- الاستفسار عن العنايه بالفم والأسنان خلال فتره الحمل
- هل أنت مهتمة بمعرفه المعلومات الصحية للعناية بالفم والأسنان لك ولأسرتك

المشاركات في هذه الدراسة هم الحوامل اللاتي يتحدثن اللغة العربية أو الانجليزية ويتلقين الرعاية الصحية في مراكز وزارة الصحة: حولي, الفروانيه, الجهراء, الأحمدي, العاصمه. و للعلم الدراسة لا تشمل فحصا للفم والأسنان.

المشاركة في هذا البحث اختياريه حيث لك كامل الحرية في المشاركة أو رفض المشاركه. في حالة قبول المشاركة الباحثة أ.سعاد الخميس سوف تقوم بمقابلتك في المركز الصحي في يوم الموعد لمقابله الطبيب المعالج حيث إن ألمقابله لا تتعدى 30 إلى 45 دقيقة.

و لتحري دقة المعلومات ولأهميتها سوف يتم تسجيل المقابلة صوتيا, وسوف يتم مسح تسجيل ألمقابله نهائيا بعد تدوين تفاصيل ألمقابله كاملة وبدقة من دون الاشاره إلى المعلومات الشخصية..

السرية التامة مكفولة لك ونحن ليس بحاجه إلى معلومات تدل على هويتك. نحن فقط بحاجه لمعرفة العمر, منطقة السكن, والجنسية, و نريد معلومات توضح كيفية العناية بصحة الفم والأسنان خلال فترة الحمل.

أ.سعاد الخميس هي الوحيدة التي لها الحق في الاستماع للحوار المسجل وتدوين محتوياته ومن ثم التخلص منه. المرشدون على البحث لهم الحق في تحليل البيانات وقراءة المحتوى.

جميع البيانات ومدونات المقابلات سوف تكون محفوظة في خزانة مغلقة في قسم الأبحاث لصحة الفم والأسنان و الصحة العامة بالأسنان في جامعة كنجز كولج في لندن.

أتشرف بالرد على استفساراتكم الخاصة في هذه الدراسة عن طريق الايميل الخاص suad.al-khamis@kcl.ac.uk أو عن طريق المقابلة الشخصية في المركز الصحية.

رفضك أو قبولك المشاركة في هذه الدراسة لا يؤثر على حقك في الرعاية والعناية الصحية المقررة لك.

في حالة قبولك المشاركة سوف تحتفظين في الإرشادات العامة للمشاركين في البحث و كذلك نود توقيعك على الإقرار المستنير. اذا كنت تودين الحصول على نتائج الدراسة الرجاء كتابه الاسم والعنوان.

في حالة تعرضك لأي اساءه أو اذى خلال هذه الدراسه الرجاء الاتصال في جامعة كنجز كولج لندن على العنوان الاتي:

أ.   سعاد الخميس/ د. بلانيت دالي

Department of Oral Health Research & Dental Public Health

King's College London Dental Institute

Caldecot Road

SE5 9RW

Tel 00442032993481   Fax 00442032993409

Email: suad.al-khamis@kcl.ac.u

Appendix K
Qualitative study consent form (English and Arabic language)

<table>
<tr><td>**CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES**</td><td>KING'S College LONDON</td></tr>
</table>

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: _ REC Reference Number: BDM/09/10-36

Looking after your dental health during pregnancy

King's College Research Ethics Committee Ref:BDM/09/10-36

- **Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part.**

- **If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.**

- **I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up to the data analysis phase**

- **I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the Data Protection Act 1998.**

- **I understand that should I wish to receive a copy of the final report I will need to give my contact details to the researcher Mrs Suad Al Khamis**

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I

agree to take part in the study. I have read both the notes written above and the Information Sheet

about the project, and understand what the research study involves.

Signed   **Date**

<div dir="rtl">

إقرار مستنير
(**Informed Consent**)

عنوان الدراسة: صحة الفم والأسنان للمرأة الحامل في الكويت

رقم المرجع: BDM/09/10-36

الباحثة: سعاد سعود الخميس

(مبعوثة الدكتوراه بجامعة King's College London /المملكة المتحدة)

الهدف من الدراسة: التعرف على العلاقة بين صحة الفم و الأسنان والحمل للنساء الحوامل.

عزيزتي:

* لك كامل الحرية في الموافقة أو عدم الموافقة على المشاركة في هذا البحث.

<u>في حالة الموافقة</u>

* فان الباحثة ستقوم بإجراء مقابلة شخصية معك وطرح عدة أسئلة تتعلق بالمعلومات المتعلقة بصحة الفم والأسنان والعناية بالأسنان وتستغرق المقابلة حوالي 30 إلى 45 دقيقة.
* وسيتم تسجيل المقابلة صوتيا على شريط تسجيل لضمان دقة المعلومات ومراجعتها وسيتم مسح التسجيل فورا بعد استخلاص المعلومات المطلوبة ولن يتم استخدام الشريط لتسجيل أي معلومات شخصية.
* ولن يتم الإشارة إلى اسمك أو ما قد يدل على شخصيتك بأي مرحلة من مراحل البحث.
* لن تستخدم المعلومات لغير أغراض البحث فقط وتتعهد الباحثة بالمحافظة على الخصوصية وسرية المعلومات وعدم تداولها خارج إطار البحث.
* من حقك التحفظ على الإجابة على بعض الأسئلة بالمقابلة مع الباحثة.
* لا يتضمن البحث إعطاء أي أدوية أو إجراء أي فحوصات أو اخذ أي عينات حيوية من المشاركات بالبحث أو التدخل في الخطة العلاجية الموضوعة لهم من جانب الطبيب المعالج ولن تشمل الدراسة فحص الفم والأسنان للمشاركات.

<u>في حالة عدم الموافقة على المشاركة بالبحث</u>

* فان ذلك لن يؤثر على حقك الكامل في تلقي الرعاية الصحية المقررة لك من جانب الطبيب المعالج.
* الباحثة على أتم استعداد للإجابة على كافة استفساراتك بخصوص البحث.

يرجى وضع علامة X   في المكان المناسب وكتابة الاسم والتوقيع.

---- أوافق   الاسم -------------------------------- التوقيع--------------

---- لا أوافق الاسم-------------------------------- التوقيع--------------

الباحثة: سعاد الخميس

</div>

INFORMATION SHEET FOR PARTICIPANTS

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

REC Reference Number: BDM/10/11-32

Title of study: Dental health education for Kuwaiti pregnant women

We would like to invite you to participate in this postgraduate research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

A recent interview study with pregnant women in Kuwait found that women would like to have more information about how to look after their teeth and gums during pregnancy. Women sometimes get problems with their gums during pregnancy but these problems can be prevented by some simple changes in oral hygiene routine such as tooth brushing and dental flossing. In our proposed study we want to find out what is the best way to provide women with this dental health education information. We have developed a dental health education learning package with three different designs. The design of the dental health education package has been informed by recent interviews with pregnant women in Kuwait. In this study we hope to find out which dental health education package is the most successful at giving women information.

Should you agree to participate in this study, your participation should take no longer than 15-45 minutes. We will ask you to complete a questionnaire which will ask you about how you keep your teeth and mouth healthy and what your usual oral health routines are. We shall then carry out a brief check on your gum health. We shall need to look into your mouth with a dental mirror and light but no other dental instruments will be used. We shall examine your gums and assess the amount of dental plaque present. After that and on the same day we shall randomly assign you to receive one of the three dental health education packages. We shall provide educational materials, a dental bounty pack containing a toothbrush and floss and show you how to carry out tooth brushing and flossing techniques. There will be an opportunity to discuss what the best method is for you. At your next scheduled antenatal appointment we would like to see you again for 10-30 minutes to check your gum health and ask you to complete a questionnaire. All participants, no matter what group they are randomly allocated to, will be offered the same dental package, and will for some participants occur at the end of your participation in the study.

You have been selected because we want to recruit women like you who are attending the governmental maternal healthcare centres and are pregnant. We shall be recruiting Kuwaiti pregnant women who are in their second trimester; provide informed consent; do not have pregnancy complications such as high blood pressure and other pregnancy complications; do not have chronic conditions e.g. diabetes; do not smoke or use tobacco; agree to follow up; and speak Arabic or English. Women who are not pregnant; are unable to provide informed consent; do not speak Arabic or English; have pregnancy complications; have no teeth; smoke or use tobacco products, and are not Kuwaiti nationals will be excluded.

Participation in the study is voluntary and you have the right to refuse. Should you agree to take part; the study will begin here at the health centre after your ante natal appointment today. We would like to see you today and again after four weeks at your next scheduled antenatal appointments.

You will not be identified by name on any reports we write. The only personal information we will require will be your name, age, education level, and occupation. Only the researcher will have access to the limited personal information about you and this will not be linked to your dental assessments, your medical records or disclosed to a third party. We shall only retain your name up until the data analysis stage. You may withdraw from the study at any time and you can withdraw your data up until the analysis stage which is the first of September 2011. You can also withdraw your data up until first of September 2011.You may withdraw from the study at any time up to this date by simply emailing or writing to the researchers at the address below. There are no risks to taking part in this study.

Mrs. Suad Al Khamis will have access to the written and clinical assessments data. The research supervisors (Dr. Blanaid Daly, Dr. Koula Asimakopoulou and Prof Tim Newton) will have access to the anonymised data for the purposes of analysis and supervision of the write up of the project. The research data and computer records will be securely retained in a locked cabinet in the Dept of Oral Health Services Research & Dental Public Health, KCLDI, London SE5 9RW, United Kingdom.

Mrs Suad Al Khamis will be pleased to discuss any aspect of the study by email suad.alkhamis@kcl.ac.uk or by appointment at the day centre where she first met

you. A decision to withdraw at any time, or a decision not to take part, will not

affect the standard of care you receive at the health centre.

It is up to you to decide whether to take part or not. If you decide to take part

you are still free to withdraw at any time and without giving a reason. If you do

decide to take part you will be given this information sheet to keep and be

asked to sign a consent form. Should you wish to receive a report regarding the

findings of this study please give your contact details to Mrs Suad AlKhamis.

If this study has harmed you in any way you can contact King's College London

using the details below for further advice and information:

Mrs Suad Al Khamis/ Dr Blanaid Daly

Dept of Oral health Services Research & Dental Public Health
King's College London Dental Institute
Caldecot Road
SE5 9RW
Tel 0044 203 299 3481
Fax 0044 203 299 3409
Email: suad.alkhamis@kcl.ac.uk ; blanaid.daly@kcl.ac.uk

Information sheet (Arabic language)

محتوى

صحيفة معلومات للمشاركين
سيتم إعطاؤك نسخة من هذه الصحيفة

الرقم المرجعي للجنة أخلاقيات البحوث:
BDM/10/11-32

عنوان الدراسة: التوعية الصحية لصحة الفم والاسنان للمرأه الكويتية الحامل

تسرنا دعوتك للمشاركة في هذا المشروع البحثي للدراسات العليا. ولكن لا تشاركي إلا إذا رغبت في ذلك، وإذا قررت عدم المشاركة فلن يضرك هذا القرار على أي نحو. قبل أن تقرري ما إذا كنت تريدين المشاركة أم لا، من المهم أن تفهمي دواعي إجراء البحث وما تنطوي عليه مشاركتك. والمرجو قراءة المعلومات التالية بدقة وتأنٍ ومناقشتها مع الآخرين إذا رغبت في ذلك. ويمكنك أن تسألينا في حالة وجود أي لبس أو إذا كنت ترغبين في مزيد من المعلومات.

هناك دراسة قائمة على المقابلات أجريت مؤخراً مع الحوامل في الكويت ووجدت أن النساء يرغبن في مزيد من المعلومات عن كيفية اعتنائهن بأسنانهن ولثاتهن أثناء الحمل. فالنساء يعانين أحياناً من مشكلات في لثاتهن أثناء الحمل، ولكنها مشكلات يمكن اتقاؤها ببعض التغييرات البسيطة في العادات اليومية للعناية بصحة الفم مثل تنظيف الأسنان بالفرشاة و بخيط الأسنان. وفي دراستنا المقترحة نود التعرف على أفضل طريقة لتزويد النساء بهذه المعلومات التوعوية لصحة الأسنان، حيث طورنا حزمة تعلّم للتوعية بصحة الأسنان ذات تصاميم مختلفة، مسترشدين في التصميم بمقابلات أجريت مؤخراً مع نساء حوامل في الكويت. وفي هذه الدراسة نرجو معرفة الحزمة الأكثر نجاحاً في تزويد النساء بالمعلومات التوعوية بصحة الأسنان من بين هذه الحزم.

إذا وافقت على المشاركة في هذه الدراسة، فلن تستغرق مشاركتك أكثر من 45-15 دقيقة. إذْ سنطلب منك تعبئة استبيان يسأل عن كيفية حفاظك على صحة فمك وأسنانك وعن عاداتك اليومية فيما يتعلق بصحة الفم. ثم نجري فحصاً سريعاً لصحة لثتك. سنحتاج إلى النظر في فمك باستخدام مرآة أسنان ومصباح، ولكن دون استخدام أية أدوات أسنان أخرى. وسنفحص لثتك ونقيّم كمية البلاك المتراكم على أسنانك. بعد ذلك وفي اليوم نفسه سنخصص لك -بشكل عشوائي- واحدة من حزم التوعية بصحة الأسنان الثلاث. وسنزودك بمواد توعوية وطقم هدية للعناية بالأسنان يحتوي فرشاة وخيطاً، ونريك كيفية غسل الأسنان بالفرشاة وطرق التنظيف بالخيط. وسوف نتيح لك الفرصة لمناقشة الطريقة الأفضل لك. في موعدك التالي المقرر لمتابعة الحمل نود أن نراك مجدداً لمدة 30-10 دقيقة لفحص صحة أسنانك وتعبئة الاستبيان. سوف تحصل جميع المشاركات، بغض النظر عن المجموعة التي سيُلحقن بها عشوائياً، على طقم العناية بالأسنان ذاته، وبالنسبة لبعض المشاركات سيكون ذلك في نهاية مشاركتهن في الدراسة.

لقد وقع عليك الاختيار لأننا نريد استقطاب نساء حوامل مثلك من مرتادات المراكز الصحية الحكومية لرعاية الأمومة. وسوف نستقطب الكويتيات الحوامل اللائي في الثلث الثاني من أحمالهن، ويعطين موافقتهن المستنيرة القائمة على علم، ولا يعانين من مضاعفات الحمل كارتفاع ضغط الدم والمضاعفات الأخرى، ولا يعانين من أمراض مزمنة كالسكري، ولا يدخّنّ أو يتعاطين التبغ، ويوافقن على المتابعة، ويتحدثن العربية أو الإنجليزية. وسيتم استبعاد من هن لسن حوامل وغير القادرات على إعطاء موافقة مستنيرة مبنية على علم ومن لا يتحدثن العربية أو الإنجليزية ومن يعانين من مضاعفات الحمل ومن ليس لديهن أسنان ومن يدخّنّ أو يتعاطين منتجات التبغ ومن لسن بمواطنات كويتيات.

المشاركة في الدراسة طوعية ولك الحق في الرفض. إذا وافقت على المشاركة فستبدأ الدراسة هنا في المركز الصحي بعد موعدك الخاص بمتابعة الحمل اليوم. ونودّ أن نراك اليوم ومرة أخرى بعد 4 أسابيع في مواعيد متابعة الحمل المقررة لك.

لن يذكر اسمك في أية تقارير نعدّها. والمعلومات الشخصية الوحيدة التي سنطلبها منك هي اسمك وعمرك ومستوى تعليمك وعملك. ولن يكون لأحد غير الباحث وحده إمكانية الاطلاع على معلوماتك الشخصية المحدودة ولن يكون هذا مرتبطاً بتقييمات صحة أسنانك أو سجلاتك الطبية أو يفصح عنه لأي طرف ثالث. ولن نحتفظ إلا باسمك حتى مرحلة تحليل البيانات. يمكنك الانسحاب من الدراسة في أي وقت مع سحب بياناتك حتى مرحلة التحليل في سبتمبر/أيلول 2011. ويمكنك أيضاً سحب بياناتك حتى 1 سبتمبر/أيلول 2011. ويمكنك الانسحاب من الدراسة في أي وقت حتى هذا التاريخ بمجرد إرسال رسالة إلكترونية أو الكتابة إلى الباحثين على العنوان أدناه. لا توجد مخاطر مترتبة على المشاركة في هذه الدراسة.

ستكون السيدة/ سعاد الخميس على اطلاع على بيانات التقييمات الكتابية والسريرية. وسيكون لدى مشرفي البحث (د/ بلانايد دالي، ود/ كولا أسيماكوبولو، وأ/ تيم نيوتن) إمكانية الاطلاع على البيانات مجهولة الاسم لأغراض التحليل والإشراف على إعداد تقارير المشروع. سيتم الاحتفاظ ببيانات المشروع وسجلات الكمبيوتر بطريقة آمنة في خزانة مغلقة في قسم أبحاث London SE5 9RW،خدمات صحة الفم وصحة الأسنان العامة، بمعهد الأسنان في جامعة كنجز كوليدج في لندن، United Kingdom .

ويسر السيدة/ سعاد الخميس مناقشة أي من جوانب الدراسة بالبريد الإلكتروني على عنوان suad.alkhamis@kcl.ac.uk أو بتحديد موعد في مركز الرعاية النهارية التي التقتك فيه أول مرة. لن يؤثر اتخاذك قراراً بالانسحاب في أي وقت أو قراراً بعدم المشاركة على مستوى الرعاية المقدمة لك في المركز الصحي.

القرار لك بالمشاركة أو عدمها. فإذا قررت المشاركة فستبقى لك الحرية في الانسحاب في أي وقت ودون إبداء الأسباب. وإذا قررت المشاركة فسوف تحصلين على صحيفة المعلومات هذه للاحتفاظ بها وسوف يطلب منك التوقيع على استمارة موافقة. وإذا رغبت في استلام تقرير بخصوص نتائج هذه الدراسة، فالمرجو إعطاء السيدة/ سعاد الخميس بيانات الاتصال بك.

إذا ألحقت هذه الدراسك بك ضرراً على أي نحو يمكنك الاتصال بجامعة كنجز كوليدج في لندن باستخدام التفاصيل المذكورة أدناه للحصول على مزيد من المشورة والمعلومات.

السيدة/ سعاد الخميس، د/ بلانايد دالي

قسم أبحاث خدمات صحة الفم وصحة الأسنان العامة
معهد الأسنان بجامعة كنجز كوليدج في لندن
Caldecot Road
SE5 9RW
هاتف: 0044 203 299 3481
فاكس: 0044 203 299 3409
بريد إلكتروني:

suad.alkhamis@kcl.ac.uk؛ blanaid.daly@kcl.ac.uk

Appendix M

Consent form (RCT) (English language)

REC Reference Number: BDM/10/11-32

Title of the Project: Dental health education for Kuwaiti pregnant women

Purpose of the Study: The aim of this study will be to test how pregnant think about oral health

Procedures: In the proposed study we shall measure the changes in your oral health knowledge and oral health behaviour before and after giving you the dental health education package. We will do this by asking you to complete a questionnaire. We also will assess the plaque accumulation and your gum health before and after the dental health education package. We will only use a mouth mirror.to do the examination.

After explaining the procedure and purpose of the study, every participant has the right to accept or refuse admission to the study. Upon agreement, the investigators promise to keep the participant's personal information strictly confidential, not to share any information outside the spectrum of this study, and not to send any samples abroad for other purposes. In case of refusal to participate, the participant will continue to receive the standard treatment.

Agree   **Participant name:**   **Signature:**

Don't Agree   **Participant name:**   **Signature:**

Investigator's Name:　　　　　　　　　　**Signature**

Informed Consent form (Arabic language)

اسم الباحت: سعاد سعود الخميس
القسم والجامعه: قسم الصحة العامه للاسنان, جامعة كنجز كولج لندن

عنوان المشروع: التوعية الصحية لصحة الفم والاسنان للمرأه الكويتية الحامل

الهدف من الدراسة (مختصر عن المشروع): الهدف من البحث هو اختبار فاعلية ا نظريات الخاصة بالتغيير السلوك الصحي لتوعية وتطوير سلوك المرأه الكويتية الحامل تجاة صحة الفم والاسنان.
الإجراءات المتبعة: في الدراسة المقترحة سيتم استخدام الفحوصات التالية) في هذه الدراسة سوف نقوم بقياس التطور بالمعلومات الصحية و السلوك الصحي الخاصة بصحة الفم والاسنان عن طريق الاجابه عن استبيان معد من قبل الباحثة وكذلك فحص الصفائح الجرثومية وصحة اللثة عن طريق النظر داخل الفم(لن يتم استخدام ادوات او اجهزه او اي نوع من العلاج).
ملحوظة :سوف يتم إجراء هذه الدراسة على **النساء الحوامل** ،جميع المشاركين لهم الحق في الانسحاب من المشاركة في أي وقت .
بعد تقديم الشرح المفصل عن طبيعة وخطوات البحث ، جميع المرضى لهم الحق في قبول أو رفض الانضمام للبحث، بناء على اتفاق مسبق، يعد المشرفين على البحث جميع المشاركين بالحفاظ على السرية التامة لجميع المعلومات ، وعدم مشاركة أي معلومات خارج نطاق هذه الدراسة ، كما أن جميع العينات المأخوذة لن تبعث لخارج البلاد لأغراض أخرى. و في حالة الانسحاب من المشاركة في البحث لن يؤثر ذلك على الرعاية الصحية التي تتلقاها المشاركه.

| موافق -- | اسم المشاركة : ------------------------ | التوقيع: ------------------------------ |

| غير موافق ------ | اسم المشاركة: ------------------------ | التوقيع: ------------------------- |

Appendix N

Tooth brushing and flossing tips leaflet (English language)

Brush the inner side of your front teeth by placing the toothbrush in an upright position behind the front teeth

Change your starting point of toothbrushing. For example if you used to brush from right to left, change it by starting from left to right, if you brush outside surfaces first, change it by starting from the tongue.

To clean your teeth effectively, remember to:

Brush 2 times a day.

Brush your teeth for 2 to 3 minutes

Brush your teeth gently, do not use strong pressure

Brush all teeth surfaces; outside, inner side and biting surfaces

TOOTHBRUSHING AND FLOSSING TIPS

Suad AlKhamis
PhD Student
Dental Public Health
King's College London

How to floss

Take a piece of floss about as long as your child's arm and wrap it around your middle finger, leaving about 2 inches between the hands.

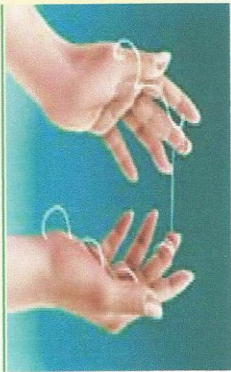Use your index finger to guide the floss between the teeth

Slide the floss between the teeth and wrap it into a "C" shape. It should wrap around the base of the tooth, where the tooth meets the gum. Wipe the tooth from bottom to the top 2 or 3 times.

Be sure to floss both sides of the tooth

Move to a new part of the floss as you move from tooth to tooth

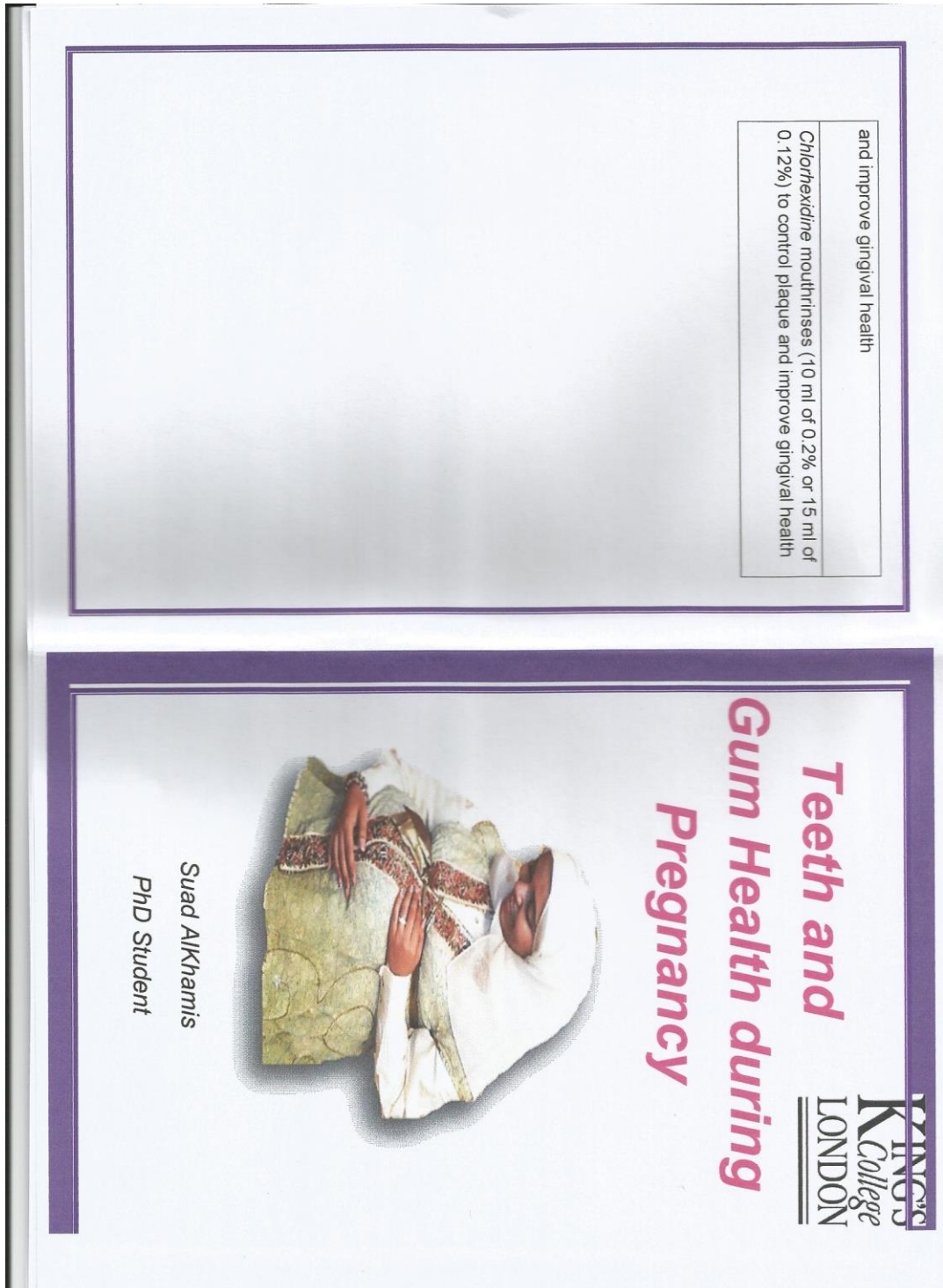Change your toothbrush when the bristles look worn, usually after 3 to 4 months.

To clean between your teeth effectively, remember to:

Clean between your teeth gently once a day by using dental floss.

Floss once a day

How to floss

Take a piece of floss about as long as your child's arm and wrap it around your middle finger, leaving about 2 inches between the hands.

Use your index finger to guide the floss between the teeth

Slide the floss between the teeth and wrap it into a "C" shape. It should wrap around the base of the tooth, where the tooth meets the gum. Wipe the tooth from bottom to the top 2 or 3 times.

Be sure to floss both sides of the tooth

Move to a new part of the floss as you move from tooth to tooth

Change your toothbrush when the bristles look worn, usually after 3 to 4 months.

To clean between your teeth effectively, remember to:

Clean between your teeth gently once a day by using dental floss.

Floss once a day

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Appendix O

Teeth and gum health during pregnancy booklet (English and Arabic language)

Teeth and Gum Health during Pregnancy

Suad AlKhamis
PhD Student

KING'S College LONDON

and improve gingival health

Chlorhexidine mouthrinses (10 ml of 0.2% or 15 ml of 0.12%) to control plaque and improve gingival health

Pregnancy and dental health

Some Kuwaiti pregnant women have incorrect beliefs and information concerning dental health during pregnancy. For example did you know that pregnancy does not cause or accelerate tooth decay; it is what you eat and drink during pregnancy which might affect your teeth. Eating and drinking foods and drinks with a high sugar content food causes dental decay. A healthy diet is good for your dental health. If you have tooth ache during pregnancy it might mean you have dental decay and you should go to the dentist.

Pregnancy is a unique time in a woman's life. Many changes in a woman's body occur

during pregnancy. These changes and how you respond to these changes (for example changing what you eat and drink or stop brushing your teeth during the first three months of pregnancy) can include changes to the health of your teeth, mouth and gums. It is important to know that dental diseases are preventable. By making simple changes in your hygiene routine and diet you can help prevent dental disease both in pregnancy and for the rest of your life. By adopting these simple changes you could also prevent dental disease in your family.

We hope in this booklet to provide you with the best information available on how you could look after your mouth both during and after pregnancy

Pregnancy and gum health

Some Kuwaiti pregnant women thought that bleeding gums is normal or said they did not know why their gums bled. You should know that gum bleeding is one of the signs of gum inflammation. Gum inflammation is caused by plaque a film that forms on your teeth every day.

Pregnant women are more likely to have bleeding gums because pregnancy hormones make their gums more sensitive and irritated by the presence of dental plaque.

We would like you to think about any changes in your mouth since you became pregnant. You may have noticed that your gums seem to bleed more easily since you have been pregnant. This

can happen because of hormonal changes in a woman's body. You can stop this happening by simply brushing your teeth and flossing your teeth.

We advise that you brush your teeth twice a day before bedtime and on one other occasion during the day. You may have morning sickness and prefer not to brush your teeth first thing in the morning. If this is the case, we suggest you wait for the sickness to pass and then brush your teeth.

Pregnancy by itself does not harm the teeth or gums and brushing and flossing can help prevent dental problems. Healthy

gums are pinkish, firm and there is no bleeding

Current advice to prevent gum disease is that adults should brush their teeth systemically twice a day by using a soft and small headed toothbrush. Adults should floss once a day before bed time.

Pregnancy and tooth decay

Women are at no greater risk to tooth decay because they are pregnant. However some women alter their eating and drinking or stop brushing their teeth during pregnancy and may inadvertently start adding sugar to their diet which puts them at risk for dental decay. Some Kuwaiti pregnant women believe that pregnancy had an active role in dental decay or accelerating dental decay; losing teeth; or calcium deficiency. Dental decay during pregnancy is caused by increase in sugary snacks and drinks and adding sugar to foods and drinks consumed at mealtimes. Brushing your teeth regularly with a fluoride containing toothpaste can help prevent dental decay.

Fluoride is an element that protects the teeth from decay. It serves to prevent, control and stop tooth decay. Fluoride can be found naturally in water in some countries or is added to dental hygiene products such as toothpaste and mouthwash. When you brush your teeth with fluoridated toothpaste, we recommend that you spit out or rinse with small amount of water rather than rinse your mouth with large amount of water. In this way you increase the time fluoride is in contact with your teeth giving better protection. Most family toothpastes in Kuwait have the correct amount of fluoride.

Current advice is that adults should brush their teeth twice a day with fluoridated toothpaste to prevent tooth decay. Adults should be encouraged to spit out excess toothpaste or to rinse with small amount of water. Adults should be control sugar intake by limiting it to mealtimes in order to prevent dental decay

the tooth (enamel)? The enamel is the hard, protective coating of the tooth, which protects the sensitive dentine underneath. When the enamel is worn away, the dentine underneath is exposed, which may lead to pain and sensitivity. Acidic foods such as pickles, lemon, orange, and grapefruit, and drinks such as lemon and orange juices, and fizzy drinks, can also cause loss of the outer layer.

Some pregnant women experience a lot of sickness during pregnancy and may find it useful to follow the following tips to protect their teeth.

- Avoid frequent intake of acidic foods or drinks – keep them to mealtimes.
- Do not brush immediately after eating or drinking acidic food or drinks.

Pregnancy sickness and dental health

Did you know that frequent nausea and vomiting may lead to the loss of the outer layer of

- Do not brush immediately after vomiting
- Chew sugarless or xylitol-containing gum after eating.
- Use a teaspoon of baking soda (sodium bicarbonate) in a cup of water as a rinse after vomiting to neutralize acid

Current advise that you brush your teeth twice a day before bed time and on one other occasion during the day. You may have morning sickness and preferred not to brush your teeth first thing in the morning. Pregnancy by itself does not harm the teeth or gums and brushing and flossing can help prevent dental problems.

Pregnancy and going to the dentist

Many women are concerned about going to the dentist while they are pregnant. Did you know that:

- Dental care is safe and effective during pregnancy.
- Pregnancy by itself is not a reason to postpone routine dental care and necessary treatment for oral health problems
- In the first trimester diagnosis and treatment, including necessary dental x-rays, can be undertaken safely to diagnose and manage dental disease that needs immediate treatment.
- Dental prophylaxis and treatment during pregnancy should be preferably undertaken during the early second trimester but definitely prior to delivery.
- Emergency dental care if needed is safe at any time during pregnancy.
- Check with your GP and OBs re any problems with your mouth and the need to attend the dentist.

Current advice is that oral health should be maintained during pregnancy and that preventive oral health care is essential before and during pregnancy. Adults should visit the dental clinic regularly.

Toothbrushing

Brush your teeth twice a day brush before bed time and any other occasion during the day for 2 to 3 minutes.

Brushing twice a day with fluoride toothpaste is efficient in reducing tooth decay. Brushing twice a day for two weeks will stop gums bleeding.

Toothpaste

Select the tooth brush that has:
✓ small head,
✓ soft bristle

Current advice is that adults should brush their teeth twice a day for a minimum 2 minutes. It is essential to brush before bed time and any other occasion during the day. Brushing twice a day with fluoride toothpaste is efficient in reducing tooth decay. Brushing twice a day for two weeks will stop gums bleeding. Adultss should use a small headed brush with soft bristles to maximise the efficiency of plaque removal.

It is not enough to choose the toothpaste according to the smell and colour; it should be chosen according to fluoride that protects teeth from decay

prevent dental decay. The action of brushing and plaque removal prevents gum disease.

Dental Flossing

Dental floss is a soft string for cleaning spaces between the teeth. To clean between your teeth effectively, remember to:

- Clean between your teeth gently once a day by using dental floss.
- Floss before brushing

Brushing your teeth regularly with a fluoride containing toothpaste can help prevent dental decay, but it can also keep the mouth fresh and is good for the gums and may make people feel their mouth is fresh

Current advice is that adults should brush their teeth twice a day with fluoridated toothpaste to

Current advice is that adults should clean between their teeth once a day by using dental floss or interdental brushes.

Top tips to help protect your teeth and gums throughout pregnancy

- Brush your teeth twice a day with fluoridated toothpaste

- Limit the food and drinks containing sugar to mealtimes.
- Regular visits to the dental clinic for check-ups are important to prevent oral diseases. Always tell your dentist if you think you might be pregnant.

mouthwash and do not rinse your mouth with water afterwards

- Brushing your teeth before bedtime is most effective
- Floss your teeth once a day before bedtime
- Spit out after brushing and do not rinse your mouth with water afterwards
- Use a fluoride mouth rinse daily at a different time of tooth brushing. Spit out after using the

Recommended doses for fluoridated toothpaste

Age	Recommended Doses for fluoride toothpaste
Children aged up to 3 years	Use only a tiny amount of toothpaste containing no less than 1,000 ppm fluoride
Children age 3-6 years	Use a pea-sized amount of toothpaste containing 1,350–1,500 ppm fluoride
All children and young adultss	Fluoridated toothpaste with 1,350 ppm fluoride or above
Adults	Fluoridated toothpaste with at least 1,350 ppm fluoride

Recommended doses for fluoridated mouthrinse

Use fluoride mouthrinse daily that contain 0.05% NaF

For your gum health use:

Use toothpaste containing *triclosan* in combination with a *copolymer* or with *zinc citrate* to control plaque

References

DH/British Association for the Study of Community Dentistry.(2009) Delivering Better Oral Health: An evidence- based toolkit for prevention (2nd Ed.) April 2009.

New York State Department of Health, (2006) Oral health care during pregnancy and early childhood: Practice guidelines. August 2006

Darby, M. L. and Walsh, M.W. (2003) *Dental hygiene theory and practice*. 2nd ed. Philadelphia: W.B. Saunders Company.

قصة الأسنان والعلاقة بعلم الجمال

إعداد

سعد الأمير

طالبة دكتوراه في المملكة المتحدة

References

DH/British Association for the Study of Community Dentistry. (2009) Delivering Better Oral Health: An evidence-based toolkit for prevention (2nd Ed.) April 2009.

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• يمكن وضع القليل من الإمساك باليد في الفم بعد ظهور الأسنان.

العمر	الكمية المناسبة من معجون الأسنان وتركيز الفلورايد في معجون الأسنان
الأطفال من 3 سنوات	الأطفال من عمر الولادة وحتى سن 3 سنوات يجب استخدام معجون أسنان يحتوي على 1000 جزء في المليون من الفلورايد
الأطفال من 3-6 سنوات	الأطفال من سن 3 سنوات يجب أن يستخدموا معجون أسنان يحتوي على 1500 – 1350 جزء في المليون من الفلورايد
الكبار والأطفال فوق سن 7 سنوات	يجب أن يستخدموا معجون أسنان يحتوي على 1350 جزء في المليون من الفلورايد
البالغين	يجب أن يستخدموا معجون أسنان يحتوي على 1350 جزء في المليون من الفلورايد

غسول الفم المحتوي على الفلورايد يمكن أن يستخدم مع معجون الأسنان المحتوي على الفلورايد بتركيز 0.05%

الأطفال الذين يعانون من تسوس الأسنان يمكن أن يستخدموا غسول فم يحتوي على الفلورايد بتركيز 0.2% أو 10 ملي 15

Appendix P

Action Plan (English language)

Oral health Education for Kuwaiti pregnant women

Planning

Brushing

_____

Could you please write your plan regarding tooth brushing?

'I have made a detailed plan regarding ....

    a) When to brush my teeth. I will brush my teeth _____

_____

_____

_____

What obstacles do you think you will face when attempting to brush a when you

have said you will do above

_____

_____

_____

 How will you overcome this problem?

Problem: _____

Solution:

_____

_____

b) How often to brush my teeth. I will brush my teeth _____

_____

_____

_____

What obstacles do you think you will face when attempting to brush a when you have said you will do above

_____

_____

_____

How will you overcome this problem?

Problem: _____

Solution: _____

_____ _____

c) How to use the toothbrush. I need to
_____
_____
_____
_____

d) How much time to spend with tooth brushing. I will spend
_____ every time I brush my teeth.

e) with which regular behaviour to combine tooth brushing

f) What obstacles do you think you will face when attempting to brush a when you have said you will do above. List these for each time of day and each behaviour

g) How will you overcome these?

Problem 1:_____

Solution:

_____

_____

Problem 2:_____

Solution:

_____

_____

Any other problems:

_____

_____

_____

Flossing

Could you please write your plan regarding dental flossing?

'I have made a detailed plan regarding ....

a) when to floss my teeth---

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b) how often to floss my teeth--

----

c) how to use the dental floss---

----

d) how much time to spend with flossing --

----

e) with which regular behaviour to combine flossing ----------------------------
----
----

h) What obstacles do you think you will face when attempting to floss a
when you have said you will do above. List these for each time of day and
each behaviour--

----

i) How will you overcome these?

Problem 1:_____

Solution:

_____

_____

Problem 2:_____

Solution:

_____

_____ 473

Any other problems:

_____

_____

_____

Action Plan (Arabic Language)

التوعية الصحية لصحة الفم والاسنان للمرأه الكويتية الحامل

<u>التخطيط</u>

تنظيف الاسنان بالفرشاة

الرجاء كتابة خطتك المتعلقة بتنظيف الأسنان بالفرشاة؟

لقد عملت خطة مفصلة بشأن...

a. متى انظف اسناني بالفرشاة. سوف انظف اسناني بالفرشاة
_____
_____
___

ما هي العقبات التي تعتقدين انك ستواجهينها عند محاولة تنظيف الأسنان بالفرشاة عندما حددتي ما ستفعلين أعلاه

_____
_____
_____
_____
_____

كيف سيتم التغلب على هذه المشكلة؟

المشكلة: _____
___

الحل: _____
_____
_____
_

b. كيف غاليا انظف اسناني بالفرشاة. سوف انظف اسناني بالفرشاة

_____

_____

_

_____

_____

____

ما هي العقبات التي تعتقدين انك ستواجهينها عند محاولة تنظيف الأسنان بالفرشاة عندما حددتي ما ستفعلين أعلاه

_____

_____

كيف سيتم التغلب على هذه المشكلة؟

المشكلة:_____

_____

الحل:_____

_____

____

_____

_____

c. كيفية استخدام فرشاة الأسنان. انا احتاج

_____

_____

d. كم من الوقت سوف تقضين بتنظيف الأسنان بالفرشاة. سوف اقضي _____ كل مرة انظف بها اسناني.

e.   مع اي سلوك منتظم سوف تجمعين مع تنظيف الأسنان بالفرشاة

_____

_____

_____

_____

f.ما هي العقبات التي تعتقدين انك ستواجهينها عند محاولة تنظيف الأسنان بالفرشاة عندما حددتي ما ستفعلين أعلاه. الرجاء كتابة العوائق الممكنة.

_____

_____

_____

_____

g. كيف سيتم التغلب على هذه المشكلة؟

المشكلة1:_____

_____

الحل:_____

_____

_____

المشكلة2:_____

_____

الحل:_____

_____

_____

الرجاء كتابة خطتك المتعلقة بتنظيف الأسنان بالخيط؟

لقد عملت خطة مفصلة بشأن..

b. متى انظف اسناني بالخيط. سوف انظف اسناني بالخيط

_____

_____

___

ما هي العقبات التي تعتقدين انك ستواجهينها عند محاولة تنظيف الأسنان بالخيط عندما حددتي ما

ستفعلين أعلاه

_____

_____

_____

_____

كيف سيتم التغلب على هذه المشكلة؟

المشكلة: _____

——

الحل: _____

_____

——

b.كيف غاليا انظف اسناني بالخيط. سوف انظف اسناني بالخيط

_____

_____

_____

——

ما هي العقبات التي تعتقدين انك ستواجهينها عند محاولة تنظيف الأسنان بالخيط عندما حددتي ما ستفعلين أعلاه

_____

_____

_____

_____

كيف سيتم التغلب على هذه المشكلة؟

المشكلة: _____

——

الحل: _____

_____

____

c. كيفية استخدام خيط الاسنان. انا احتاج

_____

Appendix Q

The Kuwait Ethical Committee consent form

<p style="text-align:center;color:red">Informed Consent (Adult)</p>

Faculty: **Hospital:**

Department: **Department:**

Title of the Project:

Purpose of the Study:

Procedures: In the proposed study we shall use the following tests (type of test, samples, volume and frequency)

Controls:

Control subjects (specify example: healthy brothers/sisters of the patients, others and what will they be subjected to if anything at all)

Note: This study will not be performed on pregnant women and neonates and all participants have the right to withdraw from the study at any time.

After explaining the procedure and purpose of the study, every participant has the right to accept or refuse admission to the study. Upon agreement, the investigators promise to keep the participant's personal information strictly confidential, not to share any information outside the spectrum of this study, and not to send any samples abroad for other purposes. In case of refusal to participate, the patient will continue to receive the standard treatment for his disease.

Agree   **Patients Name:**   **Signature:**

Don't Agree   **Patients Name:**   **Signature:**

Investigator's Name: **Signature**
Date:

Questionnaire of dental health for Kuwaiti pregnant women

Thank you for agreeing to complete this questionnaire. This questionnaire should take no longer than 15 minutes. Read each question carefully and complete the answer in the format requested, for example some questions may ask you to tick one response only, other may ask you to write down what do you think. If anything is not clear please ask the researcher to explain and clarify further.

Thank you for your help.

Firstly we would like to assess your general knowledge about dental health and pregnancy. Please choose the most appropriate answer

1.   How do you rate your dental health status?

- o Excellent
- o Good
- o Fair
- o Poor
- o Very poor

2.   If you thought that pregnancy affects the teeth and gums, how might that process happen? (you can choose more than one)

- o Baby takes calcium from the teeth
- o Vomiting because of morning sickness can cause dental erosion
- o Pregnancy accelerates dental decay
- o Pregnancy accelerates gum disease
- o Hormonal changes during pregnancy make the gums bleed
- o Pregnancy has no effect on oral cavity
- o Other (please specify)_____

3.   Have you lost one tooth for each pregnancy

- o Yes
- o No
- o Don't know

4. Do you think that you might lose a tooth for every pregnancy?

- o Yes
- o No
- o Don't know

5. Do you think that your diet and nutrition during pregnancy will affect your teeth?
- o Yes
- o No
- o Don't know

6. Smoking has an effect on the unborn child.

True	False	Don't know

7. Could you please write what is dental floss and what might be the effects of using dental floss

_____
_____
_____
_____

Section B: Self-reported dental health behaviours

We would like to ask you about your dental health behaviours (brushing and flossing). Please read the questions below and tick the answer that best describes your behaviour over the past 7 days. There are no right or wrong answers.

1. During the past week, how often did you brush your teeth?

   o Not at all,
   o Once a week
   o Every second day
   o Once a day
   o Twice a day
   o Other (please specify)_____

2. During the past week, how often did you floss your teeth?

   o Not at all
   o Once a week
   o Every second day
   o Once a day
   o Other (please specify)_____

Section C: Pregnancy and dental health behaviours

In this section we would like to know what you think regarding the following dental health behaviours. Please Mark an X in the box corresponding to your opinion or respond

I.   Tooth brushing

1. Compared with non-pregnant women, should pregnant women brush

- o more frequently
- o less frequently
- o the same
- o Don't know

2. You should brush your teeth after each meal to prevent tooth decay.

True	False	Don't know

3. A softer toothbrush is better than a hard one for cleaning my teeth.

True	False	Don't know

4. A large-headed toothbrush is less efficient at cleaning teeth than a small-headed toothbrush.

True	False	Don't know

5. I am unsure of the best way to brush my teeth.

True	False	Don't know

6. You should change your toothbrush after 3 to 4 months.

True	False	Don't know

7. Brushing my teeth will improve the condition of my gums.

True	False	Don't know

8. Brushing my teeth twice a day for 2 to 3 minutes will keep my gums healthy.

Extremely likely	Likely	Neither likely nor unlikely	Unlikely	Extremely unlikely;	Don't know

9. Brushing my teeth twice a day for 2 to 3 minutes will get rid of plaque.

Extremely likely	Likely	Neither likely nor	Unlikely	Extremely unlikely;	Don't know

		unlikely			

10. My family thinks it is important that I brush my teeth daily.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

11. I intend to brush my teeth twice a day regularly.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

12. My gums will bleed when I brush

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

13. Tooth brushing is painful.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

14. My teeth will break when I brush.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

II. **Flossing**

1. Flossing my teeth will improve the condition of my gums.

True	False	Don't know

2. I think that flossing my teeth every day would increase my resistance to gum disease.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

3. My family thinks I should floss my teeth every day.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

4. I intend to use dental floss regularly.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

5. My gums will bleed when I floss.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

6. My teeth will break when I floss.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

7. Dental flossing is painful.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

III.   Dental decay and gum disease

1. Do you think that pregnancy has any effects on the teeth and/or gums?

   o   Teeth only
   o   Gums only

o Gums and teeth
o Pregnancy has no effect on the teeth and gums
o Other (please specify)_____
o Don't know

2. Brushing my teeth with fluoride toothpaste will help prevent tooth decay.

True	False	Don't know

3. What do you think can be done to stop teeth decaying?

o Brush my teeth regularly
o Avoid sugary food
o Go to the dentist
o Cannot be avoided
o Don't know
o Other (specify)

4. You should brush your teeth after each meal to prevent tooth decay.

True	False	Don't know

5. Brushing my teeth with fluoride toothpaste will help prevent tooth decay.

True	False	Don't know

6. You should rinse with a large amount of water after brushing

True	False	Don't know

7. What do bleeding gums indicate?

o Inflamed gum
o Healthy gum
o Receding gums
o Don't know
o Other (please specify)_____

8. What causes inflamed gum disease in pregnant women? (you can choose more than one)

o Dental plaque
o Hormonal changes
o Neglecting brushing
o Plaque and neglecting
o All of the above
o Other (please specify)_____

o   Don't know

9. If you are a pregnant woman and find your gums bleed when you brush, you should stop brushing and/or reduce the amount of time you brush your teeth.

True	False	Don't know

10. Do you think that pregnancy sickness has any effects on the teeth and/or gums?

o   Teeth only
o   Gums only
o   Gums and teeth
o   I don't think pregnancy sickness has any effect on the dental cavity
o   Other

11. If you are a pregnant woman suffering from pregnancy sickness, you should brush immediately after vomiting.

True	False	Don't know

12. Having dental problems is a normal part of pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

13. Bleeding gums are a sign of gum disease.

True	False	Don't know

14. Bleeding gums are to be expected in pregnancy

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

15. Aching and rotten teeth are to be expected in pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

16. I find there is very little I can do to prevent myself getting dental problems during pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

17. My family thinks I should seek dental treatment when I have dental problems during pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

18. I intend to seek dental treatment during pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

19. I am afraid I would not be able to seek dental treatment during pregnancy.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

IV.   **Snacks**

1. Do you think eating snacks between meals is:

- o   Very good for your health
- o   Good for your health
- o   Neither good nor bad for your health
- o   Bad for your health
- o   Very bad for your health
- o   Don't know

2. Sugary snacks and drinks are best limited to meal times.

True	False	Don't know

3. Choosing sugar free snacks between meals is very important.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

4. How important would you say that not eating sweet snacks is to the health of your teeth?

very important	fairly important	not important	not at all important	don't know

5. My family thinks it is important that I eat healthy snack.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

6. From now on, I intend to avoid snacks (food or drinks) as much as possible.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

7. I am afraid I would not be able to limit food containing sugar to mealtimes only

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

V. Visit dentist regularly

1. You should visit the dentist regularly for a check-up even if you are pregnant.

True	False	Don't know

2. Going to the dentist regularly will keep me from having trouble with my teeth and gum.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

3. Going to the dentist is better than other ways of looking after your teeth.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

4. My family thinks that it is normal to see the dentist regularly for a check-up even if I am pregnant.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

5. I intend to go to the dentist for a check-up regularly.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

6. I am afraid I would not be able to visit dentist regularly'

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

7. Visiting dental clinic is time consuming.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

8. Dental treatment is expensive.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

9. Visiting dental clinic during pregnancy is not safe.

Strongly agree	Agree	Undecided	Disagree	Strongly disagree	Don't know

Section E: You

Finally, we would like to ask about you a few questions about yourself.

Name: _____ (optional)

Age: _____

Highest education level received**: _____**

Current occupation**: _____**

Household monthly income

(KD/month):_____

Number of children:

_____

Number of pregnancy (not including this one)

_____

Thank you for taking the time to complete this questionnaire

The questionnaire (Arabic language)

K*ING'S*
College
L*ONDON*

استبيان حول صحة الفم و الأسنان للمرأة الكويتية الحامل

الدراسة حاصلة على موافقة لجنة أخلاقيات البحث الكويتية (18 يناير/كانون الثاني 2011)
ولجنة أخلاقيات البحث بجامعة كينجز كوليدج في لندن (32-11/10/BDM. 17 فبراير/شباط
2011)

نشكرك على موافقتك على استيفاء هذا الاستبيان. ينبغي ألا تستغرق الإجابة على هذا الاستبيان أكثر من 15 دقيقة. يرجى قراءة كل سؤال بحرص ثم إكمال الإجابة بالتنسيق المطلوب، على سبيل المثال قد تطلب منكِ بعض الأسئلة وضع علامة على إجابة واحدة فقط، بينما قد تطلب منكِ أسئلة أخرى كتابة رأيك. فإذا كان هناك أي شيء غير واضح، فيرجى أن تطلبي من الباحثة تفسيره وتوضيحه بشكل أفضل.

نشكرك على مساعدتك.

القسم (أ): الحمل وصحة الأسنان

في البداية نود أن نقيم معلوماتك العامة حول صحة الأسنان والحمل. يرجى اختيار أنسب الإجابات

1. ما هو تقييمك لصحة أسنانك؟

   ○ ممتازة
   ○ جيدة
   ○ مقبولة
   ○ سيئة
   ○ سيئة جداً

2. إذا كنت تعتقدين أن الحمل يؤثر على الأسنان واللثة، فكيف يمكن أن تحدث هذه العملية؟ (يمكنك اختيار أكثر من إجابة)

   ○ الجنين يأخذ الكالسيوم من الأسنان
   ○ القيء نتيجة لغثيان الصباح يمكن أن يتسبب في تآكل الأسنان
   ○ الحمل يعجِّل تسوس الأسنان
   ○ الحمل يعجل أمراض اللثة
   ○ التغيرات الهرمونية أثناء فترة الحمل تسبب نزيف اللثة
   ○ الحمل لا يؤثر على الفم والأسنان
   ○ غير ذلك (الرجاء التحديد)_____

3. هل فقدت أحد أسنانك في كل حمل؟

   ○ نعم
   ○ لا
   ○ لا اعلم

4. هل تعتقدين أنك قد تفقدين أحد أسنانك في كل حمل؟

   ○ نعم
   ○ لا
   ○ لا اعلم

5. هل تعتقدين أن نظامك الغذائي وتغذيتك أثناء الحمل سوف يؤثران على أسنانك؟

   ○ نعم
   ○ لا
   ○ لا اعلم

6. التدخين يؤثر على الجنين قبل ولادته (الرجاء وضع علامة على إجابتك)

صحيح	خطأ	لا اعلم

7. هلا تتفضلين بكتابة ما هو خيط تنظيف الأسنان وماذا قد تكون الآثار الناجمة عن استخدامه

_____

_____

_____

_____

_____

القسم (ب): سلوكيات صحة الأسنان المبلغ عنها من قبل النساء نفسها

نود أن نسألك عن سلوكيات صحة أسنانك (تنظيف الأسنان بالفرشاة واستخدام خيط الأسنان).
الرجاء قراءة الأسئلة المدونة أدناه ووضع علامة على الإجابة التي تصف سلوكك على مدار الأيام السبعة الماضية كأفضل ما يمكن. ليس ثمة إجابات صحيحة أو خاطئة.

1. خلال الأسبوع الماضي، كم مرة نظفت أسنانك بالفرشاة؟

   ○ لم أنظفها مطلقاً
   ○ مرة في الأسبوع
   ○ كل يومين
   ○ مرة كل يوم
   ○ مرتين كل يوم
   ○ غير ذلك (الرجاء التحديد)_____

2. خلال الأسبوع الماضي، كم مرة نظفت أسنانك باستخدام خيط تنظيف الأسنان؟

   ○ لم أنظفها مطلقاً
   ○ مرة في الأسبوع
   ○ كل يومين
   ○ مرة واحدة كل يوم
   ○ غير ذلك (الرجاء التحديد) _____

القسم (ج): الحمل وسلوكيات صحة الأسنان

في هذا القسم نود معرفة رأيك فيما يتعلق بالسلوكيات التالية الخاصة بصحة الأسنان. يرجى وضع علامة X في المربع المقابل لرأيك أو إجابتك

أ. <u>تنظيف الأسنان بالفرشاة</u>

1. بالمقارنة بالنساء غير الحوامل، هل ينبغي للحوامل غسل أسنانهن بالفرشاة

- ○ أكثر
- ○ أقل
- ○ بالمعدل نفسه
- ○ لا أعلم

2. يجب أن تنظفي أسنانك بالفرشاة بعد كل وجبة للوقاية من تسوس الأسنان.

صحيح	خطأ	لا اعلم

3. فرشاة الأسنان ذات الشعيرات الناعمة أفضل من الفرشاة ذات الشعيرات الخشنة لتنظيف أسناني.

صحيح	خطأ	لا اعلم

4. فرشاة الأسنان ذات الرأس الكبيرة أقل فعالية في تنظيف الأسنان من فرشاة الأسنان صغيرة الرأس.
5.

صحيح	خطأ	لا اعلم

6. أنا غير متأكدة من الطريقة المثلى لتنظيف أسناني بالفرشاة.

صحيح	خطأ	لا اعلم

7. يجب أن تغيري فرشاة أسنانك كل 3 إلى 4 شهور.

صحيح	خطأ	لا اعلم

8. تنظيف أسناني بالفرشاة سوف يحسن حالة لثتي.

صحيح	خطأ	لا اعلم

9. تنظيف أسناني بالفرشاة مرتين يومياً لمدة 2 إلى 3 دقائق سيحافظ على صحة لثتي.

مرجح للغاية	مرجح	ليس مرجحاً ولا غير مرجح	غير مرجح	غير مرجح إلى أقصى درجة؛	لا أعرف

10. تنظيف أسناني بالفرشاة مرتين يومياً لمدة 2 إلى 3 دقائق سيتخلص من طبقة البلاك.

مرجح للغاية	مرجح	ليس مرجحاً ولا غير مرجح	غير مرجح	غير مرجح إلى أقصى درجة؛	لا أعرف

11. أسرتي تعتقد أنه من الضروري أن أنظف أسناني بالفرشاة يومياً.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

12. أنا أنوي تنظيف أسناني بالفرشاة مرتين يومياً بأنتظام.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

13. لثتي ستنزف عندما أنظف أسناني بالفرشاة

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

14. تنظيفالأسنان بالفرشاة مؤلم.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

15. أسناني ستتكسر عندما أنظفها بالفرشاة.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

//. تنظيف الأسنان بخيط الأسنان

1. تنظيف أسناني بخيط الأسنان سوف يحسن حالة لثتي.

صحيح	خطأ	لا اعلم

2. أنا أعتقد بأن استخدام خيط الأسنان كل يوم سوف يزيد مقاومتي لأمراض اللثة.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

3. أسرتي تعتقد أن من الضروري أن أنظف أسناني بخيط الأسنان يومياً.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

4. أنا أنوي استخدام خيط تنظيف الأسنان على نحو منتظم.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

5. لثتي ستنزف عندما أنظف أسناني بخيط الأسنان.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

6. أسناني ستتكسر عندما أنظفها بخيط الأسنان.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

7. تنظيف الأسنان بخيط الأسنان يسبب الألم.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

III. **تسوس الأسنان وأمراض اللثة**

1. هل تعتقدين أن الحمل يؤثر بأي شكل على الأسنان و/أو اللثة؟

- o الأسنان فقط
- o اللثة فقط
- o اللثة والأسنان
- o الحمل لا يؤثر على الأسنان واللثة
- o غير ذلك (الرجاء التحديد) ـــ
- o لا أعلم

2. غسل أسناني بالفرشاة و معجون أسنان يحتوي على الفلوريد سوف يساعد على الوقاية من تسوس الأسنان.

لا اعلم	خطأ	صحيح

3. ماذا في رأيك الذي يمكن أن تفعليه لمكافحة تسوس الأسنان؟

- o غسل أسناني بالفرشاة على نحو منتظم
- o تجنب الأطعمة المحتوية على السكريات
- o الذهاب إلى طبيب الأسنان
- o لا يمكن تجنبه
- o لا أعلم
- o أساليب أخرى (يرجى تحديدها)

4. يجب أن تغسلي أسنانك بالفرشاة بعد كل وجبة للوقاية من تسوس الأسنان.

صحيح	خطأ	لا اعلم

5. غسل أسناني بالفرشاة و معجون أسنان يحتوي على الفلوريد سوف يساعد على الوقاية من تسوس الأسنان.

صحيح	خطأ	لا اعلم

6. يجب أن تتمضمضي بكمية كبيرة من الماء بعد غسلها بالفرشاة.

صحيح	خطأ	لا اعلم

7. علام يدل نزيف اللثة؟

○ التهاب اللثة
○ صحة اللثة
○ تراجع اللثة وانخفاضها
○ لا أعرف
○ غير ذلك (الرجاء التحديد)_____

8. ما الذي يسبب مرض التهاب اللثة لدي النساء الحوامل؟ (يمكنك اختيار أكثر من إجابة)

○ البلاك
○ التغيرات الهرمونية
○ إهمال غسل الأسنان بالفرشاة
○ البلاك والإهمال
○ كل ما سبق
○ غير ذلك (الرجاء التحديد)_____
○ لا أعرف

9. إذا كنتِ حامل ووجدت لثتك تنزف عندما تنظفين أسنانك بالفرشاة، فيجب أن تتوقفي عن غسل أسنانك و/أو تقللي وقت غسل أسنانك بالفرشاة.

صحيح	خطأ	لا اعلم

10. هل تعتقدين أن غثيان الحمل يؤثر بأي شكل على الأسنان و/أو اللثة؟

- الأسنان فقط ○
- اللثة فقط ○
- اللثة والأسنان ○
- لا أعتقد أن غثيان الحمل يؤثر بأي شكل على تجويف الفم ○
- (الرجاء التحديد)_____ ○
- لا أعرف ○

11. إذا كنت حامل وتعانين من غثيان الحمل، يجب أن تغسلي أسنانك بعد التقيؤ مباشرة.

صحيح	خطأ	لا اعلم

12. المعاناة من مشاكل في الأسنان جزء طبيعي من الحمل.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

13. نزيف اللثة من أعراض مرض اللثة.

صحيح	خطأ	لا اعلم

14. من المتوقع حدوث نزيف اللثة أثناء فترة الحمل

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

15. من المتوقع المعاناة من آلام الأسنان ومن تسوس الأسنان في فترة الحمل.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

16. أكاد لا أجد شيئاً أستطيع عمله لوقاية نفسي من الإصابة بمشاكل في الأسنان في فترة الحمل.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

17. أسرتي تعتقد أنه يجب أن أسعى لعلاج أسناني عندما يكون لدي مشاكل بالاسنان أثناء فترة الحمل.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

18. أنا أنوي بالسعي بعلاج أسناني أثناء فترة الحمل.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

19. أخشى أنني لن أتمكن من علاج أسناني أثناء فترة الحمل.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

IV. **الوجبات الخفيفة**

1. هل تعتقدين أن تناول الوجبات الخفيفة بين الوجبات يعتبر:
   - جيد جداً لصحتك
   - جيد لصحتك
   - ليس جيد أو مضراً لصحتك
   - مضراً لصحتك
   - مضراً جداً لصحتك
   - لا أعرف

2. يستحسن قصر تناول الوجبات الخفيفة والمشروبات الغنية بالسكر على أوقات الوجبات.

صحيح	خطأ	لا اعلم

3. اختيار وجبات خفيفة خالية من السكر بين الوجبات مهم جدا.

أوافق بشدة	أوافق	لم أقرر	لا أوافق	لا أوافق بشدة	لا أعرف

4. ما مدى أهمية عدم تناول الوجبات الخفيفة الغنية بالسكر بالنسبة لصحة أسنانك؟

لا أعرف	غير مهم على الإطلاق	غير مهم	مهم إلى حد ما	مهم للغاية

5. أسرتي تعتقد أن من الضروري أن أتناول وجبات خفيفة صحية بين الوجبات.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

6. من الآن فصاعداً، أنوي تجنب الوجبات الخفيفة (الأطعمة أوالمشروبات) قدر الإمكان.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

7. أخشى أنني لن أتمكن من قصر الأطعمة المحتوية على سكر على أوقات الوجبات الأساسية فقط.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

VII. الزيارة الدورية لطبيب الأسنان

1. ينبغي أن تزوري طبيب الأسنان بانتظام لعمل فحص لأسنانك حتى إذا كنت حامل.

لا اعلم	خطأ	صحيح

2. الذهاب لطبيب الأسنان بشكل منتظم سيجنبني الإصابة بمشاكل في الأسنان واللثة.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

3. الذهاب إلى طبيب الأسنان أفضل من الوسائل الأخرى للاعتناء بأسنانك.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

4. تعتقد أسرتي أن من الطبيعي أن أزور طبيب الأسنان بانتظام لعمل فحص لأسناني حتى إذا كنت حامل.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

5. أنوي زيارة طبيب الأسنان لعمل فحص لأسناني على نحو منتظم.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

6. أخشى أنني لن أستطيع زيارة طبيب الأسنان بانتظام.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

7. زيارة عيادة طبيب الأسنان تستهلك الكثير من الوقت.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

8. علاج الأسنان باهظ التكاليف.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

9. زيارة عيادة طبيب الأسنان أثناء فترة الحمل ليست آمنة.

لا أعرف	لا أوافق بشدة	لا أوافق	لم أقرر	أوافق	أوافق بشدة

القسم (هـ): أنتِ

أخيراً، نود أن نطرح عليك بضعة أسئلة عنك أنت.

الاسم: _____ (اختياري)

السن:_____

أعلى مستوى تعليم حصلتِ عليه:_____

الوظيفة
الحالية:_____

الدخل الشهري للأسرة (دينار

كويتي/شهر)_____

عدد

الأبناء:_____

عدد مرات الحمل (بخلاف هذا الحمل)_____

نشكرك على الوقت الذي بذلتيه في استيفاء هذا الاستبيان.