

Evaluation of a midwifery initiated oral health-dental service program to improve oral health and birth outcomes for pregnant women: A multi-centre randomised controlled trial



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ABSTRACT

Background: Oral health care during pregnancy is important for the health of the mother and child. However, pregnant women have limited knowledge about maternal oral health and seldom seek dental care. Further, due to limited training antenatal care providers like midwives rarely discuss oral health with pregnant women. The Midwifery-Initiated Oral Health Dental Service program was developed to address current gaps in oral promotional interventions during pregnancy.

Objectives: To assess the effectiveness of a Midwifery-Initiated Oral Health Dental Service program in improving uptake of dental services, oral health knowledge, quality of oral health, oral health status and birth outcomes of pregnant women.

Design: Multi-centre randomised controlled trial.

Setting: Three large metropolitan public hospitals in Sydney, Australia.

Participants: Pregnant women attending their first antenatal appointment who were at least 18 years old and had a single low risk pregnancy between 12 and 20 weeks gestation.

Methods: 638 pregnant women were allocated to three groups using block randomisation (n = 211) control group, intervention group 1 (n = 215), intervention group 2 (n = 212) and followed up till birth. Study investigators and data collectors were blinded to group allocation. Intervention group 1 received a midwifery intervention from trained midwives involving oral health education, screening and referrals to existing dental pathways. Intervention group 2 received the midwifery intervention and a dental intervention involving assessment/treatment from cost free local dental services. The control group received oral health information at recruitment. Primary outcome was uptake of dental services. Secondary outcomes included oral health knowledge, quality of oral health, oral health status and birth outcomes.

Results: Substantial improvements in the use of dental services (20.2% Control Group; 28.3% Intervention group 1; 87.2% Intervention group 2; Odds Ratio Intervention group 2 vs Control Group = 29.72, 95% CI 15.02–58.53, p < 0.001), women's oral health knowledge (p = 0.03); quality of oral health (p < 0.001) and oral health outcomes (sulcus bleeding, dental plaque, clinical attachment loss, decayed/filled teeth- p < 0.001) were found in Intervention group 2. No difference in the rate of preterm or low-birth weight was found.

Conclusions: The Midwifery-Initiated Oral Health Dental Service program (Intervention group 2) improved the

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uptake of dental services and oral health of pregnant women and is recommended during antenatal care. A cause and effect relationship between this intervention and improved birth outcomes was not supported.

What is already known about the topic?

- Maintaining oral health during pregnancy is important and all pregnant women are recommended to consult a dentist for a check-up early during pregnancy.
- Despite current recommendations pregnant women seldom seek dental care and oral health is rarely discussed during antenatal care.
- There is a significant lag in evidence based oral health promotion interventions for pregnant women.

What this paper adds

- This is the first randomised controlled trial to assess improvements in the oral health and birth outcomes of pregnant women using a comprehensive oral health promotion program initiated by midwives.
- Our results show that MIOH-DS program can be successfully implemented into midwifery practice and is effective in improving dental services utilisation, oral hygiene, oral health knowledge and quality of oral health of pregnant women.
- The program includes a nationally endorsed oral health training program, evidence based oral health promotional material and a validated oral health screening tool and thus has the potential to be translated to other antenatal care providers.

1. Introduction

Inflammatory gum disease, gingivitis or periodontitis (destruction of the supporting teeth structures), are commonly experienced during pregnancy (35–100%), increasing in severity until the 36th week of gestation (Onigbinde et al., 2014). The associated inflammation has been hypothesized as being linked to adverse birth events such as preterm and low birth weight outcomes (Dasanayake and Naftolin, 2016; Papapanou, 2015). In a recent review of epidemiological evidence and clinical trials of oral health interventions during pregnancy, Dasanayake and Naftolin continue to support the association between periodontitis and pregnancy outcomes, although there is recognition of the numerous challenges to conducting trials of this nature (Dasanayake and Naftolin, 2016). A major conclusion of Dasanayake and Naftolin's review was that there is sufficient evidence to 'maintain proper oral health before, during, and after pregnancy regardless of whether it may or may not reduce preterm birth' (p.76). Therefore, although the effectiveness of periodontal treatment on improving birth outcomes has not been confirmed (Chambrone et al., 2011), it is still recommended that all pregnant women should receive oral health education, assessment and referrals to dental services, to minimise any dental infections during this period (Oral Health Care During Pregnancy Expert Workshop, 2012).

Women's oral health during pregnancy is intricately associated with the health consequences for the infant such as the potential for the transfer of streptococcus mutans from mother to child with subsequent development of dental caries (known as early childhood caries), the single most chronic childhood disease worldwide (Leong et al., 2013). Pregnant women in Australia infrequently consult dentists (30–50%) even when they have a dental problem, with the main barriers being the cost of dental care and lack of oral health awareness (George et al., 2013). The low uptake of dental services during pregnancy is common in other countries as well (< 50%) including those with universal dental schemes (Briggs, 2012) like United Kingdom, Turkey and Spain which provide free access to public dental services (Dinas et al., 2007;

Hullah et al., 2008 Martínez-Beneyto et al., 2011; Ozen et al., 2012). There is an identified need for alternate pathways to be provided to raise awareness in women as to the importance of oral health during pregnancy while encouraging dental service use (Vamos et al., 2015).

Maternal health care providers (general practitioners, obstetricians) and midwives in particular are ideally positioned to deliver key health messages to support a healthy pregnancy, while promoting the optimal health behaviours for the mother and the infant (Ten Hoope-Bender et al., 2014; Renfrew et al., 2014). Although there are national policies promoting the inclusion of oral health checks at the initial antenatal visit within Australia (National Health and Medical Research Council, 2013), UK (National Health Service Health Scotland, 2012) and USA (Oral Health Care During Pregnancy Expert Workshop, 2012), both perinatal care providers and dentists remain concerned about taking up this role (George et al., 2016a; George et al., 2017a). A recent survey of perinatal care providers (George et al., 2016a) and dentists (George et al., 2017a) identified misconceptions about the safety of dental interventions during pregnancy even though treatments like extraction and the use of x-rays are safe during this period. Perinatal care providers were aware of the risks of poor oral health and adverse maternal and infant outcomes, but did not feel they had adequate skills to assess oral health (George et al., 2016a).

To address current gaps in perinatal oral health care we developed a unique intervention- the midwifery initiated oral health-dental service (MIOH-DS) program for midwives to acquire competence in oral health care (Johnson et al., 2015). Midwives were chosen for this study as they are the main care providers for pregnant women in Australia and spend more time with childbearing women than any other health professional as well as being highly acceptable to women (Ten Hoope-Bender et al., 2014). The intervention involved midwives providing oral health education and screening to pregnant women at their first antenatal visit and referring them to appropriate dental services. It included evidence based oral health promotional material (Centre for Oral Health Strategy, 2010) for pregnant women along with an oral health training program (George et al., 2016b) and screening tool (George et al., 2016c) for midwives. The program was piloted across one antenatal clinic and we found increased use of dental services (50%) and improved oral health in the pregnant woman ($P < 0.05$) in the intervention versus the control groups (Johnson et al., 2013). Adverse pregnancy outcomes such as preterm or low birth weight were not examined. We now extend this pilot study to a multi-centre trial, to confirm these initial findings of improved dental service use and oral health, and also to test the impact of our intervention on pregnancy outcomes (Johnson et al., 2015).

The aim of this study was to conduct a multi-centre trial of the MIOH-DS program and determine its effectiveness in improving the uptake of dental services (primary outcome), oral health knowledge, quality of oral health and oral health status of pregnant women. In addition, any differences in the rates of preterm or low birthweight outcomes will be examined.

2. Methods

2.1. Study design

A three arm, multi-centre, randomised controlled trial (RCT) was designed to evaluate the MIOH-DS program. The trial was undertaken across three large metropolitan public hospitals in Sydney, New South Wales (NSW), Australia and involved two intervention groups and one control group. Detailed information about the trial design is outlined in

the published protocol and on the trial registration record (Johnson et al., 2015).

2.2. Participants

Pregnant women presenting for their first antenatal appointment at the study sites were recruited for this trial and followed up till birth (November 2012–October 2015). In Australia, the first antenatal appointment in public hospitals is always managed by midwives (George et al., 2016b). Women were eligible to participate if they had a single pregnancy between 12 and 20 weeks of gestational age and were at least 18 years old. Women were excluded if i) they had any known foetal anomalies or other risk factors that would make the pregnancy higher risk; or ii) they were unable able to attend dental treatment regularly due to practical issues such as transportation. Eligible pregnant women were recruited in the antenatal waiting room by an independent recruiter (dental assistant) and informed written consent was obtained after providing detailed study information. Interpreter services and translated study material were used for participants from non-English speaking backgrounds. Prior to randomisation, baseline information was collected through a pre-questionnaire administered by a dental assistant, which included demographic details, medical and dental aspects of the women's health (such as risk factors for adverse pregnancy outcomes, uptake of dental services, quality of oral health) and oral health knowledge. All trial participants were provided government-endorsed oral health promotional material (Centre for Oral Health Strategy, 2010) via the dental assistant to maintain equipoise.

2.3. Randomisation and masking

Block randomisation was used to allocate pregnant women to the study groups. This type of randomisation is preferred for large trials and has been used in numerous intervention studies in this area (Johnson et al., 2015). A permuted block randomisation with random block sizes was used to allocate participants, stratifying them by the presence of self-identified dental problems and hospital. Randomisation was assigned centrally using an independent telephone-based computer randomisation service provided by the National Health and Medical Research Council Clinical Trial Centre. This randomisation service was accessed by the dental assistants at the time of recruitment following consent and baseline data collection. Further details of the randomisation process have been outlined in the published protocol (Johnson et al., 2015). The dental assistants were masked to group allocation to maintain allocation concealment and minimise selection bias. The study investigators, data entry service (external provider) and statistician who analysed the data were also blinded to group allocation. Due to the nature of the trial, no attempt was made to mask group allocation from pregnant women and midwives. There was potential for some contamination between intervention groups, as women from different intervention groups attended dental appointments at the same clinic on the same day, and may have been able to interact in the waiting room. To address this, we included an item in the post questionnaire asking participants if they had discussed the study with other pregnant women. These women were excluded from analysis.

2.4. Intervention

The MIOH-DS program involved both a midwifery intervention (MIOH) and a dental intervention (DS).

The **midwifery intervention** involved midwives providing the following at the 1st antenatal visit for pregnant women:

- Oral health education to reinforce the importance of maternal oral health and advice women to consult a dentist early during pregnancy for a check up (Oral Health Care During Pregnancy Expert Workshop, 2012).

- Oral health screening to identify pregnant women at risk of poor oral health. Pregnant women were assessed by midwives (trained in the MIOH-DS program) using the maternal oral health screening (MOS), which consists of two simple questions and an optional visual inspection of the oral cavity. The MOS tool can be easily implemented by midwives and has a high sensitivity (up to 94%) in identifying pregnant women at risk for poor oral health (George et al., 2016c).
- Dental referrals for pregnant women at risk of poor oral health.

The **dental intervention** involved trained study dentists providing pregnant women priority access to free dental services in one of three public dental clinics near the recruitment hospitals, using a standardized dental treatment protocol. This was a service created specifically for this study and coordinated by the study investigators. Two of the dental clinics were on-site next to the recruitment hospitals while the third clinic was off-site in a community health centre. At the first dental appointment pregnant women received an initial oral assessment followed by treatment (if required) to maintain a functional and infection free oral cavity. The oral assessment followed a standard format and included medical history along with a periodontal and dental caries examination. Based on the assessment a treatment plan was formulated which included dental treatments like scaling, dental restorations and denture assessments. Dental treatment was provided during the second trimester (13–27 weeks) which is considered a safe and comfortable period to undertake dental procedures (Oral Health Care During Pregnancy Expert Workshop, 2012). Women requiring further complex dental treatment (like root canal therapy of posterior teeth and crowns) were referred to private dental specialists and excluded from the study as these services are not provided in public dental services in NSW (Centre for Oral Health Strategy, 2017). At the end of each dental appointment pregnant women received oral health education, oral hygiene instruction and dietary counseling from the study dentists.

2.5. Procedures

Pregnant women were allocated to one of three groups – a control group and two intervention groups. The intervention group 1 (IG1) received only the midwifery intervention and any women assessed to be at risk of poor oral health were referred to existing dental referral pathways in NSW for treatment, which generally involve a cost. These pathways included private dentists in the area, health insurance dental clinics (if pregnant women had dental insurance cover) or the free public dental services (if eligible). In NSW, low income pregnant women who are holders of health care cards can access the public dental services and they are offered an appointment within three months once assessed for routine care. Midwives provided referral letters to pregnant women, which included a checklist for dentists to complete and return to the study investigators. The checklist helped identify when the pregnant women sought a dental check-up, treatment provided and the dentist's contact details.

Intervention group 2 (IG2) received both the midwifery and dental intervention. All pregnant women in this group, regardless of whether they were identified at risk of poor oral health, were referred to the study dentists in one of the public dental clinics for an initial oral assessment and collection of baseline oral health status data. The control group did not receive any intervention apart from oral health promotional material which was provided at the time of recruitment.

In the last trimester (28–38 weeks) all three groups (regardless of whether they had a dental problem) received a final oral assessment by the study dentists, which was the end point of the study. This assessment followed the same protocol as the initial assessment. Participants in the control group who were identified to have a dental problem were referred to the study dentists to be seen post pregnancy. During this period, a post-questionnaire was also administered to all pregnant women which contained similar items to the pre-questionnaire. The

post-questionnaire was administered either by the dental assistant/midwife at the antenatal appointment, over the phone when scheduling the final dental appointment or via the study dentist at the final oral assessment. The birth outcome data for the pregnant women was collected post pregnancy from the hospital where the birth occurred.

2.6. Education for study midwives and dentists

The midwifery intervention was administered by 17 midwives working in the antenatal clinics of the three study sites. Prior to the trial, all midwives successfully completed a comprehensive oral health education program endorsed by the Australian College of Midwives (George et al., 2016b). The program significantly improved the oral health knowledge and confidence of midwives to promote oral health and ensured they were competent to administer the midwifery intervention (George et al., 2016b). Three study dentists took part in a workshop where they were trained by an experienced clinician to follow the standardized dental protocol and record the oral health status measures. Five mock oral assessments were also conducted which showed a high inter-rater reliability (> 80%) between the dentists.

2.7. Study outcomes

The primary outcome was the uptake of dental services and the secondary outcomes were oral health knowledge, quality of oral health, oral health status and birth outcomes.

- **The uptake of dental services:** To assess the proportion of pregnant women that saw a dentist, the following sources were used: the returned checklist; the database of the study dental clinics; data from the post questionnaire; and contacting private/health insurance dentists that were seen by the women (contact details obtained from returned checklist and post questionnaire).

Table 1
Characteristics of the Three Groups.

	All (n = 638)			p value
	Control n = 215 n (%)	IG1 n = 212 n (%)	IG2 n = 211 n (%)	
Demographic				
Age (Mean, SD)	29.0 (5.4)	29.1 (5.3)	29.0 (5.7)	0.96
Country of Origin ^g	135 (63.1%)	126 (59.7%)	128 (61.2%)	0.78
Main Language, English ^f	155 (72.4%)	155 (74.2%)	168 (80.0%)	0.17
Tertiary Education ^f	112 (52.6%)	114 (54.6%)	110 (52.1%)	0.86
Marital status, single ^g	35 (16.7%)	24 (11.6%)	36 (17.4%)	0.20
Lowest SEIFA Quintile	93 (43.3%)	97 (45.8%)	105 (49.8%)	0.40
Employment, not working ^b	105 (49.8%)	110 (52.9%)	118 (56.2%)	0.47
Smoking ^g	32 (14.9%)	33 (15.8%)	26 (12.4%)	0.59
Other Substance Use ^{h,g}	2 (0.9%)	0 (0.0%)	3 (1.4%)	0.24
Existing Illness/infection ^c	20 (9.4%)	15 (7.1%)	16 (7.7%)	0.68
Private health insurance ^d	35 (16.4%)	30 (14.4%)	44 (21.2%)	0.22
Pension/health care card ^e	87 (40.5%)	86 (41.3%)	75 (35.9%)	0.49
Dental				
Do you currently have any problems or concerns with your teeth, gums or mouth? yes (n = 629)	126 (60.3%)	121 (57.6%)	129 (61.4%)	0.78
Have you sought advice from a dental professional for this problem or concern? yes (n = 406) ^h	56 (41.2%)	44 (33.8%)	40 (28.6%)	0.87
Have you received any information about 'oral health care during pregnancy'? yes (n = 632)	19 (9.0%)	21 (10.0%)	10 (4.8%)	0.11
Have you seen a dentist in the previous 12 months, yes (n = 634)	73 (34.1%)	68 (32.2%)	66 (31.6%)	0.85

SEIFA: Socio-economic indexes for areas

^a Other substance use includes alcohol consumption and illicit substance use.

^b n = 629.

^c n = 630.

^d n = 631.

^e n = 632.

^f n = 633.

^g n = 634.

^h Sample size reduced due to this question being asked as a follow up to the previous question.

- **Oral Health Knowledge:** To assess this outcome, knowledge questions (previously pilot tested) (George et al., 2014) were included in the pre- and post-questionnaires that were administered to pregnant women at recruitment and end point of the study.
- **Quality of Oral Health:** This outcome was assessed using the following validated single-item global self-report of oral health (Thomson et al., 2012) which was included in the pre and post questionnaire: "On a scale of 1–5 where 1 = poor and 5 = excellent, How would you describe the health of your teeth and mouth?"
- **Oral Health Status:** The following measures were used at both the initial and final dental oral assessments to determine the oral health status:
 - The presence of inflammation and bleeding of the gums was assessed using the Sulcus Bleeding Index (Klages et al., 2005).
 - The presence of dental plaque was assessed using the Approximal Plaque Index (Klages et al., 2005).
 - Clinical attachment loss measured by the amount of periodontal pocket depth and gingival recession as well as presence of calculus was assessed using a calibrated periodontal probe (Newman et al., 2002).
 - Dental caries status was determined using the Decayed, Missing, Filled Teeth index (Aggerud, 1983).
- **Birth Outcomes:** The birth weight and gestational age was obtained from the ObstetriX data system (ODS) which is a surveillance system used by all NSW public hospitals (Taylor et al., 2000).

2.8. Statistical analysis

Sample size was calculated for the primary outcome – uptake of dental services. A service uptake rate of 50% or more for IG1 and IG2 is considered a successful outcome of the MIOH intervention compared to the expected rate of 30% in the control group. To detect a difference of at least 20% in a 3-group study ($\alpha = 0.05/3 = 0.017$) with 80%

power we computed that 124 participants were required per group. Allowing for a 10% attrition rate, and a 30% loss at end point we concluded that we needed to recruit 621 participants (207 per group) (Johnson et al., 2015).

All data was stored and assessed using SPSS 21 (George et al., 2017b). Continuous and categorical data were summarised using conventional descriptive statistics. Pearson's chi-squared analysis was used to compare proportions between groups. Logistic regression methods using general estimating equations were used. One way Analysis of Variance (ANOVA) was used to compare mean outcomes between groups and Student's t-test was used to determine the significance of within-group changes over the course of the intervention. Where scale data failed to meet requirements of normality, a Kruskal-Wallis analysis was used in place of an ANOVA to assess the between group difference. Where available, data were analysed on an intention-to-treat basis. There was no difference in the 'loss to follow-up' proportions between groups.

3. Results

There were 639 participants recruited from three maternity hospitals (209–218 women per hospital) with 638 completing the pre-intervention questionnaire. Participant randomisation successfully randomised participants on all main demographic measures and there were no significant differences between groups (Table 1). Of the 211 women in IG2, 131 attended the dental service intervention, and 156 completed the post intervention questionnaire. No pregnant women required complex dental treatment and exclusion from the study. In total 477 women across the 3 groups completed the post intervention questionnaire (Fig. 1).

3.1. Primary outcome measure

3.1.1. The uptake of dental services

Between group analyses found women in IG2 were significantly more likely to see a dentist during the course of their pregnancy compared to participants in both CG and IG1 ($p < 0.001$). In total 136 (87%) mothers in IG2 saw a dentist or had a dental check-up during pregnancy (Table 2). Women in IG1 were marginally more likely to see a dentist than women in the CG, 28% compared to 20%. Logistic regression found that after accounting for participant factors (seen in

Table 1), group allocation remained the strongest predictor of dental visits (OR: IG1 vs CG = 1.73, 95% CI: 1.02–2.91; OR: IG2 vs CG = 29.72, 95% CI: 15.02–58.83; OR: IG2 vs IG1 = 17.20, 95% CI: 8.99–32.90). Of the 213 women who saw a dentist or had a dental check-up during pregnancy, the proportion of women who reported having a dental problem varied by group allocation (Table 2). In the CG, the majority of women who saw a dentist also reported having dental concerns (68%) whereas in IG2, only 46% of women reported having a dental concern. No significant differences in uptake of dental services were observed between the on-site and offsite dental clinics ($\chi^2 = 0.54, p = 0.46$).

3.2. Secondary outcomes

3.2.1. Oral health knowledge

Participant knowledge of oral health was assessed using a 10-item questionnaire pre and post intervention. At baseline there were no significant between group differences in level of knowledge. Over the course of the intervention each of the three groups (CG, IG1 and IG2) significantly increased their knowledge level ($p < 0.001$) (Table 3), with those participants receiving the most intense intervention showing the greatest knowledge increase ($p = 0.030$). All 10 items showed significant improvement in knowledge. Of these, 7 items consistently showed improvement ($p < 0.05$) across each group.

To assess the effect of additional dental visits on oral health knowledge (i.e. additional oral health education), IG2 was further differentiated into those who did not see the dentist ($n = 29$), those who saw the dentist once ($n = 14$) and those who saw the dentist two or more times ($n = 113$) and compared to the other two groups. No significant differences in oral health knowledge were observed between the groups.

3.2.2. Quality of oral health

The health of participants' teeth and mouth was collected pre and post intervention using the global self-report of oral health item (Thomson et al., 2012). Participants were asked to rate the health of their teeth and mouth from excellent (1) to poor (5). At baseline, ratings did not differ between groups with the mean score (3.16), translating to a rating of (just below) 'good'. Post intervention, participants in IG2 rated the health of their teeth and mouth significantly better than participants in CG and IG1 ($p < 0.001$) (Table 3). Analysis of Variance

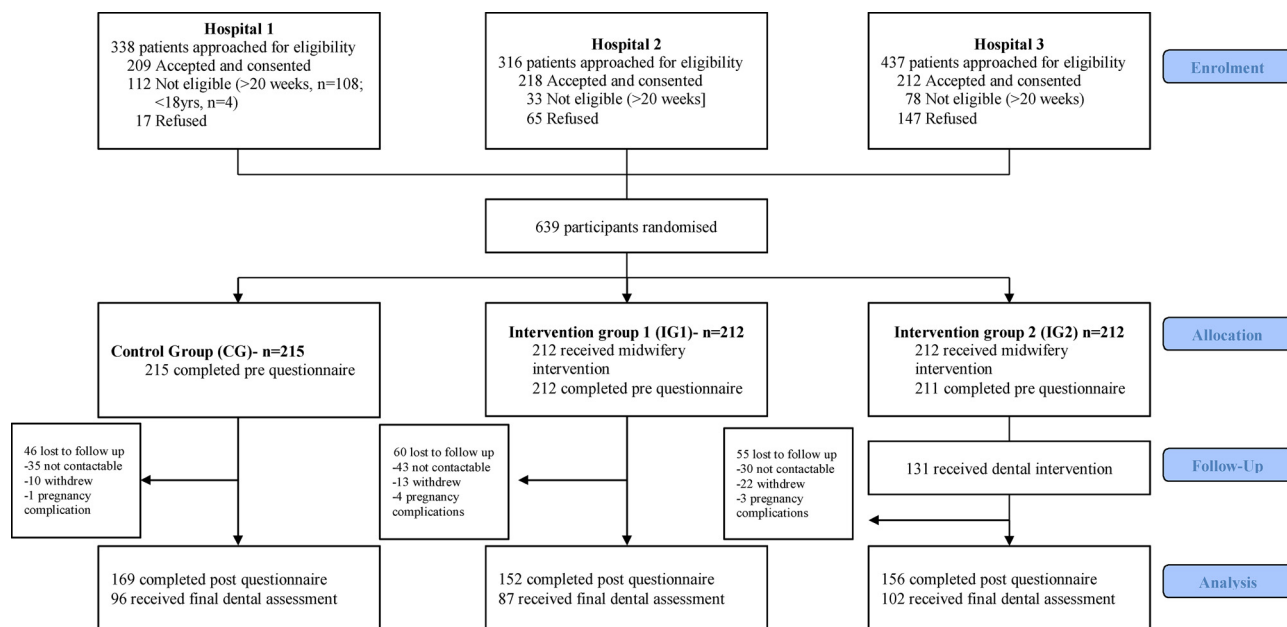


Fig. 1. Consort flow diagram.

Table 2
Differences in the Uptake of Dental Services across the Three Groups (n = 476).

		Control n = 168 No. (%)	IG1 n = 152 No.(%)	IG2 n = 156 No. (%)	Between group analysis
Did you seek advice from a dental professional for your problem/concern? ^a	Yes	34 (20.2%)	43 (28.3%)	136 (87.2%)	$\chi^2 = 171.07, p < 0.001$
Of those who saw a dentist, who self-reported a dental issue? ^a	Yes	23 (67.6%)	24 (55.8%)	63 (46.3%)	$\chi^2 = 5.33, p = 0.070$
	No	11 (32.4%)	19 (44.2%)	73 (53.7%)	

^a Post intervention questions.

Table 3
Differences in secondary outcomes across the three groups.

		Control	IG1	IG2	Between group analysis	
		Mean (SD)	Mean (SD)	Mean (SD)	F statistic	P value
Dental Knowledge						
(n = 476)						
	Pre	7.22 (1.46)	6.96 (1.57)	7.02 (1.85)	1.17	0.31
	Post	8.78 (1.20)	8.86 (1.03)	9.05 (0.94)	2.58	0.77
	Change in score	1.56 (1.65)	1.90 (1.54)	2.05 (1.92)	3.53	0.030
	within group analysis ^c	t = 12.28, p < 0.001	t = 15.23, p < 0.001	t = 13.27, p < 0.001		
Quality of Oral health						
Mean score (1 = excellent, 5 = poor) ^a (N = 471)					KW = 0.90	0.64
	Pre ^b	3.14 (1.01)	3.24 (0.99)	3.12 (0.82)	17.65	< 0.001
	Post	2.86 (0.90)	2.94 (0.92)	2.39 (0.85)	11.10	< 0.001
	Change in score	0.28 (0.95)	0.30 (0.97)	0.73 (0.92)		
	within group analysis ^c	t = 3.80, p < 0.001	t = 3.77, p < 0.001	t = 9.70, p < 0.001		
Oral Health Outcomes						
		n = ~96	n = 87	n = ~94		
Sulcus Bleeding Index (%)	Pre			34.47 (23.18)	KW = 16.05	p < 0.001
	Post ^b	34.63 (24.14)	34.21 (25.07)	21.97 (17.07)		
Clinical Attachment Loss	Pre			2.12 (0.69)	27.15	p < 0.001
	Post ^b	2.24 (0.72)	2.24 (0.85)	1.51 (0.77)		
Plaque Index (%)	Pre			61.71 (18.36)	KW = 17.53	p < 0.001
	Post	54.73 (20.64)	56.01 (19.50)	44.70 (15.86)		
Decayed teeth	Pre			1.82 (2.32)	KW = 29.39	p < 0.001
	Post ^b	2.01 (2.55)	1.47 (2.51)	0.48 (1.17)		
Filled teeth	Pre			3.57 (4.36)	KW = 29.45	p < 0.001
	Post ^b	2.09 (2.53)	3.06 (3.94)	4.96 (4.34)		
Birth Outcomes						
No. (% of total sample size)						
Gestational Period	Weeks at delivery	39.3 (1.39)	39.3 (1.41)	39.3 (1.75)	0.05	0.96
	Preterm, n (%)	7 (3.7%)	8 (4.4%)	10 (5.3%)	$\chi^2 = 0.56$	0.76
Birth weight	Birth weight (kg)	3.41 (0.52)	3.38 (0.52)	3.39 (0.57)	0.15	0.86
	Under 2500 g, n (%)	7 (3.7%)	7 (3.9%)	8 (4.2%)	$\chi^2 = 0.07$	0.97

Control = Control group, IG1 = intervention group 1, IG2 = intervention group 2, KW = Kruskal-Wallis Statistic, χ^2 = Pearson Chi-Squared.

^a Participants rated the health of their teeth and mouth from 1 = excellent to 5 = poor.

^b Non-parametric assessment (Kruskal-Wallis Test) completed as sample did not meet the assumption of homogeneity of variances.

^c Within group analysis assessed the significance of the score change within each group.

found that additional visits to the dentist increased self-reported oral health (F = 8.45, df = 4, p < 0.001).

3.2.3. Oral health status

Oral health status was determined by the study dentists at the end of the intervention for CG and IG1, and pre and post intervention for IG2. Post intervention participants in IG2 were found to have significantly less sulcus bleeding, less plaque and greater clinical attachment than participants in CG and IG1 (Table 3). No significant difference in total DMFT score was seen between the groups, however significant increases in fillings and decreases in decayed teeth were observed in IG2 compared to the other two groups.

3.2.4. Birth outcomes

Birth data was sourced from the hospitals participating in the study. Overall, 4.5% of women birthed prematurely (gestation < 37 weeks) and 3.9% of babies were born with a low birth weight (< 2.5 kg). There were no significant between-group differences in either prematurity or low birth weight across the three study groups (Table 3).

4. Discussion

This trial evaluated a new model of care (MIOH-DS program) for midwives to provide oral health education, assessment and referrals during antenatal practice. The MIOH-DS program included evidence-based resources, an oral health training program for midwives and an assessment tool. Previous work has already shown that the program can significantly improve the oral health knowledge and confidence of midwives to promote oral health (Johnson et al., 2015). Further, the assessment tool can be easily implemented into midwifery practice and identify pregnant women at risk of poor oral health (George et al., 2016c). The purpose of this trial was to assess whether the MIOH program could be translated into practice and improve the oral health and birth outcomes for pregnant women. Evaluating this program is essential as there is a significant gap in evidence-based oral health interventions especially focussing on oral health outcomes for pregnant women (Ten Hoop-Bender et al., 2014), despite clear evidence and guidelines in this area (Oral Health Care During Pregnancy Expert Workshop, 2012; National Health Service Health Scotland, 2012). A

systematic review has also found that no RCT's to date have successfully integrated oral health promotion into midwifery practice (Abou El Fadl et al., 2016). A recent non-randomised pilot study has used a nurse-midwife led oral health intervention to show a positive impact on the oral health outcomes of pregnant women, however the authors cautioned the results and highlighted the need for larger RCT's in this area (Adams et al., 2017).

4.1. Uptake of dental services

A large number of women (60%) in this study identified current dental problems like bleeding gums and dental decay and close to two thirds had not sought advice from a professional for these problems. In addition, very few women (7.9%) received any information about oral health care during pregnancy at the time of recruitment. These findings are consistent with other studies in Australia (George et al., 2013; Keirse and Plutzer, 2010) and further highlight the need for early oral health interventions like the MIOH-DS during the antenatal period. We found that the MIOH-DS (IG2) can significantly improve (87%) the uptake of dental services among pregnant women compared to current practice. This model of care seems to be the best solution to address current barriers in this area as it helps raise oral health awareness through the midwifery intervention (evidence based resources and education from midwives) and provides a pathway to affordable dental services (dental intervention). Supporting this argument is the fact that more than half the women in MIOH-DS group saw a dentist even though they didn't have a dental problem. This finding strongly suggests that the awareness building from the midwives was a contributing factor to the uptake of dental services. Similar findings have been observed in another trial where there was an increase in visits to a dentist among low income pregnant women from a targeted educational intervention directed by nurse practitioners (Cibulka et al., 2011). Adding to this argument is the fact that even in countries where pregnant women have universal access to public dental services, such as the UK, the uptake of dental services remains around 30–50% (Hullah et al., 2008). This is probably due to the fact that no comprehensive oral health education and assessment is provided during antenatal care in the UK (National Collaborating Centre for Women's and Children's Health, 2008).

4.2. Oral health status

The increased uptake of dental services in the MIOH-DS group was associated with a marked improvement in the oral health status of these women compared to the other groups. Significant improvement was observed across all the oral health measures in this group, including their gum condition (reduction in bleeding and improved clinical attachment loss) and presence of dental decay (reduced plaque and decayed teeth). These findings strongly suggest that the women were receptive to the dental treatment and oral health advice that was provided. Comparable improvements in oral health measures were observed in a recent pilot study involving a nurse-midwife led intervention program (Adams et al., 2017). It is promising that the women in this study had improved oral hygiene in their last trimester as it is known that good maternal oral health can reduce the chances of children developing early childhood caries (Plutzer et al., 2012). This is mainly due to the reduction in decay causing bacteria that can be transferred from the mothers oral cavity to the child whenever certain practices are followed such as sharing utensils while feeding (Leong et al., 2013). Reducing gingivitis (inflammation and bleeding of gums) is also important as it can progress to periodontal disease if left untreated and cause systemic infections, which is of particular concern during pregnancy.

4.3. Oral health knowledge

Another key finding is that the oral health knowledge significantly

improved in each of the groups with the amount of improvement incrementally increasing with each intervention. The improvement occurred across most of the knowledge items including those focussing on the safety of dental treatment, potential impact of poor oral health on birth and infant outcomes and feeding practices that increase the risk of early childhood caries. These findings suggest that just providing oral health promotional material to pregnant women can be beneficial in improving their oral health knowledge and awareness but to have the maximum impact the key messages should be reinforced by antenatal care providers. Having this additional dialogue can be particularly important if pregnant women require further clarification especially around their misconceptions about dental treatment. This is essential as studies consistently show that safety concerns about dental treatment are a common barrier deterring pregnant women from seeing a dentist (George et al., 2013). This reinforcement in oral health awareness from midwives could explain the observed increase in the uptake of dental services among IG1 compared to the control as receiving information about oral health has been cited as a factor influencing pregnant women seeing a dentist (George et al., 2013; George et al., 2016a).

4.4. Quality of oral health

The MIOH-DS intervention was also effective in significantly improving the quality of oral health of pregnant women compared to the control and midwifery intervention groups. Further, the quality of oral health increased with additional dental visits. The self-report item used for this outcome measure is highly correlated with various validated oral health quality of life measures (Jones et al., 2004) which suggests that the oral health quality of life of the participants may have also improved from the MIOH-DS intervention. The marked increase in quality of oral health could be attributed to the improvement in oral health status and uptake of dental services observed in this group, as both these factors have been shown to have a positive impact on quality of life in expectant mothers (Moimaz et al., 2016). Interestingly participants in the control and midwifery intervention did have significant improvement in this measure within the groups with the change incrementally increasing with each intervention. This finding could be due to the improvement in oral health knowledge observed in both the groups as studies in other populations have shown a correlation between oral health awareness and oral health quality of life (Sadeghi et al., 2014).

4.5. Birth outcomes

Finally, the MIOH-DS intervention was found to have no effect in improving birth outcomes among pregnant women. The improvement in the gingival health did not result in any significant difference in preterm birth and low birth weight across the groups. It is also noteworthy that the rate of preterm (3.7–5.3%) and low birth weight (3.7%–4.2%) was low. This result could be due to the fact that there was insufficient power in this study to detect any change in this outcome especially considering the low rates of premature births (7.5%) and underweight babies (6.3%) in Australia (Li et al., 2013). Several possible reasons have been cited why trials including ours have failed to show a true causation in this area. These include: the type of dental intervention may not be effective in completely suppressing periodontitis; irreversible damage from periodontitis may have already occurred before the intervention is administered or the timing of the intervention (usually 2nd trimester) does not allow sufficient time for the benefits to be shown (Papapanou, 2015). Clearly further research is required in this area that is targeted and addresses the many unanswered questions regarding the impact of dental treatment on pregnancy outcomes.

In summary, our trial showed that the MIOH-DS program is effective in improving dental services utilisation, oral hygiene, oral health knowledge and quality of oral health among pregnant women. To our

knowledge, this is one of the first trials that has successfully implemented and evaluated an oral health model of care for midwifery practice (Abou El Fadl et al., 2016). There is compelling evidence to show that the program is feasible to implement into antenatal care practice and is most effective in health care systems where priority access to dental care is available to pregnant women. Following up the MIOH-DS participants and their children in future pregnancies and reassessing the study outcomes may provide additional evidence on the long term effectiveness of the program.

It is important to note that the inclusion of a fourth arm in the trial containing only the dental intervention may have provided further data on the effectiveness of the MIOH-DS. However, providing affordable dental services to pregnant women does not necessarily translate to improved uptake of dental services during pregnancy with many countries that have universal dental schemes still showing poor uptake in this area (30–50%). (Dinas et al., 2007; Ozen et al., 2012; Martínez-Beneyto et al., 2011; Hullah et al., 2008). Further, our own needs assessment among the study population has shown that the main barriers for pregnant women accessing dental services is cost but also the lack of oral health information being provided during antenatal care. One of the shortcomings of this study was it only included women visiting a public hospital during pregnancy. In Australia 72% of women attend public hospitals during pregnancy as opposed to midwives, general practitioners and obstetricians in the private setting (Australian Institute of Health and Welfare Australia's mothers and babies, 2015). Therefore, the findings of this study cannot not be generalised for the entire population. Nevertheless, the program utilises midwives who are the main providers of maternity care across numerous countries and are increasingly been recognised for their role in promoting optimal maternal and child health (Ten Hoope-Bender et al., 2014). Midwifery care is also highly acceptable to women and an important public health strategy (Renfrew et al., 2014) which further highlights the potential of the MIOH-DS program both nationally and internationally.

Conflict of interest

None.

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Ethical approval

The trial was approved by the Human Research Ethics Committees of Sydney Local Health District (reference no HREC/11/CRGH/28) and Western Sydney University (H9709). The study authors had full access to study data and were responsible for the submission of the paper for publication. The study authors attest that they have obtained appropriate permissions and paid any required fees for use of copyright protected materials.

Data sharing

Full data set is available from <https://doi.org/10.17632/76zp7hg5wz.1>.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.ijnurstu.2018.03.006>.

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